University of Reading

An investigation into the suitability of the graphic presentation of patient package inserts

This version is produced in 2013.
- It contains the orgininal text and illustrations.
- I've updated the digital files from the original QuarkXpress 3.11 to Indesign CS6.
- The pictures were scanned or remade. The original were photocopied in 1993 and quality was fairly poor.

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Abstract

An investigation into the suitability of the graphic presentation of patient package inserts.

This thesis sets out to investigate the graphic presentation of information in patient package inserts, and in particular the influence of such presentation on the use of these inserts by patients. Patient package inserts are leaflets produced by the pharmaceutical industry and accompany medicines. They are supplied to provide patients with factual information about a specific medicine.

The graphic presentation can be looked at from two points of view. From the producers' point of view, the concordance between the topic (information content) and the graphic presentation can be examined. From the patients' point of view, the suitability of the graphic presentation for the use of inserts can be investigated. The use of inserts by patients is divided into three fields: initial visual perception, information processing, and the affective field. The graphic presentation is described on three levels: graphic components (verbal, pictorial, schematic, and composite), relations between components (similarity, proximity, prominence, and sequence), and the overall graphic presentation. Each combination of a specific field of use, and specific level of graphic presentation can be studied.

Three exploratory experiments were conducted. The first experiment indicated that patients can identify and group graphic components, and that they can rank their prominence and importance. The graphic presentation of the test insert that was used in the first experiment was modified in order to improve the relationship between importance and prominence. The second experiment showed an increased level of agreement between patients about the grouping and ranking of graphic components. A third experiment, using a different insert, showed that patients have clear preferences about some features of graphic presentation.

The first conclusion of this investigation is that graphic presentation does influence the use of inserts by patients in certain aspects. The second conclusion is that the level of agreement between subjects about a feature of graphic presentation is a measure of its suitability. The investigation also indicates that the suitability of the graphic presentation can be seen as an indication of the effectiveness of the graphic presentation.

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Chapter 6.

If you have a stomach upset
Vomiting and diarrhoea may interfere with absorption of the pill and reduce its contraceptive effect If you do get such a stomach upset, continue to take the pills, but you should use an additional method of contraception, (either the sheath or cap plus spermicide) for the rest of that particular course of the oral contraceptive.

Interaction with other medicines
Some medicines may reduce the effectiveness of oral contraceptives when taken at the same time. They include certain sedatives, antibiotics, anti-epileptic and anti-arthritic drugs. Suspicion that the reliability of an oral contraceptive is reduced in this way is sometimes raised by the occurrence of irregular bleeding. If you take any medicines at all while you are also taking an oral contraceptive, be sure to tell your doctor, who can advise you whether or not you should take additional contraceptive precautions.

By statute, certain information must appear in any leaflet of this kind, and must be kept separate from the rest of the contents. That information comprises the remainder of this leaflet.

In the opening paragraph of this leaflet it was said that there is an inevitable element of risk to health in the use of the pill. The following sections discuss those risks and it is of vital importance that you read and understand them. If there is any point you do not understand you should ask your doctor to explain it. If you think your health may be suffering in any of the ways indicated, do not hesitate to consult your doctor. In particular you should take note of, and act upon the section entitled 'Reasons for stopping oral contraceptives immediately'.

CONTRA-INDICATIONS

You should not take a combined oral contraceptive if you have any of the following: clots in the blood vessels (thrombotic disorders) or a history of these conditions; abnormal red blood cells (sickle-cell anaemia); high blood fats (disorders of lipid metabolism) and other conditions in which there is known or suspected to be a much increased risk of thrombosis (eg. severe forms of the conditions referred to in paragraph 2 of 'WARNINGS' or the presence of a number of these conditions); a possible pregnancy; cancer of the breast or of the lining of the womb (mammary or endometrial carcinoma) or a history of these conditions; abnormal vaginal bleeding of unknown cause; a history during pregnancy of (1) itching of the whole body (pruritus of pregnancy), (2) shingles (herpes) of pregnancy, (3) deterioration of inherited deafness (otosclerosis) or (4) jaundice not explained by infections, poisons or obstruction of the flow of bile (idiopathic jaundice of pregnancy); certain other types of jaundice (Dubin-Johnson or Rotor syndromes); any short-term or severe long-term liver disease.

WARNINGS

There is a general opinion, based on statistical evidence, that users of combined oral contraceptives experience more often than non-users various disorders of the circulation of blood. These include strokes (blood clots in and haemorrhages from the blood-vessels of the brain), heart attacks (coronary thromboses), and blood clots obstructing the arteries of the lungs (pulmonary emboli). There may not be full recovery from such disorders and it should be realised that in a few cases they are fatal. How often these disorders occur in users of modern low-oestrogen oral contraceptives is not known, but there are reasons for suggesting that they may occur less often than with the older types of pill which contained more oestrogen.

Certain conditions themselves give rise to a risk of thrombosis. They include smoking, obesity, varicose veins, some diseases of the heart and blood vessels, diabetes and migraine. If any of these conditions apply to you, the advisability of your taking a combined oral contraceptive should be discussed with your doctor before you decide to take the pill. The risk of arterial thrombosis (eg. heart attack and stroke) associated with combined oral contraceptives increases with age, and this risk is aggravated by cigarette smoking. For this reason, the use of combined oral contraceptives by women in the older age group, especially those who are cigarette-smokers, is to be discouraged.

The possibility cannot be ruled out that certain diseases may occasionally deteriorate during the use of combined oral contraceptives. The diseases are those listed as requiring careful observation under 'PRECAUTIONS'. Very rarely, tumours of the liver (hepatic adenomata) have been reported in users of combined oral contraceptives.

Reasons for stopping oral contraception immediately
You should take no further oral contraceptive tablets and should consult your doctor immediately if you experience any of the following: the very first attack of migraine (typically a throbbing headache and nausea, preceded by visual disturbances) that you experience; worsening of pre-existing migraine, any unusually frequent or unusually severe headaches; dizziness or fainting; sudden disturbance of vision; disturbance of speech; inflamed veins (phlebitis); pains in the chest or abdomen; swelling in the limbs; pain, tingling or numbness in any part of the body; unexplained cough; breathlessness; pain on breathing. Any of those symptoms might indicate the beginning or immediate risk of a serious thrombosis.

The risk of thrombosis is increased after many injuries, especially fractures, during and after many surgical operations, and during immobilisation, eg. after accidents. Combined oral contraceptives should be stopped at least six weeks before planned operations, and should be stopped immediately when immobilisation (ie. inability to move freely) is necessary.

Your doctor will probably stop the pill at once if you become jaundiced, or if he finds your blood pressure to be significantly raised, or if any of the conditions known to be capable of deteriorating during oral contraception or pregnancy (referred to under 'PRECAUTIONS') should show clear signs of deteriorating.

You should stop the pill immediately if pregnancy is diagnosed, or if there are reasonable grounds for suspecting that you may be pregnant, since it has been suggested that combined oral contraceptives, in common with many other substances, might be capable of affecting the normal development of the child in the early stages of pregnancy. It can be definitely concluded, however, that if a risk of abnormality (foetal malformation) exists at all, it must be very small.

PRECAUTIONS

Examination of the pelvic organs, breasts and blood pressure should precede the prescribing of any oral contraceptive, and should be repeated regularly.

The following conditions require careful observation while you are taking the pill: a history of severe depressive states, varicose veins, diabetes, high blood-pressure (hypertension), fits (epilepsy), the inherited form of deafness known as otosclerosis, the disease of the nervous system called multiple sclerosis, the inherited metabolic disease called porphyria, calcium deficiency with cramps (tetany), disturbed liver function, gallstones, diseases of the heart and blood vessels (cardiovascular diseases), kidney diseases, brown patches on the face and body such as occur during pregnancy (chloasma), fibroids of the womb, asthma, the wearing of contact lenses, or any disease that is prone to worsen during pregnancy (your doctor can explain any of these terms that you do not understand). The worsening or first appearance of any of these conditions usually indicates that the oral contraceptive should be stopped. The risk of the deterioration of chloasma, which is often not fully-reversible, is reduced by the avoidance of excessive exposure to sunlight.

Side-effects
Occasional side-effects may include nausea, vomiting, headaches, breast tension, changes in body weight or interest in sex (libido) and depressive moods; possible deterioration or recurrence of the conditions mentioned in paragraph 2 of 'PRECAUTIONS'.

It is not easy to decide whether or not something that you notice is the result of your taking the pill, since among millions of women during long periods of treatment many symptoms are bound to occur that are quite unconnected with the use of the pill. Studies comparing oral contraceptives with dummy tablets have suggested that true side-effects felt by the users are few and are mainly short-lasting. However, such studies may not detect rare or long-term side-effects. Most known or suspected side-effects are of a minor nature and are reversible, but not all. Ask your doctor about any change in your health or general sense of well-being that you notice while taking an oral contraceptive.

STORAGE

Protect the tablets from light and keep them out of reach of children.

Figure 0·1. Patient package leaflet for oral contraceptive pills.
(TriNovum, Ortho-Cilag Pharmaceuticals Ltd. High Wycombe, England (1983?))

Introduction.

This study sets out to investigate the graphic presentation of information in patient package inserts, and in particular the influence of such presentation on the use of these inserts by patients.

Three main objectives were defined:

- the first objective was to investigate whether the graphic presentation influences the use of inserts by patients
- the second objective of this study was to find a method of investigating the influence of the graphic presentation on the use of inserts by patients
- the third objective was to determine whether it is possible to improve the effectiveness of the graphic presentation of patient package inserts

There were at least four reasons for undertaking this study. The first three reasons are directly related to the objectives, the fourth is more general. The first reason was that the current graphic presentation of information in many patient package inserts seems to indicate that graphic presentation is not considered to be of any importance. This should be clear from the insert reproduced on the left, which is provided for women under the age of 35. The first objective was thus to find out if the use of inserts by patients is influenced by graphic presentation. It was therefore necessary to identify features of graphic presentation that might influence the use of inserts. This investigation therefore describes several ways of analysing graphic presentation. The second objective necessitated a study of the measuring, or quantification, of this influence. Part of this study will therefore look at different ways of finding out whether it is possible to detect how much influence graphic presentation has on the use of inserts. The third objective was set to find out if it is possible to improve the graphic presentation, and whether it is possible to determine the effect of the improvement on the use of inserts. The fourth reason for undertaking this study, which is not directly related to an objective, was to see which factors need to be considered when the graphic presentation of a specific type of document is investigated. The general approach for this kind of investigation has been suggested elsewhere (Wright, 1980), but the application of this approach to a specific type of document has rarely been undertaken.

The first chapter discusses the use of medicines and the ways in which patients can obtain information about medicines. This chapter reduces the scope of the

research from all printed information about pharmaceutical products to patient package inserts. The first part of chapter 2 focuses on the purpose of the supply of patient package inserts from a producers' point of view, and section 2·3 describes the content of inserts. Section 2·4 reverses the perspective and looks at inserts from a patients' viewpoint. This chapter reduces the scope from all the aspects of a patient package insert to graphic presentation only. These first two chapters are therefore a description of the context of this investigation.

Chapter 3 starts with a description of the current graphic presentation of inserts. The second part of chapter 3 focuses on the relation between users and the graphic presentation of information in documents. This second part looks at document-use in general, in order to be able to investigate whether the use of inserts is different from the use of other documents.

Two main areas are discussed in chapter 4. The first area is the description and analysis of features of graphic presentation. This chapter describes a number of frameworks for graphic presentation, and combines these into a modified framework. This modified framework is developed to describe certain features of the graphic presentation of documents. The second area is the description of evaluation techniques. Section 4·4 discusses existing evaluation techniques that could be applied to investigate influences of graphic presentation on the use of documents. Chapters 3 and 4 therefore describe the current situation related to the use of inserts, and review and develop ways to describe and evaluate the graphic presentation.

The conclusions of chapters 3 and 4 identified a need to undertake experiments. Three exploratory experiments are described in chapter 5. Chapter 6 provides a general discussion, and evaluates some of the issues raised in the first five chapters.

Three points need to be mentioned to provide some background information about this investigation. The balance between the experimental and theoretical sections in this thesis, the external developments, and the integration of several disciplines - with their specific vocabulary - are described below.

In the first place, a balance between a theoretical and a practical investigation had to be found. Approximately one-fifth of this thesis is devoted to practical experimental work. The other four-fifths describe ways to approach the graphic presentation. The lack of a standard framework for investigating graphic presentation, or even a standard method of investigation, made it necessary to develop a crude framework first. The context, ways to describe graphic presentation, and evaluation techniques had to be described in order to develop this framework. This development is described in the first four chapters. However, it was also essential to undertake experiments to determine the influence of the graphic presentation on the use of inserts. Three experiments are reported in chapter 5.

A second point that needs to mentioned is that the regulations and guidelines of the European Community about patient package inserts were published during this study. The European regulations were published on March 31st, 1992 (Directive 92/27/EEC, 1992), and came into force on January 1st, 1994. An advisory report, which outlines specific guidelines on the development of graphic presentation of inserts, was published in February 1993 (Joossens, 1993b). I was consulted in relation to work on this report, but this involvement is not described here. The main reason for this omission is that this report is related to the development and production of inserts. The objective of this investigation is to study the use of these inserts and not the development of the graphic presentation. However, it is clear that in some sections of this thesis both interests overlap.

An issue related to the introduction of the new European regulations and their adoption into national laws is that few inserts conform to these new regulations. The inserts that were developed before the new regulations came into force, are in several cases very different from the new inserts. This dilemma, whether to investigate inserts that will soon be obsolete, or to investigate inserts that still have to be developed, is reflected in the choice of the test inserts used in the exploratory experiments. The first two experiments employed an old-style insert, whereas the test insert in the third experiment conforms to the new EC-regulations. Several hundred inserts were collected in the period 1989 to 1993. Only two examples are reproduced in this thesis (figure 0·1, and 6·1)

Thirdly, it is necessary to point to two issues that always influence a study of this kind. The first issue is related to any multidisciplinary investigation. In this thesis, several disciplines had to be incorporated in order to study the influence of the graphic presentation on the use of inserts. For example, some medical, pharmaceutical, psychological, linguistic, and typographic aspects of inserts are discussed. I am aware of the difficulties in incorporating the different approaches taken by these disciplines into this study,

and I may therefore have stated the obvious in some cases. However, some of these very obvious points needed to be mentioned in order to describe other points.

The second issue is the approach in this thesis to terminology and vocabulary. Two problems need to be mentioned. The first problem is related to the 'jargon' of the different disciplines. The specific vocabulary by the pharmaceutical, medical, psychological, and linguistic disciplines may have been used in a more general way in this thesis. I have therefore tried to define and explain most terms. The second problem is related to the translation into English of sources that have been published in several different languages. The translation of these languages into English may have caused some discrepancies between the original article and my translated version. The bibliographical references therefore list the article in the language in which the article was published.

1 Information for patients.

The three sections in this first chapter aim to introduce the patient package insert and reduce the scope of this study from all information for patients to patient package inserts.

In a study investigating the influence of the graphic presentation on the use of patient package inserts, it is necessary to consider two basic issues.

Firstly, patient package inserts will always accompany a specific medicine. It is therefore useful to look briefly at the different kinds of medicines, how these can be obtained, and at which stages in this process a patient might need information.

Secondly, patient package inserts are only one kind of document which can give information about specific medicines to patients. A brief look at other kinds of documents might give an idea why inserts should be treated as a special document.

1·1 Medicines and patients.

This section is intended to identify some of the issues involved in the relation between medicines and patients. It introduces and describes medicines, patients, prescribers, pharmacists, and the pharmaceutical industry.

1·1·1 Definitions.

A common-sense definition of a *medicine* is given by the National Consumer Council. They state that all products that claim to be able to prevent disease, cure disease, and lessen the symptoms of disease can be regarded as medicines (NCC, 1991). The European Community law defines medicines as follows: 'Any substance or combination of substances presented for treating or preventing disease or any substance which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is considered a medicinal product' (Directive 65/65/EEC, 1965). The British law defines a medicine as any substance administered to humans or animals for a medicinal purpose. Medicinal purpose is defined as treating or preventing disease, diagnosing disease, contraception, inducing anaesthesia, or interfering with a physiological function (Medicines Act 1968, section 130 (1)(a)).

These definitions of a medicine make the definition of a *patient* easier: patients are people who use a medicine as a result of the recognition of symptoms of a disease. The symptoms can be recognized by the patient themselves, or by anybody else who makes the patient aware of these symptoms. This creates a clear distinction between people and patients, although this distinction is in reality not as obvious. Three groups need special mention because they are normally considered as patients, but fall outside the scope of the above definition. The first group are people who have not become aware of their symptoms yet, but need treatment. These people are considered patients in the traditional sense of the word (patient stems from the Latin verb patior which means to suffer and endure). A second group are people who are treated without medicines. A third group are people who are aware of their symptoms, and will be visiting a pharmacist or prescriber in the near or immediate future. Although they have recognized symptoms, they do not yet use medicines. These people are frequently called consumers, clients or customers, and are seen by the medical and pharmaceutical profession as patients. These three groups fall outside the scope of the above definition of patients. The main reason for excluding these groups from this investigation is because these patients will not receive, or have not yet received, any printed information about medicines.

1·1·2 Classification of medicines.

There are several ways in which people can obtain medicines. A classification of medicines according to these ways of obtaining medicines will divide medicines into two main groups.

- medicines which can be bought by a patient in a pharmacy, a chemist, or a retail shop: the over-the-counter medicines (OTC)
- medicines which can only be obtained with a prescription from a medical doctor: the prescription-only medicines (POM)

There are other classification systems. These classifications are mainly for a professional audience, and use the active ingredient of a medicine (Merck index), a particular system of the human body (British National Formulary), a group of medicine-types (Martindale) or a combination of these characteristics (Read classification).

The division between medicines that can be bought over the counter and those for which a prescription is needed follows the division that is made by the licensing authorities (The Medicines Act 1968). The division is based upon the following eight criteria, which were published by the Proprietary Association of Great Britain (PAGB, 1991):

- potential risks appearing during the pre-clinical and clinical tests and trials
- novelty of the active principle
- possibility of serious side effects in normal conditions of use
- serious risks associated with contra-indications and precautions for use
- indication requiring a medical diagnosis or medical supervision
- harmfulness of constituents under normal conditions of use, taking into account dosage, pack size, or possibly excessively extended treatment
- the need for administration by a health care professional, except when very long term illness requires active participation by the patient (eg. diabetes)
- important risk of abuse, addiction, or misuse for criminal purpose

A product will be licensed as a prescription-only medicine if it is characterized by any of the above criteria. All other products are classed as over-the-counter medicines. Three main characteristics of these over-the-counter medicines are: the symptoms can be recognised by the patient, the medicines are easy to administer, and the medicines are only for short term use.

Both groups of medicines, the prescription-only, and the over-the-counter medicines, can be divided further.

Over-the-counter medicines.
The over-the-counter medicines can, in Great Britain, be divided into general-sales-list (GSL) products and pharmacy-only (P) products. The pharmacy-only list contains medicines with ingredients which were on the prescription-only list, but are safe enough to sell, for some specific symptoms, directly to the patient. The rationale behind this is that there is always professional advice available (PAGB, 1991). This advice can be supplied by a pharmacist who, in order to trade, must be on the register of pharmaceutical chemists (Medicines Act 1968). The general-sales-list medicines can be sold by anyone. This list is restricted to some twenty active ingredients. To come back to the definition of a patient, a person buying an over-the-counter medicine can be seen as a customer. However, as soon as a person begins to use a medicine, he or she will be regarded as a patient.

Other names for the over-the-counter medicines are non-prescription medicines, or proprietary medicines. Proprietary is a particularly confusing term. *Proprietary* is defined as 'a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack' (SI 1977 No. 1055). However, as will be shown in the next section, most prescription-only medicines are currently placed on the market under a special name and in a special pack, and could therefore be seen as proprietary medicines. This change in meaning is shown in the name of The Proprietary Association of Great Britain (PAGB) which represents manufacturers of over-the-counter medicines. To avoid this confusion I will use the term over-the-counter (OTC) to indicate all medicines that can be obtained without a prescription.

There are large differences between the lists of over-the-counter medicines in the various countries in Europe. These differences are caused by different definitions of over-the-counter products. It has been suggested by the Association Européenne des Spécialités Pharmaceutiques Grand Public, that is the European proprietary manufacturers' association, that it will take at least ten to fifteen years to create a generally acceptable common list within the European Community. However, over-the-counter medicines are in general national products and rarely cross borders (AESGP, 1991). The importance of this point for the information supply to patients will become clear in section 2·4·2.

Prescription-only medicines.
The second group of medicines is the prescription-only group. Prescription-only medicines will always combine a product (a medicine) with service (medical care). Medicines can be prescribed in Great Britain by doctors who are fully registered according to the Medicines Act 1968. Several other professions are also included in this act: dentists, veterinary surgeons, and veterinary practitioners. There are also several names for a doctor, such as general practitioner, medical specialist and physician. In this thesis, I will use the word *prescriber* to indicate any person who has the professional right to prescribe medicines for patients.

At least three issues related to prescription-only medicines need to be discussed. These issues are related to the production, the dispensing, and the use of these medicines. They need to be discussed because they make a difference when a patient comes in contact with a prescription-only medicine. However, from a legal point of view, prescription-only medicines are seen as one large group.

The first issue, which is related to the production of prescription-only medicines, is the difference between generic and proprietary medicines. A simplified explanation of this difference is as follows. Medicines consist of a combination of specific active ingredients and excipients (non-active ingredients). A great deal of research in the pharmaceutical industry goes into the development of these ingredients. If a combination (formula) seems effective as a treatment, it can be patented, and therefore be owned and sold. The owner of the formula is the only one who is allowed to trade in this specific formula. Nearly always, such a medicine is brought onto the market under a special brand name. These medicines are called proprietary medicines. However, the patent protecting a medicine expires after a certain amount of time, and after this expiry date everyone is allowed to trade with the previously patented formula. Medicines using the same

ingredients are called generic, and these medicines are clinically equivalent to the original patented version. However, because the manufacturers of generic medicines do not have to include the high research and development costs, generic medicines can be sold more cheaply. Prescribers can prescribe both generic and proprietary medicines and pharmacists can supply both groups.

The second issue is related to the dispensing and packaging of medicines. There are two main ways of retailing medicines. One way is for the pharmacist to buy medicines (proprietary and generic) in bulk, and repack these for the patient in a smaller package or bottle. The second way is for the pharmacists to buy the medicines prepacked from the manufacturer. This is sometimes called original pack dispensing (OPD), or unit pack dispensing. These medicines are proprietary medicines in the original sense, that is, according to the definition of *The Medicines (Data sheet) Regulations* (SI 1977 No. 1055). The number of prepacked medicines is increasing. Four main reasons for this increase are (Griffin, 1991):

- the stability and integrity of the product is maintained
- the dose is accurate; measuring is not necessary
- each pack has its own security, or tamper-evident feature
- information can be supplied with each pack which improves the recognition of the medicine by pharmacists as well as by patients

The shift from repacked to prepacked medicines will be especially noticeable in Great Britain and the Netherlands where a large number of medicines still need repacking (Mann, 1991). In the USA and most other European countries, the prepacked medicines form the largest group already.

The third issue is related to the person who is administering the medicine. There are some groups of medicines, such as vaccines, anaesthetics, medicines for diagnosis, and most injectable or infusable medicines, which will nearly always be administered by a health care professional. This form of administration is called *parenteral*, indicating that patients will rarely administer these medicines on their own. However, the largest group of prescription-only medicines will be administered by the patients themselves.

The relation between medicines, prescribers, pharmacists and the pharmaceutical industry is strongly influenced by political factors (reimbursement schemes, price regulations, licenses), legal factors (registration procedures, patent protection) and economic factors. Two examples might make this influence clear.

- The use of over-the-counter medicines is promoted by the British Government (Department of Health, 1989; 1991). One of the reasons for this promotion is the need to reduce health care costs. It is assumed that patients who buy over-the-counter medicines will make less use of the national health services, and pay for their own medicines as well.
- The choice between generic and proprietary medicines has political, legal, and economic implications. The medical implications have been discussed by Collier (1988) and Cruickshank (1988). The price of prescription-only medicines, for both the generic and proprietary medicines, is also influenced by negotiations between the Department of Health and the pharmaceutical industry. Examples of these price control regulations are the Pharmaceutical Price regulation scheme and the introduction of limited lists of medicines that will be reimbursed (Taylor & Maynard, 1990).

These political, legal and economical factors will not be pursued in this thesis. Furthermore, it should be clear that the development, production, and use of medicines is a large area in which several interests continuously compete. For ease of discussion, I will use the word *health carer* for every person who has a professional involvement with medicines.

1·1·3 Concluding.

This first section has introduced and defined medicines, patients, prescribers, pharmacists and the pharmaceutical industry. It has pointed to three issues related to the classification of medicines: prescription-only versus over-the-counter, prepacked versus repacked, and self administration versus parenteral. The influence of political, legal and economical factors is mentioned, but none of these factors will be further pursued.

1·2 Information about medicines.

When a carpenter is ill, he expects to receive a draught from his doctor that will expel the disease by vomiting or purging, or else to get rid of it by cauterizing, or a surgical operation; but if anyone were to prescribe for him a long course of diet, and order bandages for his head, with other treatment to correspond, he would soon tell such a medical advisor that he had no time to be ill, and hint that it was not worth his while to live in this way, devoting his mind to his illness, and neglecting his proper occupation; and then, wishing his physician a good morning, he would enter upon his usual course of life, and either regain his health and live in the performance of his business; or, should his constitution prove unable to bear up, death puts an end to his troubles. Yes, and for many in that station of life, this is thought the proper use to make of medical assistance.

Plato (The Republic. Book 3: 406).

1·2·1 The relation between medicines and information.

Pharmaceuticals are intrinsically dangerous. Incorrect use can be harmful and can in some cases be lethal. Even correct use can cause unexpected and damaging effects. The risks need to be considered when the use of a medicine is still preferred above other possibilities such as a change in life style or eating habits. The British National Formulary states in the first line under general guidance: *Medicines should be prescribed only when they are essential, and in all cases the benefit of administering the medicine should be considered in relation to the risk involved* (BNF, 1991). Pharmaceutical products are considered safe when the risks of taking these products is acceptable. Acceptable risk and safe are relative terms and need to be interpreted carefully, by the prescriber as well as by the patient, in relation to every situation in which a medicine is used. When the use of medicines is unavoidable, a decision as to which specific medicine to use needs to be made.

This decision can be made by the patient, or by the prescriber. The first possibility is when a patient decides to use a medicine without consulting a health care professional. Only the over-the-counter medicines are available in this case. As was mentioned in the previous section, over-the-counter medicines are for short term treatment; the symptoms are easily recognized and the products are easy to administer. If the situation does not improve after a few days the patient is advised to consult a prescriber. The second possibility is when a patient consults a prescriber. The decision as to which medicine to use is made by, or in co-operation with, a prescriber. In this case, prescription-only medicines can be considered.

One of the essential prerequisites for a considered choice of medicine, is the availability of information. Two developments need to be mentioned. The first development is related to the information supply. The amount of information to give to patients and the amount to withhold from them has been debated throughout the development of medicine (ABPI, 1987; Gibbs, 1990). Withholding information, especially, was seen as beneficial for patients. It is now considered essential that patients receive a certain amount of information in order to use a medicine effectively (Hermann, Herxheimer & Lionel, 1978; Haecht, Stichele & Bogaert, 1989). New legislation specifies that all medicines in the European Community must be accompanied by printed information (Directive 92/27/EEC, 1992). The second development is the right to be informed. This development was started by consumer organisations and has become a right incorporated in the Consumer Protection Act 1987. Manufacturers are legally bound to provide sufficient information with a product to make its safe use possible. This act is also applicable to pharmaceutical industries and medicines.

The combination of these two developments provides a basis for a larger involvement of patients in decisions about their treatment. The prescriber was previously solely responsible for these decisions but this has now shifted to a shared responsibility (Herxheimer, 1976). Both patient and prescriber are responsible for a successful use of the medicine, although there are several cases in which a patient prefers not to be involved in the decisions about their treatment (Ingelfinger, 1980). In practice, the responsibility for the treatment is frequently shared, but this is dependent on the prescriber as well as on the patient. The liability issues in this situation are still a hazy area (Diamond, 1991).

As a result of these developments, both prescribers and patients are responsible for their information supply. One of the reasons for making information about medicines available is to ensure that the properly informed doctor can have a factually based dialogue with an adequately informed patient (Mann, 1991).

The remainder of this section is divided into three parts. Section 1·2·2 discusses reasons why information about medicines should be supplied and by whom.

Sections 1·2·3 and 1·2·4 elaborate on the time of supply of this information by prescribers and pharmacists. Section 1·2·5 looks at the information supply from a patients' point of view.

1·2·2 The supply of information to patients.

The potential benefits and disadvantages of providing patient information have been the subject of intense debate and speculation amongst prescribers, pharmacists, lawyers, drug manufacturers, and the layman (Drug information Journal, 1977; Bogaert, Stichele, Kaufman & Lefebvre, 1989; Mann, 1991). Supporters of information supply state that information might:

- improve patients' knowledge about their medicines
- improve compliance with dosage instructions
- improve satisfaction with the provided information (additional information, or more appropriate information)
- improve doctor-patient communication
- encourage patients to store and dispose of medicines safely
- inform patients about hazardous interactions with other substances such as alcohol or food
- inform patients about early recognition and reporting of side-effects
- reassure patients about the benefits of appropriate drug treatment
- enhance the placebo response, due to the 'attention-placebo effect'

Opponents state that information might:

- make patients unnecessarily anxious
- cause patients to reject a beneficial drug treatment altogether
- cause patients to experience side effects by suggestion
- create more demanding patients
- promote inappropriate self-medication
- increase prescription drug exchange among patients
- 'de-mystify' the medication and reduce the placebo effect
- finally, some argue that patients do not really want to be informed about their drugs.

I will come back to this discussion in section 2.2 when the literature about the advantages and disadvantages of a specific type of printed information for patients, the patient package insert, is reviewed.

There are traditionally two sources from which information about specific medicines can be obtained: from the prescriber during the consultation, and from the pharmacist during the dispensing. The next section describes the supply of information by prescribers. Section 1·2·4 describes the information supply by pharmacists to patients.

Three reasons can be given why it is necessary to look at these two sources. Firstly, the current methods of supplying information about medicines by prescribers and pharmacists need to be described. The prescriber and the pharmacist are the first providers of information about medicines to patients. In the second place, this description gives an overview of the printed information that is currently available. And in the third place, it might show where additional information about specific medicines is needed.

1·2·3 The consultation.

The consultation is the time when patients are in direct contact with prescribers. The consultation can have three outcomes, one of which is of interest to this study. The first outcome is when a patient is treated within the surgery or in a hospital. Medicines are prescribed and supplied directly to patients. Patients can obtain information about these medicines immediately from a health carer. The second outcome of a consultation is when a patient is prescribed a medicine to administer without the assistance of a health carer. A prescription form is supplied to the patient, together with a spoken explanation. The majority of consultations end with the issue of such a prescription form (George, 1987). The third outcome of a consultation is when a patient does not receive a prescription, or is referred to another prescriber. Only the second outcome of the consultation will be pursued here.

The difficulties in supplying information about specific medicines during a consultation can roughly be divided into four areas: communication, information, misunderstanding, and characteristics of the consultation. These areas are of course interrelated and are only separated here for ease of discussion, although other divisions have been used. For example, a linguistic analysis of the consultation divided the difficulties in communicating into three groups: jargon, cultural, and discourse problems (Shuy, 1983).

Communication.

The ethical code of practice of the medical profession relates positive health outcomes directly to the quality of clinical communication. Serious communication problems are common in clinical practice (Wilkin &

Metcalfe, 1984; Haecht et al, 1989). The Toronto consensus statement, a result of discussions about fundamental issues in medicine, highlighted several of these problems (Simpson, Buckman, Stewart et al, 1991). One of the basic reasons for this deficiency is that prescribers are poorly trained in communication skills. This lack of training has recently been recognized and research shows that any of these skills can, and should be taught (Pendelton & Hasler, 1983; Maguire, 1990).

A second reason for communication deficiencies is that consultations are in a spoken form. Several studies have indicated that spoken* advice is often forgotten by patients (Bradshaw, Ley, Kincey & Bradshaw, 1975; Ley, 1979; Pieterse & Blom, 1983). The supply of printed documents to patients as a standard procedure is a relatively recent development in clinical practice (Dixon, 1991; Miller, 1991). Prescribers and patients need to find ways to make the best use of these documents. There is some evidence that the provision of printed information by prescribers is not fully used, despite the amount of such information available (Sloan, 1984; Gibbs, 1990). Experiments which involve supplying additional printed information to patients during the consultation have frequently been undertaken, and it was shown that information is best remembered by patients when it is supplied in both spoken and printed form (Ellis, Hopkin, Leitch & Crofton, 1979; Regner, Hermann & Ried, 1987). However, it should be emphasised that printed information cannot be seen as a replacement for spoken advice. Three statements illustrate this. A statement of the Association of the British Pharmaceutical Industry (ABPI) mentioned that 'Printed information would augment and reinforce the advice given by a prescriber' (ABPI, 1987). An editorial in *The Lancet* stated that 'leaflets must not become an excuse for allowing the spoken part of the communication process to lapse' (Lancet, 1987). George (1987) stated: 'printed information should reinforce rather than replace information given by doctors and pharmacists'. It seems therefore vital to provide a combination of printed and spoken information to patients.

A third reason for communication deficiencies is that the patient is fairly passive (Arntson, 1991). Patients are frequently reluctant to ask about their medicines. There are at least five reasons for this behaviour (Gibbs, 1990). It might be that the patient waits until the prescriber takes the initiative. Secondly, a patient might not want to bother a prescriber with 'silly' questions. Thirdly, the prescriber gives the impression of being too busy to answer. Fourthly, questioning implies a lack of respect and confidence in the prescriber's judgement. Fifthly, patients are anxious about the outcome of their illness.

Information deficiencies.

A second problem area related to the communication of information about specific medicines between prescriber and patients is the availability of factual information for prescribers. Two issues need to be mentioned. In the first place, the reliability of the source. Most of the information that prescribers receive about a specific medicine originates from the marketing departments of the pharmaceutical industry. Although this information supply is tightly regulated and controlled, there is concern about the applied promotional techniques (Boissel, 1991).

The second issue is the problem for prescribers of locating information sources. A prescriber in the United Kingdom receives on average 80 kilograms of mail every month, resulting in approximately 180 pages of reading matter every day (Greenwood, 1988). This is simply too much to read, and a selection is therefore essential. Several investigations have tried to find out which sources are the most effective. The preferences of prescribers for their sources of information, and their influence on prescription choices have been investigated in several studies (Peay & Peay, 1984; Abate, Jacknowitz & Shumway, 1989; Wyatt, 1991). The use of commercial sources is compared with the use of scientific sources, and it was shown that commercial sources influence prescribing decisions (Avorn, Chen & Hartley, 1982). The data sheet, which was especially introduced in Great Britain to solve part of this problem, lists all the relevant information about a specific medicine. Data sheets should provide 'an objective statement of the essential particulars about the medical product' (SI 1972 No. 2076). The control of the information in data sheets is undertaken by the Medicines Control Agency, which grants the licence for marketing a medicine. The licence is granted on the basis of a substantial amount of research which is collected during the development of a medicine. The data sheet presents a summary of these research results

*A standard terminology problem arises here: the use of the words spoken (verbal, oral, aural) and printed (written, visual, graphic). I will use spoken for the aural/oral conversation between prescribers and patients, while printed will be used for the supply of information on paper.

together with the characteristics of a medicine. However, deficiencies in the data sheet have frequently been mentioned (Herxheimer & Lionel, 1978; Herxheimer, 1987; Medawar, 1988). These issues indicate that there is a problem for prescribers in finding accurate and reliable information about medicines, which in turn leads to a communication deficiency when information about medicines needs to be supplied to patients.

Misunderstanding.
There are at least three reasons why misunderstanding occurs during the consultation. The first reason is that prescribers do not reflect the cultural and educational background of their patients. There is an educational and a cultural gap between prescribers and patients (Pendelton & Bochner, 1980). The second reason for misunderstandings between prescriber and patient is that even an uninformed patient has an opinion. Patients often have their own ideas about illnesses and these often differ from accepted orthodox ideas. What prescribers say will be interpreted in terms of the patient's own framework of ideas (Verbeek-Heida, 1992). The third group of misunderstandings is caused by language difficulties. Patients often do not know the meaning of words used by prescribers. This has been the subject of a number of studies (Boyle, 1970; Mazzullo, Lasagna & Griner, 1974; Dunkelman, 1979; Spiro & Heidrich, 1983; Tuckett, Boulton & Olson, 1985; Stone, 1991). Even a university education does not ensure a full understanding of some common medical terms, and it is suggested that studies showing misinterpretations of medical terminology are heavily time and culture bound (Cole, 1979; Ley, 1988).

Characteristics of the consultation.
Two reasons support the idea that the communication of information about specific medicines is reduced by characteristics of the consultation. In the first place the structure of the consultation may hamper the recall of information. The sequence of the discussion during the consultation may mean that the diagnosis is more likely to be remembered than the treatment and its administration (Verbeek-Heida, 1992). Ley and Spelman (1965) found that only 44 per cent of advice and instruction statements were recalled, whereas 86 per cent of diagnostic statements were recalled by patients. Some of the difficulties in the provision of information about medicines by prescribers might therefore be caused by this characteristic of a consultation. The diagnosis might be seen, by the prescriber as well as by a patient, as the most important aspect of the consultation. The choice of the treatment, and the discussion about the treatment comes in second place.

The second influential characteristic is the duration of the consultation. The amount of information is simply too great to convey in a limited amount of time (Fletcher, 1980). The average consultation length in Great Britain was found to be approximately seven minutes (Wilson, 1985). The list size, that is the number of patients registered with a prescriber, influences this patient contact time. The longer the list, the shorter the consultation (Wilkin & Metcalfe, 1984).

It is clear from the four points above – communication, information, misunderstanding, and the characteristics of consultations – that there are difficulties in the provision of adequate information about medicines during the consultation. Several initiatives have been undertaken to alleviate this situation. The training in communication is improving, the information supply to prescribers is improving, the misunderstandings are being investigated, and are avoided were possible, and several problems relating to the consultation have been improved.

1·2·4 The dispensing.

The communication between pharmacists and patients or customers is less structured then a consultation. Both spoken and printed information can be supplied. Two issues influence the information supply from pharmacists to patients: different types of medicines and recent changes in the role of the pharmacy.

The first issue that relates to the supply of information about a medicine are different types of medicines, and packaging of these medicines. It is necessary to go back to the difference between prescription-only medicines and over-the-counter medicines. A person can come into a pharmacy for several reasons, two of which are of interest to this study: to obtain a prescription-only medicine, or to buy an over-the-counter (OTC) medicine. Spoken advice can be supplied about both groups of medicines. However, there is a risk of supplying conflicting information about prescription-only medicines because the pharmacist is unaware of the contents of the discussion during the consultation (McMahon, Clark & Bailie, 1987; Stone, 1991).

The majority of information about OTC-medicines

is given in printed form. OTC-medicines are always sold in a package which is produced by the manufacturer. In Great Britain, the instructions, and other information about an OTC-medicine is printed on the outer package. In other countries of the European community, packaging of OTC-medicines looks very much like packaging produced by the pharmaceutical industry for prescription-only medicines. Only information that is of interest to the pharmacist is printed on the outer package. The continental packages for OTC-medicines frequently contain an insert which presents information for patients. Therefore, most information about OTC-medicines will be supplied in a printed format, and a pharmacist is available to provide spoken advice. The information that is needed for safe and effective use of a non-prescription medicine has been investigated by the AESGP (1991).

Pharmacists also supply printed information about prescription-only medicines. This printed information is presented on a label. There are at least two types of label: labels for use by the pharmacist, and labels for use by the patient. The first type of label is for bottles and packages which contain medicines that are used for storage. The required amount is taken from these bottles and packages, and is dispensed to patients in smaller containers. These labels have been investigated (Boorman, 1973; Dennis, 1975). The second type of label is for patients, and these labels are personalised. These labels mention the name of the patient, the name of the medicine, the dosage, and may contain a warning. The pharmacist places these labels on the packaging of medicines that have been repacked (frequently in a small brown bottle), or on the packaging which is supplied by the manufacturer. Packaging supplied by the manufacturer can contain other information about the medicine as well. In future, the amount of prepacked medicines in Great Britain will increase, despite resistance in some pharmacies, to bring the British situation in line with the European market.

The supply of printed information by pharmacists to patients as standard practice is relatively new. The requirement to present the name of a medicine on a medicine container was enforced only 30 years ago. Before that, there has been no legal requirement to offer any helpful printed information to patients (Malahy, 1966; Dunlop 1973). The addition of cautionary and advisory texts on labels for dispensed medicines became a matter of professional conduct on 1-1-1987. The label for patients has been the object of many investigations; all of which showed inadequacies in the labelling systems (Dodds & King, 1989). Studies into the efficiency of drug labelling have been conducted by comparing typewritten and handwritten labels (Hailstone & Foster, 1967; Veitch & Wright, 1982). Both investigations concluded that handwritten labels were inadequate and inefficient, and that typewritten labels were recommended. The use of Plain English labels was investigated in 1989. It was concluded that patients (n=326) remembered information better and more correctly when plain English labels were used (Barber & Raynor, 1989). An investigation carried out by the Consumers Association pointed in the same direction (Which? way to Health, 1992).

The interest of pharmacists in improving the supply of printed information for patients seems ambivalent. The introduction of any additional information or change in existing practice has met fierce opposition, and takes a long time. An example of this attitude is provided by Gibbs and her colleagues in 1990 who found that only 25 per cent of pharmacies that were approached were willing to participate in a study aiming to find out how information supply influences patients (Gibbs, Waters & George, 1990). However, there are also signs that this attitude is changing. Several initiatives indicate that pharmacists would like to be more actively involved, and take a more advisory role (Nuffield Foundation Inquiry, 1986).

The increase in the use of prepacked medicines means that two traditional roles for the pharmacy are disappearing. The production of medicines, and the supply of information with these medicines are both being taken over by the pharmaceutical industry. One way for pharmacists to regain some of the lost ground, is to supply printed information about a group of medicines. For example, printed information about medicines with the same active ingredients could be produced. The term generic leaflet is sometimes used for this type of document. This term is confusing because generic is also used for the non-proprietary medicines. Generic leaflets are not for generic medicines, but contain information about groups of medicines such as antibiotics, beta blockers, and penicillins. I will use the term *generic* only as an opposite of proprietary medicines. Several studies have indicated that leaflets provided by the pharmacist are indeed useful (Gibbs, 1990; Consumentenbond, 1991).

A second option is the supply of individualized leaflets with the help of a computer. Expert systems, and a network of computers between pharmacists and prescribers, could make the provision of individualized leaflets for every single patient possible (Lamy, 1990).

The OPADE project, a European wide research project which is a follow up to a Swedish initiative, is currently investigating this possibility (Gillie, Berry & Banbury, 1992). However, this type of printed information supply to patients is still in an experimental phase.

The previous two sections highlighted some of the issues in relation to the supply of information by prescribers and pharmacists to patients. Traditionally, there has been very little co-operation between prescribers and pharmacists in bringing information about medications to the patient (Stichele, 1991a). It can be concluded that both pharmacists and prescribers are essential, but not sufficient providers of information.

1·2·5 Information available to patients after the dispensing.

After the consultation and a visit to the pharmacy a patient has to make decisions without the direct help of health carers. There are two kinds of information available to a patient at this time. There is information that is remembered from the spoken advice of prescribers and pharmacists, and there is printed information. The nature of the printed information depends on the type of medicine. Repacked prescription-only medicines will have a label; prepacked prescription-only medicines have the manufacturer's packaging, a label and sometimes an insert. Over-the-counter medicines have the outer packaging and sometimes an insert (Wells, 1991).

Some reference books can be consulted by patients. The data-sheet compendium, which is a complete collection of all data sheets, has been available for the general public in Great Britain since 1991. Reference books in other countries, such as the *Swedish Lay Pharmacopoeia* and *The Physicians' Desk Reference* in the United States are best-sellers among the general public (Stichele, 1991a). These reference books have frequently been used to show that there is a need for this kind of book. A large number of additional printed materials is available, but the supply of these depends very much on the prescriber or pharmacist (Fowler, 1985; Morris, Tabak & Olins, 1991; Dixon, 1991).

The issue of which other sources of information are available for patients and how these sources influence the use of medicines and attitudes towards medicines, has recently provoked some interest. For example, Verbeek-Heida (1992) investigated some aspects related to this issue, and found that in nearly all cases (52 out of 54) a discussion took place with relatives, friends or colleagues. The information that patients obtain from non-medical sources, and the ideas patients have about medicines outside a medical environment, have rarely been investigated.

The main information sources that a patient could use are mentioned above; prescribers and pharmacists, reference books, and non-medical sources. Three issues arise here. The first issue is whether patients want to be informed about their medicines. The second issue is whether this information should be provided in a spoken or a printed format, and the third issue is the preference of the patient for the provider of this information. Five recent studies in Great Britain indicate that patients want to receive printed information. A postal questionnaire sent to a sample of 1 in 200 in the Southampton region showed that 62 per cent of the 443 respondents felt that not enough was explained about medicines by doctors and pharmacists. The conclusion of this investigation was that most patients would welcome printed information (Ridout, Waters & George, 1986). In a national survey, by means of a questionnaire, the vast majority (90 per cent of 8831 respondents) wanted further printed information (Busson & Dunn, 1986). An investigation in 1987, which tried to investigate the source of information found that only 21 per cent of patients (n=154) had ever received printed information. Yet 74 per cent claimed that they would find printed information valuable (McMahon et al, 1987). Gibbs (1990) concluded from her research that almost all patients (n=1492) thought that the introduction of printed information would be a good idea. Dodds and King (1989) found that attitudes towards information are not uniform across a patient population (n=289). The need seems more evident in younger and better educated patients. Only 6 per cent of patients surveyed stated that they had ever received a leaflet with prescribed medicines before, but 82 per cent said that they would like to receive a leaflet with every medicine. However, some investigations indicated that some patients, in some circumstances, do not want to receive any information at all (Ingelfinger, 1980; Wilkie, 1992).

In research undertaken in 1988, it was found that 62 per cent of participating patients (n=317) preferred a combination of spoken and printed information (Culbertson, Arthur, Rhodes & Rhodes, 1988). Dodds and King (1989) found that 33 per cent of patients (n=289) would like to receive information in a spoken format, and 54 per cent preferred printed information; 13 per cent were unsure. Harvey and Plumridge (1991) interviewed 247 literate outpatients with a prescription for penicillin. These patients were given standardised

spoken counselling by a pharmacist, and a medication information leaflet. Preferences were assessed by means of a prepaid mail questionnaire. One hundred and fifty five patients (63 per cent) responded. Thirty percent of these respondents preferred to receive information from a pharmacist, 21 per cent preferred a leaflet, and 45 per cent preferred the combination.

The preferences of patients for the source of information have also been investigated. Joubert and Lasagna (1975a) found that patients (n=137) felt that prescribers and pharmacists should provide drug information with each prescription. Fleckenstein and his colleagues (1976) found that patients (n=828) would prefer to receive information about oral contraceptives from a prescribing doctor first, and from printed sources second. The national survey (n=8831) found that 58 per cent would like to receive printed information from a pharmacist, and 38 per cent would like to receive printed information from the prescriber. However, the questionnaires were completed in the pharmacy, which might have biased these results (Busson & Dunn, 1986). In a telephone survey (n=204), Cosler and his colleagues found that preferences for the source is dependent on the perceived importance of drug class. The preference for prescribers positively correlated with perceived drug importance (Cosler, Schulz, Baldwin & Cohen, 1986).

These results suggest that patients say that they would like to receive more information. The preference for the source (pharmacist or prescriber, printed or spoken) is difficult to determine, and results are inconclusive. However, printed information seems to be appreciated by patients as a valuable addition to spoken advice.

The problems in supplying information about medicines to patients described above are longstanding and are not likely to be solved by spontaneous remission. It seems to be essential to supply patients with information about medicines. The current practice of obtaining medicines does not make this supply easy. The structure of the consultation means that information about medicines always becomes secondary to the diagnosis. Spoken advice from prescribers is poorly remembered and printed information is difficult to supply. The pharmacist can supply spoken and printed information about over-the-counter medicines. For prescription-only medicines this supply of spoken advice is less useful because of the lack of knowledge of what was said during the consultation. The supply of printed information about groups of medicines seems a possibility for pharmacists.

1·2·6 Concluding.

Three conclusions can be drawn.

- Information and medicines are intrinsically linked. It is essential for an appropriate use of medicines by patients that information is supplied together with the medicine. Patients would like to receive more information about their medicines.
- This information can be supplied in spoken form during the consultation, and during the dispensing of medicines. This information can also be supplied in a printed format. Patients prefer to receive information from their prescriber or their pharmacist, and regard additional printed information as valuable.
- Patients need information about their medicines after medicines have been dispensed. Hardly any additional information is available for patients after medicines are obtained.

1·3 Printed information about medicines.

This section introduces patient package inserts. It describes some of the advantages and disadvantages of patient package inserts, and it distinguishes inserts from other types of document that supply information about specific medicines to patients.

1·3·1 Reasons for choosing patient package inserts.

The first two sections of this thesis focused on the need to supply information about medicines to patients, and patients' needs to receive information about their medicines. Several kinds of printed documents have been developed in the last three decades with the specific purpose of informing patients about medicines. One of these kinds of document, which is intended to supply patients with information about a specific medicine, is the patient package insert. Patient package inserts (PPIs) are developed and produced by the pharmaceutical industry, and have accompanied some products for the last twenty five years. New legislation will come into force, specifying that all medicines must be accompanied by an insert, unless all information can be presented on the outer packaging. Most medicines will therefore be accompanied by such an insert, because the amount of information required will be too much to be printed on the outer package alone (Directive 92/27/EEC, 1992). The information itself will be further discussed in chapter 2. This section looks at some differences between inserts and other printed sources of information about specific medicines for patients.

There are several differences between inserts and other sources of printed information about medicines. These differences need to be considered in order to be able to determine whether the production of these inserts is worthwhile. At least three differences between inserts and other documents giving information about specific medicines can be identified.

The first difference between inserts and other documents is that inserts are supplied with the medicine itself, and not separately. The insert presents information about one specific medicine and is included in the package that the patient receives. The chemical substance (the medication) and the information that goes with it (the insert) are linked as a single branded product (the package) in the course of retail distribution (Stichele, 1991a; Gibbs, 1990). This linkage has the advantage that information is always available when a medicine is dispensed. Printed information about medicines that come from other sources, such as that supplied by prescribers, pharmacists and patient organisations, is physically separated from the medicine itself.

The inclusion of inserts in medicine packages has however three disadvantages. A patient who uses several medicines at the same time will receive several inserts. Some of the information in two or more inserts will overlap, and is potentially contradictory. This seems unavoidable at the moment, because there is no organisation to compare different inserts. A second disadvantage is that prescribers, unless they have a pharmacy attached, will not have access to specific inserts. The information in inserts needs to be available to prescribers in order to discuss this information with patients, and to avoid giving advice that contradicts information in an insert. An annual compendium of inserts is probably a solution, but until this compendium is produced, it will be difficult for prescribers to obtain inserts. The third disadvantage is only relevant to OTC-medicines in Great Britain and in the Netherlands. The inclusion of an insert might mean that the pharmaceutical industry will provide information on an insert, that would previously have been presented on the outer package. This regulation might mean that less information is available for the consumer of OTC-medicines at the time of purchase.

A second difference between inserts and other printed documents is that prescribers, pharmacists and the pharmaceutical industry can be certain that specific information is supplied with a medicine. The supply of printed information about medicines by other means, in both quantity and quality, is less certain.

A third difference is that the content of an insert is strictly regulated and controlled, unlike the information in other documents. It can be assumed that the information content of an insert is accurate and correct. The control of the information in inserts is undertaken by the Medicines Control Agency. The agency checks whether the information content of an insert is the same as the information in a data sheet. However, the insert and the data sheet do not have to apply the same wording. Prescribers will initially have some scepticism about the accuracy of the information in inserts, because inserts are developed and produced by the pharmaceutical industry, and much of the promotional material presenting information about medicines comes from the same pharmaceutical

industry. Therefore, no matter how accurate the information is claimed to be, inserts will initially be treated with suspicion.

Apart from these three differences between inserts and other printed documents, three other points need to be mentioned. The first point relates to the pharmaceutical industry, the second and third points are related to patients.

In Great Britain, the change caused by the requirement to accompany medicines with information by means of an insert will be larger than in any other European country. At the moment, approximately 35 per cent of the prepacked medicines in Great Britain are accompanied by an insert (Rennison, 1992). The prepacked segment is at the moment approximately 40 per cent of the total market. Medicines that need to be repacked account for the other 60 per cent. Therefore, an estimate for the total number of inserts in Great Britain at the moment is that only 14 per cent of the prescription-only medicines are accompanied by an insert. The other 86 per cent need a new insert and that is a larger number of new inserts than anywhere else.

A second point is that patients in Great Britain will notice the change caused by the introduction of inserts. Patients will have access to information about medicines which has rarely been available before. For prescription-only medicines, inserts will provide the only direct contact between the pharmaceutical industry and patients. This contact did not exist until recently and was in fact restricted by the code of practice for the pharmaceutical industry (Königsberger, 1987). For over-the-counter medicines, this direct contact between the industry and consumers has existed for much longer.

The third point, apart from the changes for the pharmaceutical industry and patients in Great Britain, is that the supply of more printed information to patients might increase problems as well. Patients might simply receive too much printed information. This has been noticed in recent investigations which showed that patients disregarded important information because of the amount of information they received (Fowler, 1985; Dixon, 1991; Verbeek-Heida, 1992).

Two questions seem to be important in order to establish if the advantages of the supply of inserts outweigh the disadvantages. On the one side is the pharmaceutical industry, which develops and produces inserts*. The question on the producers' side is whether inserts warrant the effort in time, money and materials that has to be invested. On the other side are the patients. The main question here is whether the insert is a useful document in answering queries. The question of the pharmaceutical industry can only be answered when patients use inserts. It is therefore useful to look at the interaction between patients and inserts first. I will come back to this issue in section 2·5.

1·3·2 Summary chapter 1.

It will be clear from this chapter that prescribers, pharmacists, and manufacturers of pharmaceuticals are at present convinced of the need to develop and produce printed information for patients. Patients like to receive printed information about medicines, and a patient package insert might be an appropriate type of document to convey information about specific medicines.

This chapter has provided a background to this investigation by describing how patient package inserts fit into the larger context of providing patients with information about their medicines.

The next step in this investigation is to find out what the aims of producers and the requirements of patients are when inserts are considered as a source of information. In chapter 2, the historical background of inserts is briefly discussed, before the producers' aims and the patients' requirements are related to the information content of inserts.

* I will call the people involved in the development and the production of inserts the producers. This is the group of people who write, design, test, control, approve, print and pack inserts. The development is the process in which the insert is created, from its initial stages to its final form. This process includes the writing and designing. The production encompasses the multiplication of the insert.

2 Patient package inserts.

In this chapter the scope of this investigation is progressively narrowed down from several issues relating to inserts towards the graphic presentation of information in inserts only. The chapter starts with a description of patient package inserts from the viewpoints of medical and pharmaceutical professions. Section 2·1 presents a short historical overview as an introduction to the current situation. The following section, 2·2, describes some of the aims of producers for supplying inserts to patients. This leads towards a description of the information contents of an insert in section 2·3. The opinions about inserts, and information requirements of patients are discussed in section 2·4. The sequence of these sections indicates a shift from the producers' domain to the patients' domain. This shift is described in the last section of this chapter. Section 2·5 also describes several reasons why inserts are an appropriate type of document to study the influence of graphic presentation.

The description of these areas is necessary in order to provide a frame, or background, for this investigation. This frame can be used as a reference against which the influence of the graphic presentation can be investigated.

2·1 Historical development of patient package inserts.

In order to discuss the current situation with patient package inserts, it is necessary to give a brief overview of the historical development of patient package inserts. This overview supplies a background for the current situation in Great Britain, and describes the scale of the development of inserts.

2·1·1 A short history.

The first legally required printed information about a specific medicine aimed at patients appeared in the United States in 1968. The American Food and Drug Administration (FDA) introduced regulations to extend the labelling on medicine packaging for a specific type of inhaler. The extended labelling was in fact a two-line warning stating that patients should not use more than the indicated dose. The reason for this additional warning was that an overdose could cause the condition the inhaler was intended to treat. Extended labelling regulations were applied to insulin and oral contraceptives in 1970. In the last case it was an abbreviated warning, but the label also stated that a brochure about the oral contraceptive was available from a prescriber. About one third of patients said that they had asked for, and had received this brochure (Morris, Mazis & Gordon, 1977).

Medicines in America were accompanied by an insert aimed at the prescriber, and these inserts were regulated by the FDA. The purpose of the supply of these inserts was not clear, and the medical profession's reaction was sometimes furious. The American 'stuffers' as they were called, were described thus by the editor of Clinical Pharmacology and Therapeutics: 'The stuffers are generally printed in Lilliputian type on Bible paper, and are hard to handle and very difficult to read'. He concluded that good stuffers were sorely needed (Modell, 1967). This initial reaction towards inserts in medicine packages can be seen as typical of the reactions of prescribers and patients in the following two decades.

In 1976, a study into the effects of oral contraceptive leaflets was conducted by Fleckenstein. This was claimed to be the first study into patient-oriented labelling. The main conclusion was that the impact of inserts on patients (n=828) was positive (Fleckenstein et al, 1976). Prompted by this study, the Food and Drug Administration (FDA) issued regulations in 1977 requiring the distribution of patient package inserts with all estrogenic medicines. These first patient inserts were based on the stuffer, despite some warnings that the mistakes that were made with the prescriber-oriented stuffers should be avoided (Fleckenstein et al, 1976). In 1979, the FDA started a programme to include inserts with 375 medicines, but this idea met fierce opposition from the pharmaceutical industry. The FDA program was therefore reduced to ten groups of commonly prescribed medicines as a first step towards a systematic, rather than a medicine by medicine approach. This program was cancelled by the Reagan government in January 1982 (New Scientist, 1981; Hayes, 1982). Volunteerism, rather than regulation, was seen as a more appropriate way to supply information about medicines to patients (Morris, 1989). The American pharmaceutical industry helped to set up a National Council on Patient Information and Education (NCPIE) as an example of this voluntary approach (Rogers, 1987). There are two major reasons why a federal approach could not have worked in the USA. In the first place, there was the fear of an increase in liability claims. In the second place, the pharmaceutical industry did not welcome an increase in the power of the already very influential FDA (Joossens, 1990a; Lamy, 1990). This development of the patient package insert in the United States should be kept in mind when the European development of inserts is considered.

The European development.

In contrast with the American move towards market initiatives, European countries moved towards a common approach. An important step was taken in 1987 when, following an initiative by the Belgian government, the Council of Health Ministers unanimously requested the Commission and the Member States to begin to study the possibility of making patient information leaflets (initially for over-the-counter medicines only) more understandable. Up to 1989, each individual country had developed its own regulations. After that date, it became clear that European regulations could be expected, and the need to issue national regulations diminished. The development of the EC regulations has been described by Donnelly (1991).

There are major differences in the regulations regarding the supply of information with medicines within the European Community. For example, the insert is obligatory in Germany and France, is

voluntarily included in Portugal and is prohibited in Denmark. The regulations of the individual countries were sometimes based upon research, and sometimes based upon the experience in the USA and other countries. The developments in the individual countries of the European Community were described by Bogaert and his colleagues (1989), and by Mann (1991). The most comprehensive comparison of the European countries is given by Joossens (1990a, 1990b). He concluded that there are large discrepancies between the European countries when the regulations on patient package inserts are compared. These discrepancies can be classified in four groups:

- there are three different types of inserts: one for prescribers, one for patients, and a combined insert for both groups
- the different regulatory authorities apply different laws, and some regulatory authorities modify inserts during the registration process
- there are different viewpoints on the appropriate safety levels (pharmaco-vigilance) of medicines. This influences the content of inserts
- there are differences between the regulations in the different countries about the necessity to keep the information in inserts up to date

These discrepancies are the reasons why a single medicine can be accompanied by very different information in each country in which the medicine is available. The differences can be in the amount of information, or in the content itself. This is obviously not a satisfactory situation.

The most recent development in Europe was the introduction of directive 92/27/EEC which should harmonize the different national regulations (Directive 92/27/EEC, 1992). From this point on, I will refer to this Council Directive as the *EC-regulation*. This EC-regulation made the inclusion of information with all medicines obligatory. Information could be presented on the outer package, but the length of the list of information sections that must be included makes it clear that inserts are preferred. Inserts that are produced according to the new regulations will be introduced from January 1994 onwards. Current inserts will be accepted until the product licence needs to be renewed. This renewal is necessary every five years, and all medicines within the European Community should therefore have a new insert before 1999. In addition, current inserts need to be updated and modified because the EC-regulations stipulate the inclusion of slightly different information, and a different sequence of this information. Several issues are still unclear, and working groups have been installed by the European Commission to investigate these issues. Especially article 12, third hyphen, is of interest to this investigation. This article states that: 'the commission shall publish guidelines concerning the legibility of particulars on the labelling and package leaflet'. I will come back to this point in section 3·1.

The situation in Great Britain.

Most of the guidelines for the production of inserts in Great Britain are based on the results of research which was undertaken at Southampton University, where the Clinical Pharmacology group has investigated the supply of printed information over a period of several years since 1983 (e.g. George, 1983; Ridout et al, 1986; Gibbs, 1990). Based on this research, the Association of British Pharmaceutical Industries advised its members to include a leaflet for patients in medicine packages (ABPI, 1987). This advice was supported a year later with the publication of guidelines on the production of package inserts (ABPI, 1988). An adaptation of these guidelines of the ABPI to make these guidelines conform to the EC-regulation was circulated on November 26, 1992 (Wells, 1992).

2·1·2 Pharmaceutical statistics.

The implementation of a European directive, approximately 25 years after the first printed information was supplied to patients, will affect the supply of information for all medicines. Several numerical indicators may serve to illustrate the scale of the realization of this directive.

- In 1992 approximately 468 million prescriptions were issued in Great Britain (Central Statistical Office, 1993). This is 8.1 prescriptions per person. This figure means that nearly every person in Great Britain will receive several inserts per year.
- The total number of different medicines is difficult to establish. Both over-the-counter medicines and prescription-only medicines need to be counted. Medawar (1984) stated that there are approximately 6500 preparations available in Great Britain. Nearly 4400 different packages, and over 2300 brandnames of medicines are mentioned in the British National Formula. There are 3070 different products, in 690 different strengths, in 637 different packages, and in 123 different presentations currently available (BNF, 1991). These figures indicate that in Great Britain at least 4400 different patient package inserts will have to be developed in the next five years. Within the

European Community, in which nine languages are officially recognized (English, French, German, Italian, Spanish, Portuguese, Dutch, Danish and Greek), inserts have to appear in all nine languages. A total number of different inserts that is affected by this directive will be approximately 40,000.

Three groups of patients are frequently mentioned when the supply of patient package inserts is discussed (ABPI, 1987). These three groups – the blind, the illiterate and the non-English speakers – have specific requirements for the supply of information about medicines. Precise definitions on who should be included in these three groups vary substantially, and estimates of numbers of these groups in the population are therefore difficult to give. A report by the Royal National Institute for the Blind found that there are approximately 300,000 blind people and 457,000 partially sighted people in Great Britain. If residential institutions are included, these numbers rise to 380,000 and 579,000 respectively. The total number of registered blind people or people eligible for registration as partially sighted in Great Britain in 1987 would therefore amount to 959,000 (Bruce, McKendall & Walker, 1991). However, this figure does not take into account the fact that some patients may not necessarily wear their spectacles or contact lenses when they read inserts. If this group is included, the total number of patients with an eye condition that will hamper the reading of inserts will be higher again. The total number of non-English speakers and illiterate people in Great Britain is even more difficult to estimate. However, even if the worst estimates are added together (2 million people with a deficient eye sight that hampers reading and 4 million people who cannot read English) it will still only add up to 11 per cent of the population in Great Britain. Although it is essential to consider the special requirements of these three groups, each of them represents a large number of different problems which cannot be addressed in this study. I will therefore concentrate on the 89 per cent of the people who can read English inserts without too many problems.

2·2 Producers' reasons for supplying printed information.

The supply of printed information to patients has proven to be a fruitful area of research in the last twenty-five years. Investigations have frequently assumed that supplying printed information will improve patients' knowledge about medicines, which in turn will lead to improvements in compliance. The following overview will refine this assumption. This section sets out to describe producers' reasons for supplying patient package inserts. These reasons can be seen as the aims that producers hope to achieve when inserts are supplied to patients. It is essential to describe these aims of producers because the results of the supply of inserts to patients will be compared with these aims. In order to investigate the influence of the graphic presentation on the results of the supply of information, it is necessary to describe these producers' aims first.

Section 2·2·1 looks at general aims in supplying patient package inserts. Sections 2·2·2 to 2·2·5 review investigations that have tried to establish whether these aims are achieved. Section 2·2·6 draws some conclusions about reasons for producers to supply patient package inserts to patients.

2·2·1 General reasons for supplying patient package inserts.

An early formulation of the reasons for supplying patient-oriented labelling stated that labelling was essential: 'to inform the patient of the correct use of the medication and what it is being used for, and to warn of possible side-effects and adverse reactions' (Fleckenstein et al, 1976). The primary objective of the supply of inserts was assumed to be the same for all medicines, although this particular study only investigated oral contraceptives. In a statement outlining the opinion of the Association of the British Pharmaceutical Industry (ABPI) the reasons for supplying inserts were formulated as: 'inserts would augment and reinforce the advice given by the doctor, inserts could increase compliance, and inserts would increase the patients' involvement in their treatment' (ABPI, 1987: p 15). In a later report, this was phrased as: 'to improve patients' understanding of the use of their medicines' (ABPI, 1988: p 3). Stichele stated that the aim of supply was to improve the rationality of the process of drug utilization, and to satisfy the patient's right to

know (Stichele, 1991a). The European Community formulated the aims for supplying inserts in a proposal in order as follows (Donnelly, 1991).

- to encourage the safe and appropriate use of medicinal products and, in particular, the completion of a full course of treatment
- to satisfy the consumer's wish to be properly informed

In the EC-regulations, the aim of supplying inserts was described as: 'the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information' (Directive 92/27/EEC, 1992).

As a summary, it can be stated that there are two main aims for supplying information about medicines in patient package inserts. The first is to improve the effectiveness of the use of medicines: the supply of information provides patients with information that could lead to a more effective use of medicines. The second is to inform patients about medicines: the patient has a right to know.

The following three sections, 2·2·2 to 2·2·5, review investigations related to these aims. At least five factors need to be taken into account when this literature is reviewed.

- The pharmaceutical industry is a relatively new source of information about medicines. The number of studies that have investigated the pharmaceutical industry as a source of information about medicines for patients is therefore small. Many more studies have used printed information from other sources such as prescribers, pharmacists, and patient organisations. The results of these studies have influenced the producers' reasons for supplying patient package inserts.
- A second issue is that in several investigations the printed information is supplied in combination with spoken information. The result of the supply of printed information is in that case difficult to establish.
- There are differences in types of medicines. For example, there are differences between over-the-counter medicines and prescription-only medicines, between parenteral and self-administered medicines, and between long-term and short-term medicines. A fourth difference between medicines is how important a patient perceives the medicine to be. These differences need to be taken into account when printed information about medicines is supplied. Some investigations have recognized these, others have ignored these differences.
- There are differences in prescribing patterns and medicine use from country to country. The majority of studies have been in the USA and on the European continent. The direct application of these results to Great Britain might be inappropriate.
- The patient package insert is not a standardized format. Several kinds of printed documents have been called inserts, but the size, contents, and graphic presentation have varied considerably. The results of investigations using these different types of inserts are therefore difficult to compare.

These five factors need to be taken into account when the results of investigations are reviewed. The reasons of producers for supplying printed information are reflected in the types of results that have been investigated. These reasons can be divided into four categories:

- knowledge changes in patients
- attitude changes of patients
- compliance changes of patients
- changes in the reactions of patients

These are convenient discussion categories and embrace most of the investigations. The success of the supply of inserts, according to a producer, is evaluated by comparing the results of the supply of inserts with the aims of the supply. However, this is not the only way of looking at the results of the supply of inserts to patients. Section 2·4 will look at the supply of inserts from a patient's point of view.

It is not my intention to give a comprehensive overview of all the studies that have been undertaken to investigate the results of the supply of printed information to patients. Several other overviews of these studies have been published. The most notable are by Morris & Halperin, 1979; Ley, 1982; Mazzuca, 1982; Tuckett & Williams, 1984; Eraker, Kirscht & Becker, 1984; Ley & Morris, 1984; Mullen, Green & Persinger, 1985; Mantel, 1988; Morris, 1989; Stichele & Bogaert, 1989; Haecht et al, 1989.

Two aspects have received special attention in the following review. In the first place, the producers' aims for supplying inserts have been subdivided. The aims have been categorized into four groups, each of which is further subdivided. This division of the producers' aims into groups should reveal in which groups most results of the supply of inserts can be observed. In the second place, the evaluation methods that have been applied to investigate these groups are considered. These evaluation methods might be applicable to investigate the graphic presentation of information in inserts. These methods will be further discussed in section 4·4.

2·2·2 Change in patients' knowledge.

One of the first reasons for supplying printed information about medicines is to increase patients' knowledge. The increase in patients' knowledge about medicines can be subdivided into at least four different areas. These areas are general knowledge, knowledge about the treatment, knowledge about the instructions, and knowledge about side-effects. These areas originate from lists which tried to suggest the minimum information that a patient needs to know about a medicine. These lists were compiled by prescribers and pharmacists, and were mainly based upon experience (Hermann et al, 1978; Herxheimer & Davies, 1982). It is clear that investigations have attempted to provide evidence for an increase in patients' knowledge in these areas. Some of these investigations have observed an increase in all areas, others concentrated on a single area. This is the reason that some studies are mentioned several times in the following review.

General.

First, the need for improvement in general knowledge of patients about medicines had to be investigated. Several studies indicated that patients have an inadequate level of knowledge about their medicines. Most of these studies asked patients general questions, without the supply of any additional information. Three investigations that were undertaken in Great Britain are examples of this kind of study. Two of these studies were mentioned in section 1·2·5. A national survey instigated by Boots (n=8831) revealed an unsatisfactory state of knowledge (Busson & Dunn, 1986). Patients who had handed in their prescription received a questionnaire containing 19 questions. The patients were asked how much they thought they knew about their medicines. This method of asking, together with a low response rate (31 per cent), make the results of this study questionable. However, another study undertaken in 1986 confirmed these results. The results of a questionnaire study in Southampton showed that patients (n=443) did not know enough about their medicines (Ridout et al, 1986). The third example is an investigation into the knowledge of patients (n=50) about sublingual glyceryl trinitrate. This study was conducted in 1988 with the aid of a questionnaire. The conclusion was that patients showed a depressing lack of knowledge of their drug treatment (Bailie & Kay, 1988). These three examples of studies indicate that patients have an insufficient general knowledge about their medicines. As mentioned in section 1·2·5, these studies concluded that additional printed information would be beneficial for patients.

Several other investigations have tried to establish the influence of the supply of printed information on general knowledge about medicines. Wiederholt and Kotzan (1983) investigated whether the inserts that were suggested by the FDA would have been successful for benzodiazepines. They used an 11 question multiple choice exam. Patients (n=67) who received an insert scored higher than those who did not (n=69), and it was concluded that the insert was effective in communicating information about medicines to patients. An investigation into the influence of printed information about oral contraceptives found that 54 per cent of the women (n=50) answered fewer than 7 out of 18 questions correctly. Although the conclusions stated that printed information was not optimal, patients who had read the leaflet scored significantly better in a recall questionnaire (Sands, Robertson & Orlando, 1984). Gibbs and her colleagues interviewed seven hundred and nineteen patients (419 received printed information, 300 did not) at the patients' homes in Hampshire. Patients who received leaflets were better informed about every item of knowledge, except for the name of the medicine (Gibbs, Waters & George, 1989a). In a second study, in which patients were also interviewed, these results were confirmed. Patients who received leaflets (n=252) were better informed about every item of knowledge tested than those who did not (n=247)(Gibbs, Waters & George, 1989b). I will refer to several of these studies when specific areas of patients' knowledge are discussed.

Three overviews demonstrate convincingly the positive relation between the supply of printed information and an increased knowledge in patients. Ley found that in 31 out of 32 studies, the knowledge of patients about their medicines had increased (Ley & Morris, 1984; Ley, 1988). Haecht (1992) listed 24 studies which show the same result. However, these generalizations should be carefully interpreted. These studies used different evaluation techniques, different types of printed information, different types of medicines, and were undertaken in several countries. A subdivision of the results of some of these studies into three areas of knowledge seems necessary to determine in which areas the main improvements in knowledge are found.

Knowledge about the treatment.

One of the reasons for supplying inserts is to improve patients' knowledge about the treatment, and the

motives for using a medicine. A study in Edinburgh investigated the effect of providing printed information on patients' understanding and recall of general information and specific recommendations. Thirty patients received printed information, 26 patients did not. Patients were questioned when they returned to the hospital, and responses were recorded verbatim. A significant improvement of knowledge about the diagnosis and the treatment in the printed group was found (Ellis et al, 1979). Sandler and his colleagues investigated whether a booklet given to patients who were discharged from hospital increased knowledge and recall. Booklets were given to 65 patients, 66 patients served as control. Patients were interviewed when they returned to the hospital. It was found that 85 per cent of the patients who received a booklet knew the reasons for taking their medicines. The figure for the control group was 42 per cent (Sandler, Mitchell, Fellows & Garner, 1989). A study in Northern Ireland investigated the effects of the supply of printed information about phototherapy (n=16). Patients received a questionnaire with 24 questions prior to receiving a booklet about the therapy. Two weeks later, patients were asked to complete the same questionnaire. It was found that printed information contributes to a greater knowledge about the therapy (Morrow, 1984). Although these investigations did not use inserts, it seems that the supply of printed information increases patients' knowledge about the treatment and the reasons for using a medicine.

Knowledge about instructions for use.

Another reason for supplying inserts is to inform a patient about how to use the medicine. Several of the studies mentioned earlier found that patients did not know how to take their medicines. In the Boots survey (n=8831) 55 per cent of the subjects did not know exactly how, when or with what they should take their medicines (Busson & Dunn, 1986). Other investigations tried to find out whether the supply of printed information does alter patients' knowledge about the instructions for use. In a study mentioned earlier, investigating whether a booklet given to patients (n=65) discharged from hospital increased knowledge and recall, 58 per cent of the patients knew the frequency of the dose of their medicines. The figure for the control group (n=66) was 38 per cent (Sandler et al, 1989). Both these scores are low for an effective use of a medicine, but they indicate that the supply of printed information does improve the knowledge of patients. A large scale investigation in England, Wales and Scotland, by means of a postal questionnaire, was undertaken in 1988. This study investigated the effect of the supply of inserts for three specific types of medicines. Patients who had received a prescription for these specific medicines were approached by pharmacists, and were asked to participate in a study. Half of the pharmacists dispensed a leaflet with the medicine (n=1809), the other half did not (n=1601). The results showed that significantly more patients who received a leaflet (77% vs 67%) knew how to take their medicine (Gibbs et al, 1990). The increase in knowledge in this study is not as large as in the investigation of Sandler and his colleagues. This variation in the level of improvement seems important. I will come back to this point in section 2·5, and to this specific investigation in section 3·1, where the graphic presentation of the leaflets of this study is discussed.

Knowledge about side-effects.

Several studies have indicated that patients have insufficient knowledge about possible side-effects of medicines. These studies investigated the knowledge of patients without the supply of printed information. In the Boots survey (n=8831) 80 per cent of the subjects did not know about potential side-effects of their medicines (Busson & Dunn, 1986). An investigation in England found that 73 per cent of the patients (n=154) did not know any side-effect which could result from taking medicines (Ridout et al, 1986). These figures are clearly very high. Several of the studies mentioned earlier have indicated that the supply of printed information does increase knowledge about side-effects in patients. A pilot study, one of the first of this kind in Great Britain, was undertaken in 1983. The effect of the supply of a printed leaflet on patients in general practice was investigated. Patients (n=109) received a leaflet from a prescriber when they received a prescription for specific groups of medicines. Other patients (n=98) did not receive a leaflet. All patients were interviewed between 4 and 10 days after the consultation. The group who received a leaflet were more aware of potential side-effects (George, Waters & Nicholas, 1983). In the study of Gibbs in 1988, which was mentioned earlier, a postal questionnaire was used. The results indicated that the knowledge of side-effects was significantly higher amongst patients who received a leaflet (Gibbs et al, 1990). Although the experimental approaches in these studies differed, both methods indicate that patients' knowledge of side-effects improves when printed information is supplied. There are several other issues involved when information

about side-effects needs to be supplied to patients. I will come back to these issues in section 2·3.

It can be concluded that the supply of printed information about medicines has a positive influence on patients' knowledge. This review also showed that there is a variation in the improvement of the different areas of patients' knowledge about medicines. The number of studies reviewed is too small, and the differences between the studies are too large, to make conclusive judgements about the changes in knowledge in each area. However, this review revealed that different investigations found different levels of improvement in patients' knowledge. This seems particularly relevant to this study, because the influence of the graphic presentation could probably be detected in these differences in improvements. I will come back to this point in section 2·5.

2·2·3 Change in attitudes of patients.

A second main reason of producers in supplying inserts is to change some attitudes of patients. Two areas are suggested in which printed information could influence the attitude of patients towards medicines: the satisfaction with the information supply and with the treatment, and the risk-benefit assessment. Patient package inserts are expected to improve patients' satisfaction with the information supply and with the treatment, and to reassure them of the appropriateness of the medicine. An overview of the results of experimental research in this area is difficult, because of the different ways of defining, and measuring, attitudes of patients (Fitzpatrick & Hopkins, 1983).

Satisfaction with the information supply and the treatment.

This first area, the satisfaction of patients with the supplied information, seems a rather obvious point to investigate. It would seem clear that the supply of information does improve the satisfaction of patients with the information supply. However, several studies have investigated whether this is the case. Studies undertaken in Southampton indicated that improved satisfaction with the information appears to be one of the major beneficial effects of the supply of printed information. In a study mentioned earlier, patients who received printed information were more likely to be completely satisfied with the information they had been given, and with their treatment in general (George et al, 1983). However, this increase in the satisfaction with the treatment in the patients who received printed information was not statistically significant. Several consecutive investigations showed the same result. It was found that the supply of printed information was associated with an improvement in patients' satisfaction with the treatment itself, but that this improvement did not reach statistical significance. These results were obtained by interviewing patients at their homes, and asking them to rate their satisfaction on a five point scale (Gibbs et al, 1989a; 1989b; 1990).

Ley (1988) stated that patients are more satisfied when they receive information. He emphasised the importance of patients' satisfaction with information, by stating that there is a direct relation between the satisfaction with the supplied information and the satisfaction with the treatment. However, empirical evidence for this relation was not mentioned. In a Belgian study, 75 per cent of a sample of the Belgian population (n=398) stated that inserts are reassuring, that they can always be consulted, and that they reinforce the prescriber's instructions. Patients who had received printed information were more satisfied (Stichele, Haecht, Braem & Bogaert, 1991). Several other studies have indicated this as well. Examples of these studies are those undertaken by Gotsch & Liguori, 1982; Lehrl, Fischer & Cziske, 1982; Desponds, Melle & Schelling, 1982; Morris & Olins, 1984; Fincham & Wertheimer, 1985; Tullio, Eraker, Jepson et al, 1986.

The results of investigations into the satisfaction of patients with the supplied information are conclusive. It is clear that patients are happier with, than without printed information (Haecht et al, 1989). However, the correlation between patients' satisfaction with the information, and patients' satisfaction with the treatment is unclear.

Risk-benefit assessment.

The second area of patients' attitudes that might be influenced by the supply of printed information is the risk-benefit assessment. It can be argued that a risk-benefit assessment has to be made twice. The first time is during the consultation for prescription-only medicines, or while purchasing a medicine for OTC medicines. The risks and benefits of a specific medicine are compared with the risks and benefits of other medicines in the same group. The second time is when a patient has to decide whether to take a medicine or not. This is the time when the patient needs information to be reassured.

Jungermann and his colleagues (1988) stated that there are two types of information that need to be communicated about risks. In the first place the

principal ways in which things may go wrong. This type of information should tell patients what can happen when medicines are not taken, or when too many medicines are taken. The reactions of patients to this kind of printed information has rarely been researched. A high correlation between subjects' assessment of risk and their intention to take a drug was found in the United States. This risk assessment was dependent on the number of side-effects and their rate of occurrence. The results of this study are difficult to apply to inserts, because they were obtained by interviewing undergraduate business students who cannot be seen as representative of the patient population. However, this study is worth mentioning because it highlighted some of the difficulties in informing people about risks. For example 'abnormal bruising', when listed as a side-effect of a medicine, caused more concern than 'a tendency to develop black and blue marks' (Keown, Slovic & Lichtenstein, 1984).

The second type of information about risks that needs to be communicated is the incidence with which these things have gone wrong in others following the same treatment. This information could increase the fear for side-effects resulting in the refusal of a patient to take the medicine. It could also increase the anxiety in patients (Tice, 1978; MacLeod, 1979). A study on estrogen users (n=100) which investigated the effect of the supply of information illustrates this point. Estrogens can be prescribed for several reasons. The insert did not make these differences clear, thereby causing severe apprehension (Weintraub, Glickstein & Lasagna, 1981). However, there is little evidence of patients refusing or discontinuing treatment when information about side-effects is provided (Gibbs, 1990).

This section can be concluded by stating that the supply of printed information does influence patients' satisfaction with the information supply, and can influence the risk-benefit assessment. However, several issues, such as the way in which side-effects and the balance between beneficial effects and risks are mentioned still need to be investigated.

2·2·4 Improvement in compliance.

A third main reason for supplying printed information is to improve patients' compliance. A definition of compliance is difficult to give. The whole concept seems questionable because it is based on a paternalistic point of view: patients are compliant when they obey the instructions of prescribers. An alternative approach is described by Neuberger (1991), who suggested that a patient should be provided with a choice.

However, in order to investigate the effectiveness of medicines, and the influence of printed information on this effectiveness, it is essential to look at medicine taking behaviour of patients. Five different types of non-compliance can be identified (Ley, 1988).

- not taking enough medicine (underdosing)
- taking too much medicine (overdosing)
- not observing the correct interval between doses (erratic dosing)
- not observing the correct duration of the treatment
- taking additional non-prescribed medications

The effectiveness of printed information in reducing non-compliance will thus depend on the type of non-compliance involved.

Apart from these differences in types of non-compliance, there are several different assessment methods. For example patients' reports (self reports), pill and bottle counts, blood and urine tests, mechanical devices, direct observation, outcome (that is the progress of illness or condition), and a prescribers' judgement, are all used to measure compliance rates. A novel assessment technique was introduced in 1989: a standard pill bottle with a microprocessor in the cap to record every bottle opening (Cramer, Mattson, Prevey et al, 1989). The validity of this technique still has to be proven, but it has shown to be a reliable investigation technique (Stichele, 1991b).

The implicit assumption that the supply of information would directly lead to an improvement of compliance does not seem to be true for all medicines. The literature is rife with unsuccessful attempts to improve compliance with long term treatments by supplying printed information (Gibbs, 1990). Three outcomes of these studies have been reported. The first group of studies found that patients are more likely to comply when information is supplied. The second group of studies could not find this relation. The third group of studies found a negative relation. The outcome is negative when the supply of information would lead to fear which could lead to non-compliance. Ley (1988) stated in an overview that 15 out of 25 studies found that the supply of information increased compliance. The other 10 studies did not detect improved compliance. Haecht (1992) lists fifteen studies indicating that the supply of information does not influence compliance as well as eleven studies that indicate the opposite.

The literature leads to the conclusion that

supplying printed information is not sufficient to obtain compliance from a patient. However, printed information can be considered as a necessary, but not sufficient condition for compliance (Morris & Halperin, 1979; Gibbs, 1990). Clearly, other factors are involved in the transition between being informed to being compliant. Some of them are of a practical nature, such as the tailoring of the regime, or the ways in which patients seek and handle medical expertise. Other influential factors could be poor communication, satisfaction with the treatment, continuity of care, the level of control that patients feel they have over the situation, the complexity of the drug regimen, the patients' health beliefs, and explanatory models, and the way these factors influence illness behaviour (Gibbs, 1990). It is clear that these factors fall outside the scope of this investigation.

2·2·5 Patient's reactions expected by producers.

Apart from an increase in knowledge, a change in attitudes, and a higher rate of compliance, several other patient reactions can be seen as aims for supplying information. Opponents of the supply of information suggest that the supply of information might lead to three actions among patients:

- an increased experience of side-effects caused by suggestion
- an increased inappropriate use of medicines, and experiments with medicines by patients
- an increase in the number of questions to prescribers and pharmacists that would otherwise not have been asked

Experiments have demonstrated that these fears are not supported by empirical evidence.

Experience of side-effects does not seem to be increased by the supply of printed information. Several studies found that patients who had received printed information about their medicines were no more likely to experience side-effects than those who had not. Haecht (1992) lists thirteen studies indicating this result, for example Morris & Halperin, 1979; George et al, 1983; Myers & Calvert, 1984; Gibbs et al, 1989a; 1989b.

Several studies suggest that the reporting of adverse reactions, rather than actual experience of adverse reactions, may be enhanced by printed instructions. In a study in 1982, inserts were supplied to hypertensive patients (n=249). It was found that patients who had received an insert were more able to relate side-effects to their medicine (Morris & Kanouse, 1982). Similar results were found in several studies undertaken in Belgium. This investigation also indicated that more complaints about health matters were mentioned by a patient after an insert was received (Haecht, 1992).

The second point, that patients would start experimenting with medicines and that inappropriate use of medicines would increase, has not been investigated.

The third point, that the number of questions will increase, seems to be true. This was stated by supporters of inserts as one of the major advantages of inserts: to enable and help patients to communicate well with health carers about the treatment (Herxheimer, 1989; Stichele et al, 1991). Three studies illustrate this point. Sands and his colleagues (1984) investigated the number of questions asked by oral contraceptive users (n=50), and found that readers of an insert ask more questions. In a study in Northern Ireland investigating the effects of the supply of information about phototherapy (n=16), it was found that printed information contributed to an increased number of questions from patients (Morrow, 1984). Belgian research indicated that patients (n=317) talked more about the side-effects, when they had received an insert (Haecht et al, 1991).

There are at least two additional possible reasons for developing and producing patient package inserts. These producers' aims have not been described yet, because they are not directly related to patients. The first reason is to include an insert solely for marketing and advertising reasons. The manufacturers of over-the-counter medicines in Great Britain seem to support this aim. The second reason for including inserts is to divert responsibility and liability away from the pharmaceutical industry, pharmacists and prescribers. Both of these issues are frequently discussed, but a clear consensus has not yet evolved. These two producers' aims will not be taken further in this thesis.

2·2·6 Concluding.

Two issues need to mentioned when a conclusion about the reasons for supplying printed information to patients is to be drawn. Firstly, the reasons themselves: it is doubtful if inserts can fulfil the producers' aims in all the areas that have been discussed in this section. However, this review indicated that some results can be expected in specific areas. The results of the supply of patient package inserts can be grouped into three categories. The supply of printed information can:

- improve the knowledge of patients. There is a variation

in the level of improvement for different types of information
- improve patients' satisfaction with the information supply. The relation between satisfaction with the information supply, and satisfaction with the treatment has not been proven
- increase the number of questions asked by patients

The conclusion of Morris (1989: p 119), who stated that inserts should be regarded as 'an educational vehicle without many demonstrated (positive or negative) behavioural effects' has proven to be too negative a view.

The second issue that needs to be addressed in this conclusion are the investigation methods. Several methods were used to investigate the results of the supply of printed information to patients. The number of studies that have been undertaken, in combination with the variation in information suppliers, different types of medicines, different countries and differences in documents, make a careful interpretation of these conclusions necessary. However, it seems that interviewing patients provides reliable experimental results. I will come back to this point in section 4·4·3.

The results of the supply of inserts, which are discussed above, are all related to the second aim of the patient package insert, as defined in section 2·2·1. The patients' side of the aim of inserts, that is the right to be informed, has not been mentioned yet. The next section describes the information content of patient package inserts. Section 2·4 will discuss whether this content fulfils the information requirements of patients.

2·3 The content of an insert.

This section deals with the information content of inserts. The previous section has described the reasons for supplying inserts to patients. This section looks specifically at information that is included in an insert. This information needs to conform to the EC-regulations (Directive 92/27/EEC, 1992). Section 2·3·1 identifies current regulations, guidelines and opinions on how this information should be supplied. Section 2·3·2 looks at the individual information sections. Section 2·3·3 looks at some research findings relating to the language, wording, text length, and text style of inserts. The patients' requirements for information are then discussed in section 2·4, and are compared with the information sections that are discussed in section 2·3·2.

2·3·1 Factors influencing the contents.

Four basic factors determine the content of an insert.
- the content of a patient package insert must be consistent with the product licence (SI 1977 No. 1055; ABPI, 1988). The regulatory authorities must compare the content of an insert with the information about a medicine on which the product licence was granted. This is to prevent the patients' receiving more or different information about a medicine than prescribers and pharmacists
- references to other medicines are not allowed (SI 1977 No. 1055)
- the content of an insert must not be promotional in nature or text (ABPI, 1988). This is only applicable for prescription-only medicines. The professional organisation for OTC-medicines, PAGB, does seem to have an different view, and does not object to an insert containing promotional information
- the pharmaceutical industry, that is the licence holder of a medicine, is responsible for the development and production of inserts. This is not as obvious as it seems. The development of inserts for a complete pharmacological or therapeutic groups of medicines, especially when several pharmaceutical manufacturers co-operate, is seen as beneficial. The main reason is that names and descriptions can be standardized for groups of medicines, which in turn could reduce patients' confusion. Inserts for oral contraceptives in Britain, and medicines with the same active ingredient in Germany, are examples of this approach. These inserts for these groups of medicines are (nearly)

1. Sections to appear on an outer packaging (article 2).	2. Sections to appear on a small pack (article 3.3).	3. Sections to appear on a blister pack (article 3.2).	4. Sections to appear on a package insert (article 7). Section number		
					Name
•	•	•	•	**A**	- invented name/trade mark
•	•	•	•		- common name (International non-proprietary name)
					Active ingredients
•			•		- qualitatively
•	•		•		- quantitavily per dosage unit
•					**List of excipients**
			•		- qualitatively
			•		- quantitatively
•			•		**Pharmaceutical form**
•	•		•		**Content** by weight, volume, number of doses
•			•		**Pharmaco-therapeutic group** (or: type of activity)
•		•	•		**Name of license holder**
•			•		**Address of license holder**
			•		**Name of manufacturer**
					Therapeutic indications (and pharmacological characteristics)
			•	**B**	
					List of information before taking the medicine
				C	- contra indications
			•		- appropriate precautions for use
			•		- interactions
•			•		- special warnings
			•		- effects on the ability to drive vehicles or to operate machinery
			•		- details of excipients for safe and effective use
			•		
•[1]					**Instructions on the use**
				D	- the dosage
•	•		•		- method of administration
•	•		•		- route of administration
			•		- frequency of administration / appropriate time
			•		- duration of the treatment
			•		- action in case of overdose
			•		- action in case of underdose
			•		- risk of withdrawal effects
			•		
					Description of undesirable effects
			•	**E**	- action to be taken
			•		
					Reference to expiry date
			•	**F**	- warning against use after expiry date
•			•		- special storage precautions
			•		- warning against visible deterioration
			•		
					The date the leaflet was last revised
			•	**G**	
					Not in the insert
					- The expiry date in clear terms
•	•	•			- Special precautions for disposal
•					- Number of authorization
•					- Batch number
•	•	•			- Special warning that the product should be stored
•					out of reach of children

• = obligatory
· = if appropriate

[1] = In case of self medication only.

Figure 2·1. Information sections according to the EC-regulations (Directive 92/27/EEC, 1992)

identical for all producers. However, the pharmaceutical industry remains responsible for the supply of inserts

The four factors mentioned above have created a legal problem that has not been resolved. The inserts, which are developed by the pharmaceutical industry, are controlled in Great Britain by the Medicines Control Agency (MCA). This agency checks whether the information about a medicine in an insert conforms to the product licence of that medicine. The ownership of the copyright of the text in inserts is fuzzy when the MCA has made substantial changes. This is directly related to the ownership of the rights for the graphic presentation. It is not clear whether the graphic presentation of inserts can be protected. The liability for the text is similarly doubtful. If the information is approved, it does not mean that the MCA will take responsibility for the text (Balthazar, 1993). The different legal grounds for the control agencies (or regulatory authorities) in the different European countries, and the different laws in these countries, make the legal situation a confusing area.

2·3·2 Information sections according to EC-regulations.

The list of information sections that have to be included in an insert is based upon research and common sense. Little disagreement exists about the necessity to include the majority of the sections. However, the actual content of the separate sections is still open to debate. The purpose of this section is to list several issues in this debate, rather than to give a complete overview of the separate information sections in an insert. **Figure 2·1** lists all the information sections as they are required by the EC-regulations (Directive 92/27/EEC, 1992). Two points need to be mentioned beforehand. The first point is that the information sections in an insert must appear in this order. This requirement clearly influences the graphic presentation. This point will be further discussed in section 2·4·1. The second point is that these regulations do not distinguish between prescription-only medicines and OTC-medicines. This point is mentioned in section 2·4·2.

Identification of the medicine.

This first section is included to identify the medicine. Several different names can be used: the traditional Latin name, the brand name, the common name and the active ingredient. The British Pharmacopoeia lists all these possible names and is used as the standard in Great Britain. The British law states: 'Name of the medicinal product, followed by the common name if the product contains only one active ingredient and if its name is an invented name', and 'Where available in several forms and/or strengths, that must be included in the name' (The Medicines Act 1968). Proprietary medicines will have a distinct name to separate the medicine as much as possible from similar branded medicines. It was therefore necessary to stipulate in the ABPI guidelines that the proprietary name of the product should not appear unduly prominent or frequently (ABPI, 1988). The ABPI statement suggests that the front and the back of an insert should be 'headed up': 'What you should know about ... (brand name)' and 'The name of your medicine is ... (brand name)'. Whether patients would use any of these names to refer to their medicine remains doubtful.

This section must provide a quantitative statement of the ingredients, the pharmaceutical form and content, and the pharmacological and/or chemical category. The regulations stipulate that a 'full statement of the active ingredients and excipients expressed qualitatively and a statement of the active ingredients expressed quantitatively, using their common names' must be included. The ABPI suggests that this section should be headed: 'What's in your medicine?' and states that on the front of a leaflet a statement like: 'this is one of a group of medicines called ... (The general pharmacological and or chemical category)' should be incorporated. The EC-regulation adds: 'these terms should be easily comprehensible for the patient'. A sceptic stated that this advice is useful in known categories, but what about fibrinolytics or mucolytics?

The inclusion of the name of the licence holder, the address of the licence holder, and the name of the manufacturer is necessary. However, the ethical code of the pharmaceutical industry prevents providing any specific information to inquisitive patients who contact the industry on their own behalf, and these patients must be referred back to their prescriber. An address of a relevant patient organisation seems therefore more appropriate to appear on an insert in this section.

Therapeutic indications.

The description of therapeutic indications is dependent on each individual medicine. This section should describe symptoms, confirm the appropriateness of a medicine, and reinforce the advice of the prescriber. However, in some groups of medicines, this information needs to be considered carefully. In cases of

medicines for AIDS or cancer it is suggested that the purpose of the medicine should not be mentioned. A practical suggestion is given by the ABPI who stated that the phrase: 'Doctors sometimes prescribe this medicine for other purposes; consult your doctor for information' could be used in these circumstances.

Information which is necessary before taking a medicine.

This section contains warnings for patients which are important before and during the administration. Most of these warnings are specific to certain medicines or certain groups of patients. One exception is the warning to keep medicines out of the reach of children. The ABPI advises that this information should be included under the heading: 'Before you take your medicine'. Two kinds of warnings can be distinguished: the medicine-specific warnings and the patient-specific warnings. The medicine-specific warnings should warn against clinically significant or potentially dangerous interactions with other medicines or foods (alcohol, tobacco)(ABPI, 1988). This kind of warning could also mention the effects of the medicine on the ability to drive vehicles, or to operate machinery (Directive 92/27/EEC, 1992). The patient-specific warnings should, for example, say whether the medicine can be used by children or the elderly, in case of pregnancy, or by patients with specific disorders such as allergies, asthma or diabetes. Not surprisingly, these groups of patients see this section as important (Rupf, 1991). Patients are frequently aware of the dangers of mixing medicines with alcohol, but other specific warnings are not seen as important. The actual wording of these warnings still needs to be investigated according to article 12 of the EC-regulations.

Instructions for proper use.

There is a difficulty in mentioning the method of administration, the route of administration and the times of administration in an insert. For prescription-only medicines, the pharmacist will add a label to the outer packaging of prescription-only medicines. This label gives personalized instructions according to the prescriber's prescription form. In order not to supply contradicting information, the instructions for use in the insert must therefore be general. The ABPI advice states that the back of the insert should refer the patient to the label on the bottle, or to the instructions given by the doctor. Specific reference to meals should be listed where appropriate (ABPI, 1988). Several other instructions should be mentioned in this section. The average duration of the treatment, especially where it should be limited, must be mentioned. The EC-regulations state that emergency procedures must be stated in case of an overdose. There is however a problem in mentioning this overdose information for some medicines related to suicide attempts. Switzerland has no section for overdosing, because the Swiss commission simply forgot to add this section to the regulations (Rupf, 1993). Two other points that must be mentioned if they are appropriate for a medicine are the action to be taken if a dose is missed (underdosing) and possible withdrawal effects.

Undesirable effects.

There are several issues in the discussion of undesirable or side-effects in inserts. There are at least two difficulties preventing a straightforward listing of side-effects. In the first place, there is no clear agreement as to what a side-effect, an adverse drug reaction, or an adverse effect actually is. The second difficulty is in the perception of the severity and the frequency of side-effects. Keown found considerable differences between the attitudes of prescribers, pharmacists, and lay people concerning the number of side-effects that should be listed (Keown et al, 1984).

The main reason for mentioning side-effects is that appropriate actions can be suggested on the inserts if these adverse reactions occur. These undesirable effects should be recognizable by patients. Practical advice can prove especially useful here. The second function for mentioning side-effects in an insert is to explain the risks involved in the use of a medicine. The severity and the frequency need to be explained, but there is very little research evidence about the ways in which these risks could be communicated.

Expiry date and the date of last revision.

This is the last section that must be included in an insert. The insert must refer to the expiry date on the outer packaging, and must include a warning not to use a medicine after this date. The insert should also carry a warning against certain visual signs of deterioration. A final fact that must be mentioned on every insert is the date that the insert was last revised.

These seven sections must be included in all patient package inserts from 1994 onwards. There are at least three additional information sections that could be included. These sections are suggested by interested parties, such as by consumers organisations, and patient organisations (Joossens, 1990a). These three sections are:

- a statement on how to recognize whether a medicine is working
- the procedure to be followed if further information is required
- and a section about the nature and duration of the expected effects

However, this information is not required by the EC-regulations.

2·3·3 Language, length and comprehensibility.

Some issues related to language, text length, and comprehensibility of information in inserts are discussed in this section. These issues are directly related to graphic presentation. In order to discuss these, a division between the information content of inserts and its graphic presentation was necessary. This division is possible because the majority of regulations and research make a clear distinction between these two. In section 2·5, this division is related to the separation between development and production of inserts, and use of inserts.

Language in inserts.

The language of the insert must be the official language, or languages, of a member state (Directive 92/27/EEC, 1992). Nine languages are recognized as official. Languages such as Welsh, Gaelic, Frisian, Basque and so on, are excluded and will not appear in inserts. In Great Britain this follows the requirements of the leaflet regulations which state that all information should be given in the English language (SI 1977 No. 1055).

At least two points need to be mentioned when the language of inserts is discussed. These points are related to the development of inserts: the choice of words, and the language style. A thorough review of studies in these areas would divert too far from this investigation. However, these areas do influence the graphic presentation of inserts.

The first point that needs to be made relates to the vocabulary of information in inserts. Words like 'stronger', 'new' or 'safe' can only be used in specific circumstances or should be avoided. 'Safe' in pharmaceutical jargon means something that the committee thought was not too dangerous given the therapeutic situation (Urquhart, 1989). 'New' can only be used for a restricted period after the registration. Several studies indicated that patients often do not know the meaning of words that are used in a medical context. Some of these studies are mentioned in section 1·2. Several ways to reduce the number of words that can be misunderstood are suggested. The use of plain English (Barber & Raynor, 1989), and the application of standardized vocabulary (Joossens, 1990a) for the headings of information sections have been recommended. A dictionary providing common words in three languages for medical terminology, has been developed in Belgium. The use of such a dictionary is essential when a consistent use of vocabulary is required.

A second point is the style of language in inserts. The term 'style' is used rather loosely here, and is only used to encompass those few studies that have been undertaken in this area. Two issues have been investigated. The first is the choice between a summary and detailed information (Joubert & Lasagna, 1975a; 1975b; Kanouse, Berry, Hayes-Roth et al, 1981). Both studies found that patients were divided on this issue. Some patients prefer a summary, some detailed information, and others prefer both. A second issue is the tone of language. Morris and Kanouse (1981) found that, according to patients (n=456) the tone of language in inserts should be frank, instead of reassuring. However, studies into the style of language in inserts are rare, and their results cannot be generalised. The results of experiments that have been undertaken into the language of inserts are inconclusive. The few experiments that have been undertaken do not seem to point towards results that could be incorporated in the development of inserts. During a recent conference on patient inserts, a linguist pointed out that these issues can have a significant influence on the results of the supply of inserts to patients (Maes, 1993). In order to investigate the influence of these issues, it is necessary to have some sort of framework. Several of this type of framework have been developed by linguists or psycho-linguists. Examples of this approach are the text analysis methods as developed by Kintsch (1974), Kintsch & van Dijk (1978), Meyer (1975), and Werlich (1976). These methods have frequently been compared, for example by Weaver and Kintsch (1991). Two types of text have been distinguished: expository text and narrative text. The purpose of expository text is to update a person's knowledge about some event or state in space and time. Patient package inserts are therefore clear examples of expository text. A further subdivision of expository text can be made with the help of a taxonomy of expository text (Mosenthal, 1985). However, this taxonomy does not seem to be applicable to the study of graphic presentation, because the text features described in this taxonomy will not be

differentiated by graphic presentation. In general, these text analysis methods take very little notice of the graphic presentation and will therefore not be pursued here.

Length of the insert.

The second area that needs to be mentioned is the length of an insert. This length is not mentioned in any of the regulations. However, the length does influence graphic presentation, and it has received some attention from researchers. The length of an insert can be seen as a difficult compromise between complete and short. The inclusion of all the information about a medicine would make the insert too long to be useful. A short insert can be incomplete and this is unacceptable from a patient's point of view as well as from a legal view point. However, it is clear that not every eventuality can be mentioned in an insert, and that patients can always be referred to a prescriber or a pharmacist (Wells, 1989).

The majority of investigations into the length of inserts have asked patients for preferences. Patients prefer detailed information according to the conclusions of several studies (Benson, Gordon, Mitchell & Place, 1977; Morris et al, 1977; Mazis, Morris & Gordon, 1978). An investigation in the Southampton area found that of a group of 443 patients, 54 per cent wanted detailed, and 43 per cent wanted short information (Ridout et al, 1986). Dodds and King (1989) found that none of their patients (n=289) thought that too much information was included in the leaflet. Stichele and his colleagues asked patients (n=398) about the preferred length of an insert and the reply was that 88 per cent wanted exhaustive information. However 67 per cent of the same patientgroup stated in a separate question that they preferred a short package insert (Stichele et al, 1991).

The results of the studies investigating the length of inserts are inconclusive. Differences between medicines will mean that there will inevitably be substantial differences in the amount of information. The indications, the complexity of the instructions for use, and the length of the list of side effects will directly influence the length of the insert. However, it seems preferable to supply complete information in preference to a reduction in the length of an insert (Rupf, 1991).

Comprehensibility.

A third area that needs to be mentioned is that patients must be able to understand information. Without this requirement, an insert would not be of much use to patients. However, comprehension of information is difficult to regulate because of the difficulties in specifying, and measuring what is meant by understanding. The EC-regulations state that inserts should be written in 'clear and understandable terms for the patient' (Directive 92/27/EEC, 1992). The same proposal states that the inserts must take the particular conditions of certain categories of patients into account. These categories are not further specified, but it is clear from previous drafts of the regulations that blind, partially sighted, and illiterate patients are meant.

Every country within the European Community has its own formulation of this comprehensibility requirement. Belgian law states that an insert must 'provide the consumer with this information in understandable wording'. The target reader is defined as 'a mentally healthy adult with a formal education to the age of 16' (Stichele & Bogaert, 1989). The target age for readers in Great Britain according to the ABPI leaflet is 9 years old (ABPI, 1988). According to the same guidelines, the front page of the insert should be easier to understand than the back of the insert. What the reading age of the front page should be is not specified. How this specification could be met is not specified either.

These requirements on comprehensibility are difficult to adhere to without specifying as to what is meant by comprehensibility and how to measure it.

2·3·4 Concluding.

The information content of an insert is not as straightforward as is suggested in several regulations. At least three factors make the identification of the contents difficult:

- some information, like the severity and frequency of side effects, is difficult to communicate
- the length, language, and comprehensibility seem to necessitate a difficult compromise
- inserts should use a standardized vocabulary to indicate the ingredients, excipients, pharmaco-therapeutic group and therapeutic indications. This standardized vocabulary is certainly not established yet.

The issues mentioned in this section directly influence the graphic presentation. The current graphic presentation of the information sections in inserts is discussed in section 3·1. The influence of graphic

presentation on the use of these information sections in inserts is discussed in section 3·2. The next section, 2·4, describes the patients' requirements and opinions about these information sections.

2·4 Reactions from patients.

This section looks at the information supply in inserts from a patients' point of view. Until now, a paternalistic view of communication has been adopted. As long as the information about medicines was supplied to patients, and the patient received this information, the producer was satisfied. This section describes some investigations that have studied reasons for patients to read inserts, and some of the requirements that patients have with regard to the information content. These investigations were undertaken to find out whether the second aim of the supply of inserts, that is the patients' right to know, can be achieved. This section is divided into two parts. The first part describes the patients' requirements, the second part describes some objections that can be raised against the supply of inserts to patients.

2·4·1 Patients' requirements.

As was seen in section 1·2, patients would like to receive more printed information about their medicines. As suggested in section 2·2 this supply is not straightforward. In order to fulfil the patients' right to know, it is essential to take two points into account. In the first place, it is clear that there are differences between patients. Patients cannot be seen as a homogeneous group. These differences between patients need to be considered when inserts are supplied. In the second place, there are several different reasons for patients to consult an insert. This section tries to find whether there is agreement between patients in their requirements for information.

Why are inserts read?

Two investigations have tried to find motives of patients for reading inserts. In a Belgian survey (n=398) 83 per cent of the patients said that they read the insert to be able to carry out the treatment; 57 per cent for reassurance; 50 per cent to find out more about the drug; 31 per cent to decide whether the drug should be taken or not. These answers were obtained by asking patients to tick yes or no to these four predefined motives (Stichele et al, 1991). Rupf (1991) found that 56 per cent of the patients (n=84) read the insert for safety reasons, 27 per cent looked for specific information, and 17 per cent read the insert to find general information. In this study only one answer could be given. This last study also confirms the Belgian research by stating that the insert reaffirms the information

Investigators Year	Drug group Sample size	Percentage of patients that had read the inserts
Fleckenstein et al. 1976	oral contraceptives (n=828)	(64 % noticed) 91 % read
Eklund & Wessling 1976	antibiotic therapy (n=360)	66 % read
Morris et al. 1977	oral contraceptives	94 % read
Udkow et al. 1979	estrogen (n=154)	81 % read 6 % read by relative
Kanouse et al. 1981	5 types of medicines (n=1821)	70 % read
Gotsch & Liguori 1982	antibiotics (n=186)	96 % read
George et al. 1983	penicillins (n=56) NSAID (n=43)	92.8 % read 95.3 % read
Sands et al. 1984	oral contraceptives (n=50)	(90 % had received insert) 61 % read 29 % read part 10 % did not read
Bundesfachverband der Arzneimittel Hersteller 1988	general (n=2127)	71% read regularly 18% only for new medicines 5 % sometimes 2 % rarely 3 % never
Documed 1988	General (n=500)	67 % always 20 % sometimes 13 % never
Gibbs et al. 1989a	NSAIDs, b-adrenoceptors inhaled bronchodilators (n=419)	97% read
Servicio di informazione 1990	5 drugs (3OTC, 2POM) (n=6992)	78 % - 93 % read
Haecht et al. 1991	NSAIDs (n=317)	71 % read 7 % read by relative 8 % did not read
Stichele 1991a	hypertensives (n=1049)	(16% of packages contained an insert) 65 % read 35 % did not read
Stichele et al. 1991	general (n=398)	89 % read 4 % read by somebody else 7 % did not read
Rupf 1991	antihypertensives and antibiotics (n=102)	78 % read 11 % read part 11 % did not read

Figure 2·2. Studies investigating the number of patients saying that they had read patient package inserts

from the prescriber.

The results of these two studies suggest that there are at least three distinct groups of information that patients require.

- information related to safety: side-effects and risks
- instructions for use
- indications

These three groups of information are similar to the information sections in the European regulations.

When patients (n=398) were asked which information sections they would read thoroughly (as opposed to not, or only superficially), 88 per cent answered side-effects. The instructions for use would be read thoroughly by 85 per cent, contra indications by 82 per cent, and indications by 79 per cent of the patients (Stichele et al, 1991). The study by Rupf (1991), mentioned above, found that patients (n=84) were most interested in the undesirable effects (28%), the indications (25%), and the instructions for use (20%). A third study, which was undertaken in an urban practice in Munich (n=315), found that 92 per cent of the patients were particularly interested in the side effects, 80 per cent were interested in the indications, 67 per cent of the patients were interested in the instructions (Siegel, Grund & Schrey, 1985). The differences in percentages in these three studies may be caused by the differences in evaluation method. The similarity in the sequence of importance ranking of the information sections seems remarkable. The information related to safety aspects is seen as most important by patients in all studies. The instructions and indications share the second rank.

Two discrepancies between the information as included in inserts, and the patients' requirements for information are apparent. The first discrepancy is related to the sequence of the information sections. The sequence set out in the EC-regulations is different from the sequence of the importance of these information sections according to patients.

The second discrepancy between the information provision and the patients' requirements is related to the name of the medicine. The name of a medicine is important for health carers, and is mentioned in the first section on an insert. Several investigations have asked patients to recall the name of their medicine. This recall was frequently very poor (Eklund & Wessling, 1976), and recall of the name of the medicine by patients did not improve when printed information was supplied (Gibbs et al, 1989a; 1989b). This low recall of the name of a medicine by patients does seem to indicate that patients do not find the name of a medicine very important. The influence of these discrepancies on the effectiveness of the insert remains to be investigated. Both points are minor, and it is evident that most of the patients' requirements for information are included in the EC-regulations.

Are inserts read?

Figure 2·2 indicates that most investigations have found that the percentage of readers reporting that they have read an insert is higher than 70 per cent. Ley states that it seems reasonable to expect that just under three quarters of patients will read leaflets about their medicines (Ley, 1988). Research in 1989 in Belgium (a country with inserts in nearly every medication package) found that 19 per cent of a group of patients (n=1049) who had attended education after the age of 18 did not read inserts. This figure increased to 42 per cent for patients who had not had any education, or only secondary school. Gender did not influence these findings (Stichele, 1991a). Rupf (1991) asked patients who did not read the insert for a reason. Two groups emerged. The first group did not read the insert because they thought that they could not understand the insert, because it contained too much information, or because the 'print size' was too small. A second group did not read it because they trusted their prescriber or pharmacist.

Patients' opinions about inserts.

Several investigations have specifically asked patients whether they like to receive inserts, and whether they thought that inserts are a useful document. Stichele and his colleagues found that 86 per cent of a sample of the Belgian population (n=398) stated that the insert is useful (Stichele et al, 1991). Rupf (1991) found that 88 per cent of his sample of Swiss hypertensive and antibiotic patients identified advice in the insert which they found useful. In a study in the USA, which investigated the use of inserts by oral contraceptive users (n=828) 86 per cent of the women who read the insert said they found it helpful (Fleckenstein et al, 1976).

It is difficult to say whether the supply of patient package inserts to patients can be fully evaluated at this stage. The introduction of inserts has been slow, and not all medicines are accompanied by an insert yet (Joossens, 1990a). However, the opinions of patients are positive, and it seems that the patients' requirements for information about medicines can be fulfilled with the supply of inserts.

2·4·2 Objections against the supply of inserts.

There are several objections to the development and production of patient package inserts. I will list eight of these objections below. The issues raised by these objections do not directly influence the graphic presentation, but they can hamper the development of inserts.

- The first objection is related to the reliability and accuracy of the information in inserts. The patient package inserts must be developed and produced by the pharmaceutical industry. This information may therefore be biased. The patient package insert still has to prove its reliability.
- I specified in chapter 1 that I would not comment on political, legal, and economic aspects of patient package inserts. One major issue is, however, worth mentioning. The legal status of the insert is still not established, and it is not known whether patients can claim malfunction of a medicine based on information in inserts. This issue is still not resolved (Heacht et al, 1989). Some argue that this needs to be clarified first, before a large scale introduction of inserts can commence.
- The influence of the regulating authorities (European Community, national, professional organisations) on the relation between prescribers and patients increases with the introduction of inserts. The introduction of an insert, which must be included in each medicine package, forces prescribers and patients to consider this external information source. The supply of an insert will therefore alter the relation between prescribers and patients. This is one of the main reasons that the patient package insert programme in the USA was aborted (McMahon, 1975; Roth, 1982).
- A fourth objection to the supply of inserts is that the insert is supplied too late to be of much use for the patient. The information about specific medicines should be available at the consultation stage for prescription-only medicines, and at the dispensing stage for over-the-counter medicines. The insert is only available after these stages have been completed.
- A fifth objection is related to the EC-regulations. In these regulations, all medicines are treated in the same way. Parenteral products, long term medicines, over-the-counter medicines are all legally bound to include an insert. It can be argued that this single approach cannot be the most effective.
- The fundamental difference between prescription-only medicines and over-the-counter medicines is not taken into account. In Great Britain, there is a very clear difference between these groups of medicines. The main difference between over-the-counter medicines and prescription-only medicines is that the information about OTC medicines should be available to the consumer at the time of purchase. The information should therefore appear on the outer packaging. This is the current situation in Great Britain. An insert would reduce the accessibility of this information about over-the-counter medicines for consumers.
- The poor quality of an insert aimed at prescribers (the stuffer) might have caused an aversion of the patient against any insert that is included in medicine packaging. The patient might expect to find an incomprehensible insert, and therefore not use it.
- Some people still remain sceptical that the leaflets will be read.

Despite these objections, there seem to be more advantages than disadvantages in supplying inserts to patients.

2·4·3 Concluding.

Section 2·4 can be concluded by stating that the supply of inserts does fulfil part of the patients' requirements for information about medicines. This fulfilment was stated as one of the aims for supplying inserts. Indications, side-effects, and instructions for use are the sections that patients are most interested in. These sections are therefore most likely to affect patients' knowledge, attitudes, and behaviour. The investigations that are reviewed in section 2·2 support this conclusion. This section also indicated that it is essential to include the patient in the evaluation process in order to see whether the supply of inserts is effective in achieving the aims of the producer, and fulfilling the requirements of patients.

The conclusions of this section and of section 2·2 are used as a starting point for the investigation of the influence of graphic presentation on the use of inserts by patients. In section 2·5, some of the issues related to these conclusions are discussed, and the scope of this investigation is focused onto graphic presentation.

2·5 Investigating graphic presentation.

This section brings together some of the issues that have been raised in the second chapter. The first section introduces a division between the producers' domain and the patients' domain. The second section describes some reasons for using inserts as a vehicle to study the influence of graphic presentation. The third section concludes this chapter.

2·5·1 The producers' domain and the patients' domain.

Two aims for supplying inserts were formulated in section 2·1·1. The first aim for supplying inserts is to improve the effectiveness of the use of medicines. The second aim for supplying inserts is to satisfy the patients' right to know. This section uses these two aims to introduce a division between the domain of the producer of inserts, and the domain of the patient as a user of inserts. This division is only introduced at this point, and will be expanded in section 3·3.

The first domain, the producers' domain, incorporates the development and production of patient package inserts. The general aims for supplying inserts were described in section 2·2·1. Section 2·2·2 described four main areas in which results from the supply of inserts are expected. These four areas are:

- an increase in patients' knowledge
- a change in attitudes of patients
- an increased compliance
- an increased number of reactions

An insert is seen as successful by a producer when responses of patients in these areas can be observed. It was shown, by means of a literature review, that results in several of these areas can be achieved when inserts are supplied to patients.

The second domain describes the patients' views about inserts. This side was described in section 2·4. Three main reasons for patients to use an insert were described. Patients use inserts to find information about side-effects and risks, instructions for use, and indications. Insert are seen as a successful document by patients when specific information can be found and applied.

In order to achieve the producers' aims and to fulfil the patients' requirements, it seems essential to develop patient package inserts. The most effective insert is therefore defined as the insert that achieves most of the producers' aims and fulfils most of the patients' requirements. The aims for supplying inserts have been determined by producers during the last 20 years. The requirements of patients were ascertained by asking patients about their information needs. The results of these investigations were integrated in the list of information sections of the EC-regulations, as they are described in section 2·3. It was therefore recognized at an early stage, that it is essential to investigate, and incorporate, the patients' requirements in order to develop an effective insert. It is evident that the supply of printed information does affect responses of patients.

This study set out to investigate the influence of graphic presentation of information on the use of inserts by patients. Two research questions were posed. Firstly, the question whether graphic presentation can influence responses of patients about the supply of printed information. The second question is whether it is possible to quantify this influence.

It is obvious that the influence of graphic presentation can only be observed in those areas in which responses of patients have been identified. Several areas in which responses have been investigated were described in sections 2·2 and 2·4. Especially the difference in the levels of improvements, as mentioned in section 2·2·2, seems to be an appropriate measure to detect the influence of graphic presentation. I will come back to these points, and the division between the producers' domain and the patients' domain, in sections 3·3·2 and 4·4·3.

2·5·2 Reasons for studying the graphic presentation of inserts.

This section lists six reasons why inserts are an interesting type of document for studying the influence of graphic presentation. The reasons for studying the graphic presentation of inserts are described in section 3·1·6.

- The first reason why inserts are an appropriate type of document to study graphic presentation is that it is important for patients to use an insert. A high percentage of patients say that they read inserts, and state that they are useful. This is a requirement for the investigation into the influence of their graphic presentation, because it assures that the information, and therefore the graphic presentation, will be looked at by patients.
- The second point is that an insert contains several different types of information. Instructions, warnings, advice, and background information are all included in different information sections as they are mentioned

in the EC-regulations. This makes it highly unlikely that an insert will be read as continuous text. The influence of graphic presentation on the use of these different types of information is therefore interesting.

- The third reason is that the patient package insert is a relatively new type of document. The graphic presentation has not yet been regulated, and no 'style' has been established yet. Alterations in the graphic presentation are still possible, which makes it a worthwhile area to investigate.
- The fourth reason is that current graphic presentation of information in inserts has been criticized by producers as well as by patients. Investigations should therefore be supported. It seems therefore useful to investigate whether and how graphic presentation of inserts can be improved in a practical way.
- The fifth reason is that patients can have several different purposes for reading an insert. The relation between graphic presentation and these different purposes is interesting to investigate.
- The last reason is that the extent of the influence of graphic presentation can be investigated. The influence of graphic presentation on the areas that have been described in section 2·2 and 2·4 can indicate the extent of the influence of the graphic presentation.

It is clear that not all these areas can be investigated in this thesis. A specific area for this study is described in section 4·4·4.

2·5·3 Summary chapter 2.

This chapter divided the investigation into two domains: the producers' domain, and the patients' domain. The producers' aims for supplying inserts are described in section 2·2. The main aim for supplying printed information to patients is to improve the effectiveness of the use of medicines. This aim can be subdivided into four areas: increase in patients' knowledge, a change in the attitudes of patients, an increase in patients' compliance, and an increase in reactions from patients. It was concluded that results in several of these areas can be achieved when inserts are supplied.

Section 2·4 describes the patients' requirements for information. This section shifts the view of this investigation from a paternalistic approach to a collaborative approach. It was concluded that most of the requirements of patients can be fulfilled with the provided information content. Section 2·5·1 suggests that it is essential to incorporate patients in a study investigating the influence of patient package inserts. This section also focuses this investigation onto graphic presentation of information in inserts. Section 2·5·2 provides six reasons why inserts are an appropriate type of document for the study of graphic presentation of information.

The current graphic presentation of inserts, and some aspects of their use are discussed in chapter 3.

3 Graphic presentation: current situation and document use.

This chapter relates the graphic presentation of information in inserts to the use of inserts by patients. Two main factors have to be described: the current graphic presentation of inserts, and their use by patients. This chapter is divided into three main sections.

Section 3·1 looks at inserts to find a rationale for their current graphic presentation. At present, some issues relating to graphic presentation are strictly regulated, some are described in guidelines, and others are left open. It seems useful to identify these issues to see how the current graphic presentation of inserts has developed, and what the present situation is. The variety of graphic presentations seems to indicate that regulations, guidelines and opinions of patients and producers have not resulted in a clear consensus. This section tries to find some reasons for this variety.

Section 3·2 looks at the use of inserts. A patient is viewed as a specific user, and inserts are viewed as a specific type of document. This generalization was necessary, because little research has specifically been undertaken on the use of inserts by patients. It is therefore assumed that the use of inserts by patients is similar to the use of any documents by users. The main purpose of section 3·2 is to look at possibilities of subdividing insert use; two different ways of subdividing the use of inserts into several aspects are described.

In section 3·3, the relation between graphic presentation and document use is discussed. The separation between the producers' domain and the patients' domain, as introduced in section 2·5 is used to discuss this relation. The development of graphic presentation, as described in section 3·1, is part of the producers' domain. The aspects of the use of inserts, as described in section 3·2, are in the patients' domain. These two domains are brought together in a matrix structure. This matrix will be used as a starting point for chapter 4. It will be demonstrated that it is necessary to separate these two domains when the influence of graphic presentation on the use of inserts by patients needs to be investigated.

3·1 Graphic presentation.

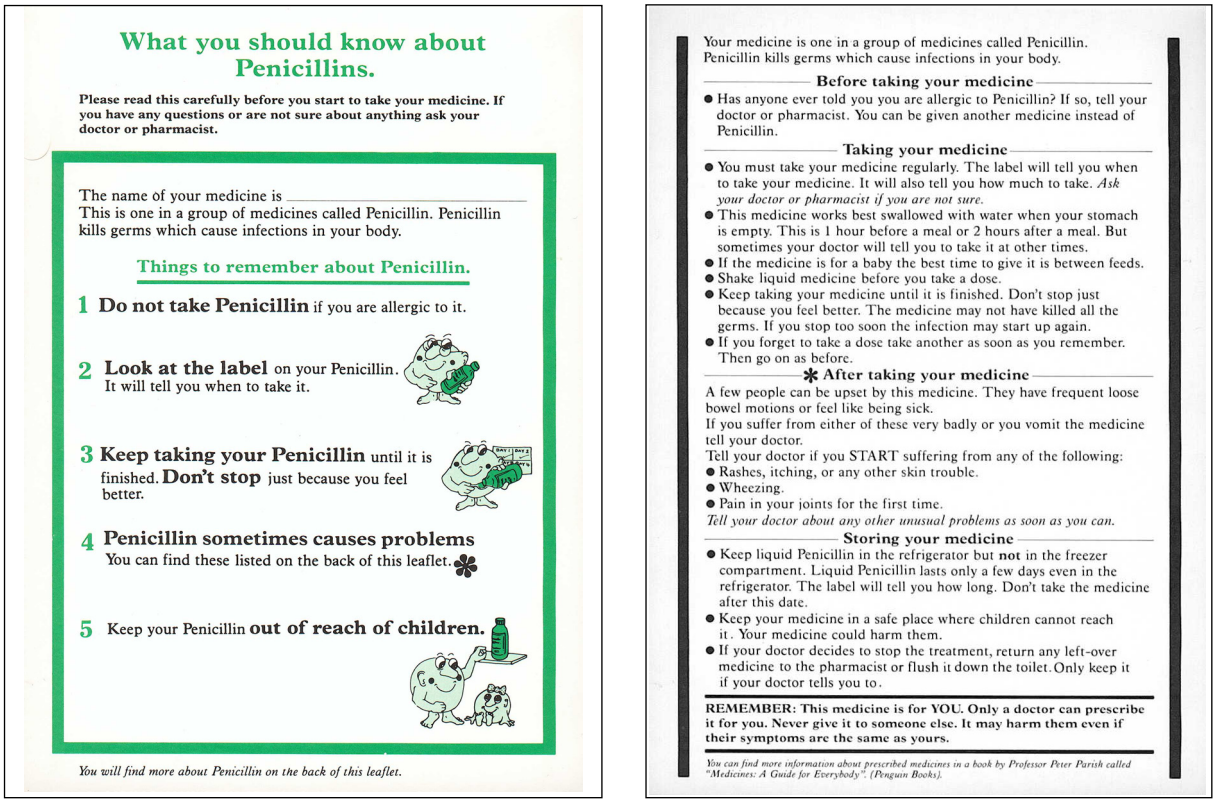
In this section, the graphic presentation of patient package inserts is discussed. The regulations, the guidelines, and the prevailing opinions of producers and patients about specific features of graphic presentation are described. The features of graphic presentation that are discussed in this section are the overall graphic presentation, issues relating to text specification, and the use of pictograms and illustrations in inserts. Section 3·1 concludes that several features of graphic presentation are not regulated, or mentioned in the guidelines, and that the current graphic presentation of inserts is not satisfactory for producers or patients.

3·1·1 Regulations.

The main regulation that influences the graphic presentation of inserts is the Council Directive 92/27/EEC 'on the labelling of medicinal products for human use and on package leaflets' (Directive 92/27/EEC, 1992). These EC-regulations give producers of inserts a base to work from, but only a few features of the graphic presentation of information in inserts are mentioned. During the different stages of development of the EC-regulations relating to medicine labelling, graphic presentation increased in importance. In proposals before 1990, graphic presentation was not mentioned at all. A 1990 proposal included the statement: 'the particulars referred to in articles 3 and 4 shall be easily visible, clearly comprehensible and indelible'. Articles 3 and 4 referred only to the outer packaging and the immediate packaging of medicines. It was suggested that mock-ups of the outer packaging and the immediate packaging should be submitted to the regulatory authorities, but a draft package leaflet was considered to be sufficient. It was recognized that more advice on the readability of particulars on the labelling of medicines and inserts was necessary, and that therefore guidelines should be published at a later stage (Official Journal of the European Communities, 1990a). A committee opinion of this proposal appeared in September 1990 (Official Journal of the European Communities, 1990b). The committee approved the proposal and added several comments about graphic presentation. A suggestion was made that consultations with consumer organizations should be held to establish adequate rules on the content and form of patient inserts. An amendment for the wording in relation to the graphic presentation of information on the outer and immediate packaging suggested using 'easily legible' instead of 'easily visible'. The committee also urged the Commission to examine the feasibility of using pictograms as a means of informing patients. I will discuss the use of pictograms in section 3·1·4.

Several amendments by the European parliament were made to the wording about graphic presentation of package inserts. It originally stated that: 'the package leaflet must be written in clear and understandable terms for the patient' (Official Journal of the European Communities, 1990a). In an amendment, it was suggested that information in inserts should be presented: 'in such a way that it is clear, easily legible, and understandable for the patient' (Official Journal of the European Communities, 1991). The EC-regulations phrase this now as: 'the package leaflet must be written in clear and understandable terms for the patient and be clearly legible'. The EC-regulations appear to make a distinction between 'easily legible, clearly comprehensible' (article 4.1), and 'in clear and understandable terms for the patient and be clearly legible' (article 8). What this difference entails and how it can be controlled is not made clear. The late introduction of requirements in relation to the graphic presentation, the variation in description, and the adjournment of the publication of guidelines, indicate the difficulties of regulating graphic presentation.

In article 12 of the EC-regulations, it is stated that the Commission shall publish guidelines on the legibility of particulars on the labelling and package leaflet (Directive 92/27/EEC, 1992). The Centre de Recherche et d'Information des Organisations de Consommateurs (CRIOC), which is the organisation investigating these guidelines, published a final report in February 1993 (Joossens, 1993b). I will from here on refer to this report as the *EC-guidelines*. This report contains specific advice on the development of graphic presentation and has been accepted by the Department General in Brussels. It has been redrafted, translated and forwarded to the Ministries of Health in the member countries of the European Community (Commission Directive III/3958/93, 1993). At the moment, it is difficult to predict if these recommendations will be accepted throughout the European community. The subsidiarity principle, the collapse of the Maastricht treaty, and the political situation in each country will make a smooth progress of these recommendations into regulations doubtful. I will therefore treat these recommendations as guidelines, although they might become regulations.



What you should know about Penicillins.

Please read this carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is _____
This is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Things to remember about Penicillin.

1 **Do not take Penicillin** if you are allergic to it.

2 **Look at the label** on your Penicillin. It will tell you when to take it.

3 **Keep taking your Penicillin** until it is finished. **Don't stop** just because you feel better.

4 **Penicillin sometimes causes problems**
You can find these listed on the back of this leaflet. ✽

5 Keep your Penicillin **out of reach of children.**

You will find more about Penicillin on the back of this leaflet.

Your medicine is one in a group of medicines called Penicillin. Penicillin kills germs which cause infections in your body.

Before taking your medicine

- Has anyone ever told you you are allergic to Penicillin? If so, tell your doctor or pharmacist. You can be given another medicine instead of Penicillin.

Taking your medicine

- You must take your medicine regularly. The label will tell you when to take your medicine. It will also tell you how much to take. *Ask your doctor or pharmacist if you are not sure.*
- This medicine works best swallowed with water when your stomach is empty. This is 1 hour before a meal or 2 hours after a meal. But sometimes your doctor will tell you to take it at other times.
- If the medicine is for a baby the best time to give it is between feeds.
- Shake liquid medicine before you take a dose.
- Keep taking your medicine until it is finished. Don't stop just because you feel better. The medicine may not have killed all the germs. If you stop too soon the infection may start up again.
- If you forget to take a dose take another as soon as you remember. Then go on as before.

✽ After taking your medicine

A few people can be upset by this medicine. They have frequent loose bowel motions or feel like being sick.
If you suffer from either of these very badly or you vomit the medicine tell your doctor.
Tell your doctor if you START suffering from any of the following:

- Rashes, itching, or any other skin trouble.
- Wheezing.
- Pain in your joints for the first time.

Tell your doctor about any other unusual problems as soon as you can.

Storing your medicine

- Keep liquid Penicillin in the refrigerator but **not** in the freezer compartment. Liquid Penicillin lasts only a few days even in the refrigerator. The label will tell you how long. Don't take the medicine after this date.
- Keep your medicine in a safe place where children cannot reach it. Your medicine could harm them.
- If your doctor decides to stop the treatment, return any left-over medicine to the pharmacist or flush it down the toilet. Only keep it if your doctor tells you to.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

You can find more information about prescribed medicines in a book by Professor Peter Parish called "Medicines: A Guide for Everybody". (Penguin Books).

Figure 3·1. Front and back of the ABPI insert (Sharon Gibbs). Original size: 148 by 210 mm. Original in 2 colours, reduced to 50 per cent

British regulations.

The British legal requirements for the contents of inserts are set out in *The Medicines (leaflets) Regulations 1977* (SI 1977 No. 1055). These regulations incorporated the European Directive (Directive 75/319/EEC, 1975) into British law. The British regulations do not make any reference to graphic presentation. At the moment, there is therefore no legal obligation to pay attention to the graphic presentation of information in inserts in Great Britain. However, the EC-regulations will come into force on January 1st 1994. In Great Britain, these regulations will only be applicable to newly registered products. For existing products, inserts will need to be introduced as soon as possible, and in any case no later than with the renewal of the product licence.

In Great Britain, the control of the legislation is undertaken by the Medicines Control Agency (MCA), which is part of the Ministry of Health. This agency checks whether the content of an insert includes the legally required information, and whether this information conforms to the product licence. In practice, the MCA frequently checks a typewritten draft of the insert, because there is no legal obligation to control its graphic presentation. The graphic presentation of the insert that a patient will receive might therefore be very different from the graphic presentation of the approved insert. If the MCA will follow the EC-regulations is still being discussed.

Guidelines.

The main influence on graphic presentation of inserts in Great Britain are guidelines published by the Association of British Pharmaceutical industry (ABPI, 1987; ABPI, 1988). From here on I will refer to these two publications as *the ABPI-guidelines*. These ABPI-guidelines are to a large extent based upon research undertaken at Southampton University between 1983 and 1991. However, this research was carried out on generic leaflets which were supplied by general practitioners or pharmacists, and these were not developed to be included in a medicine package. It has also been shown that many inserts in Britain follow the ABPI-guidelines to a certain extent (Brown, 1989). A modification of the ABPI-guidelines, which was published in November 1992, suggested alterations to make them conform to the EC-regulations (Wells, 1992). The insert that is used as an example in these guidelines was developed at the University of Southampton (Gibbs, Waters & George, 1987; 1989a; 1989b). This insert is mentioned in section 2·2·2. **Figure 3·1** shows both sides of this ABPI-insert. Reactions to these ABPI-inserts vary. One prescriber stated that these leaflets were 'patronizing and incomplete' (Medawar, 1989). In a comparison of inserts in twelve European countries, these ABPI-inserts were described as: 'a bit too simple' (Joossens, 1990a). The same author later described the same leaflets as 'Mickey Mouse inserts' (Joossens, 1993a).

There are then two major sources influencing the graphic presentation of inserts in Great Britain: the EC-regulations and the ABPI-guidelines. One way of overviewing the existing regulations, guidelines, and research is to divide the issues into four groups. The first group, the overall graphic presentation, has to do with issues in relation to the graphic presentation of the complete insert. The other three groups look more closely at specific features: text, pictograms and illustrations. This division is not an attempt to provide a framework for the discussion of the graphic presentation of information in inserts, but a convenient way of discussing the current situation. A more elaborate framework will be introduced in chapter 4. One additional point needs to be mentioned before investigations into features of the graphic presentation of inserts are reviewed. The articles describing investigations rarely reproduce the printed testing material itself. For example, in the description of the test leaflet for an experiment, the only reference to graphic presentation was: 'at the bottom of this page was a message in heavy type' (Sandler et al, 1989: p 871). Such descriptions of graphic presentation are frequently not sufficient and it is therefore difficult to make a balanced judgement about these investigations.

3·1·2 The overall graphic presentation.

This section deals with general recommendations, and reviews some research into the overall graphic presentation of inserts. The first point that must be mentioned is the use of the term *overall graphic presentation*. This term is preferred over other terms such as configuration, lay out, graphic organisation, or graphic structure. These last four terms seem to refer more to the spatial arrangement of graphic components. Overall graphic presentation is a more general term, referring to features of the graphic presentation that are related to a complete insert. It is an overall descriptor of all the meaningful marks in a

document and encompasses the spatial, graphic, and substrate features. This terminology is further discussed in chapter 4.

The ABPI-guidelines suggest an A5 size as an appropriate format, used on both sides, unless this is impracticable (ABPI, 1988; Wells, 1992). Unfortunately, the variation in sizes of medicine packaging makes it very difficult to state what would be an optimal format for a package insert. The format of an insert is therefore not specified in any other guideline or regulation.

The ABPI-guidelines also suggest that one side of the insert should be used for the important and immediately relevant information, and the other for supplementary and more detailed information. This reverse side should be clearly marked as a continuation page. The information on the front of the leaflet should refer the patients, where appropriate, possibly by the use of symbols, to more detailed information on the back of the leaflet (ABPI, 1988: p 3). The diamond and the asterisk in figure 3·1 on the front of the insert are examples of these symbols. The ABPI-guidelines state that: 'sub-dividing the information into sections will make the leaflet more patient friendly' (ABPI, 1988: p 3).

A rationale for the overall graphic presentation in the ABPI inserts is rarely given. One article describing the overall graphic presentation states that 'the contents were organised into self-contained sections of related information to increase understanding and recall' (Gibbs et al, 1987). A further description of these inserts stated that 'headings were used so that people could scan the information and pick out points of interest as well as to increase patients' expectations about the ease of readability and comprehension'. The main sources for these considerations were publications by Hartley (1978) and Wright (1981).

Apart from the guidelines in Great Britain, several other countries have produced national guidelines which mention overall graphic presentation. In America, the Nonprescription Drug Manufacturers Association (NDMA) published guidelines to improve readability (NDMA, 1990b). These guidelines state that: 'creative layout of label copy, particularly in the case of smaller type, can improve readability, while poor layout and placement can lead to reader fatigue and confusion'. However, the advice to use a creative layout, as opposed to a poor layout, seems difficult to follow. The guidelines of the NDMA suggest that boldface type, colour type, colour highlighted background and boxes around copy can help to draw attention, to provide emphasis, or to break copy into more manageable segments for the reader. It is stated that 'dividing copy into paragraphs - with proper spacing between paragraphs - can enhance readability and improve reading comfort' (NDMA, 1990b).

Another point relating to the overall graphic presentation is the contrast of the printed marks with the background. This is mentioned in the NDMA guidelines, which state that colour contrast, the glare of the paper, and the show-through are three aspects that need to be considered, but that it is hard to discuss these in general terms (NDMA, 1990b).

Some general remarks about graphic presentation are made in investigations into the use of inserts by patients. Morris and Kanouse (1981) conclude after an investigation into the tone of written drug information that 'it is important to use graphic and other communication techniques in a manner consistent with the overall flow of the information'. Consumer organisations in England and Belgium state that inserts must be in a standard format, with the same sections and headings, and in a standard graphical style. However, this graphic style has not yet been developed (Herxheimer, 1989; Joossens, 1990a).

There are two other sources of advice about the overall graphic presentation of information in inserts. The first source is the internal documents of the pharmaceutical industry (e.g. Higson, 1990). The second group is guidelines published in professional journals. Examples of these articles are guidelines to improve printed information for the elderly in America by Boyce (1981) and by Ralph (1982). Suggestions for prescribers to improve printed information for patients have been published by Muir Gray (1982) and Albert (1992). Similar guidelines have been suggested for nurses by Bosse Mathis (1989) and for pharmacists by Raynor (1992).

Little empirical research has been undertaken to verify the value of these regulations, guidelines and advice for the overall graphic presentation of inserts. Three recent studies have specifically asked patients for their opinions about the overall graphic presentation of a package insert. In a study undertaken in France, a patient who looked at several inserts for a period of 5 seconds described the presentation style as: 'les notices évoquent une tristesse que symbolisent les images d'antichambre d'un vieux dentiste' (the inserts evoke a sadness which is symbolized by images of a waiting room of an old dentist) (CERA, 1991). In a study in Switzerland, visual clarity was one of the main reasons why patients (n=500) preferred patient inserts to inserts

aimed at prescribers (Documed, 1988). However, the results of these studies are difficult to interpret, because the test inserts are not reproduced in the publications. The third study was also undertaken in Switzerland. One hundred patients were interviewed: 54 patients received information aimed at prescribers, 46 patients received information aimed at patients. Of the 46 patients receiving a patient insert, 43 patients found the visual clarity of their package insert good, and the other three found it satisfactory. Only 10 out of 54 patients who received an insert for prescribers found that the visual clarity was good, 23 found it satisfactory, and 21 found it poor (Rupf, 1991). This study reproduced some of the inserts in the report. The differences in the graphic presentation between the prescribers' inserts and the patients' inserts seem small. However, the responses of patients show that these small differences in graphic presentation are clearly noticed. This study will be mentioned again in section 4·4.

One conclusion can easily be drawn in relation to the overall graphic presentation of information about specific medicines in inserts. Issues relating to the overall graphic presentation are poorly regulated, and guidelines are scattered, incomplete, vague and difficult to apply.

3·1·3 The graphic presentation of text.

One of the main issues in the graphic presentation of text is legibility. Legibility encompasses all the graphic factors related to the ease, speed and accuracy with which a text can be read by a user. Legibility is dependent on the combination of several factors. Only those factors that are mentioned in the literature about inserts are discussed below. These are: type size, line space, typeface, type weight, upper and lower case, and line length.

A standard problem in the description and measurement of type sizes and line space crops up here. **Figure 3·2** on the next page outlines some of the issues involved. The description of some of these issues seemed necessary for discussing the graphic presentation of text in inserts. Figure 3·2 should therefore be treated as an extended note.

Type size.

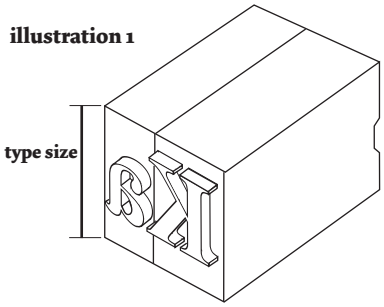
Only two countries in the European Community legally enforce a type size for the text in inserts. Spain specifies that the type size in inserts should not be smaller then 7 points. Swiss regulations stipulate a type size of at least 8 points for patient information, and 7 points for prescriber's information (IKS, 1988). In Great Britain, only the type size for the scientific information (data sheet) is legally enforced. The type size is specified as a minimum of 6 Didot Univers (SI 1972 No. 2076). However, very few typesetters in Britain will use Didot points. The type size in most British data sheets does therefore not conform to these regulations. The type size for text in patient package inserts is not further regulated.

The ABPI-guidelines specify that the front of the insert should have a larger typeface (ABPI, 1988: p 3). What a larger *typeface* is, is not further explained. The NDMA specifies that type should be at least 4.5 points if it is printed in black ink on a white substrate (NDMA, 1990b). This type size presumably originates from Federal regulations on the labelling of the ingredients on containers and packages of food. These regulations specify a minimum type size of 4.5 points and where limited space does not allow for 4.5 point, an exception allows the use of 2.5 point type. The special task force on labelling, who devised the guidelines for the NDMA, suggested in their staff notes that a magnifying lens should be supplied (NDMA, 1990a). Fortunately neither the type size nor the magnifying lens, were seriously considered when a standard type size for European patient inserts was determined.

Several other type sizes are proposed in literature describing patient information. Muir Gray suggests the 'use of large print'. The size of this 'large print' is described as the size of capital letters on an ordinary typewriter. This size is 'a good size of writing for older patients'. However, it is especially mentioned that 'this size is not sufficient for most of us' (Muir Gray, 1982). What a 'sufficient size for most of us' is, is not further specified. Guidelines in Belgium state that the type size should be not less than 8 points (Hauwermeiren, 1986). Other factors for the specification of type are not mentioned. The EC-guidelines state that the x-height of typefaces used in inserts must be at least 1.5 mm, with a line space of 3.5 mm. For countries where several languages appear on a single insert, these values can be reduced to 1.4 mm x-height, with a line space of 3.2 mm (Joossens, 1993b).

Several investigations have tried to find out what an appropriate type size for printed information for patients is. The results of these investigations are difficult to compare, because the test texts were not reproduced. The Michigan Health Council interviewed 51 older adults to determine their preference for type size. They found that 2 percent of the people chose 9 point type; 8 per cent choose 10 point type; 20 per cent

illustration 1



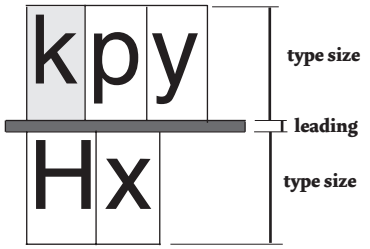


illustration 2

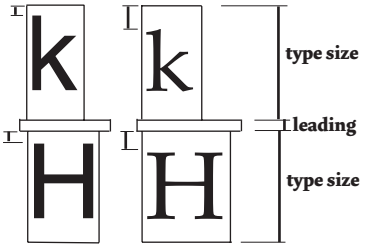


illustration 3

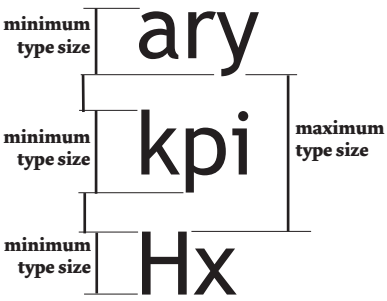
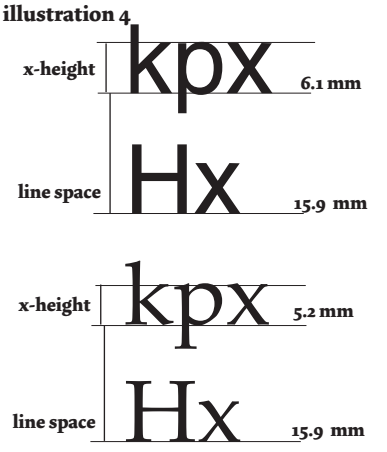


illustration 4



Type size

Originally, letters were printed by pressing inked pieces of metal type onto paper. The type size is the vertical dimension of the metal on which the letterform is cast (illustration **1**). Type size is normally expressed in points. Two different systems are most common. One Anglo-American point is 0.351 millimetre, and one Didot point is 0.376 millimetre. The dimensions of type size on some photographic and digital typesetting equipment may be stated in millimetres.

Type size versus appearing size

Type size, whether in metal, photo, or digital typesetting is rarely a measurement of the printed image. Usually, it includes some undefined space, above or below the kp or Hp-height. In addition, the design of letterforms varies considerably and two faces with the same size specification can appear to be different in size (illustration **2**).

The space between lines

With metal type, extra space between lines was obtained by inserting strips of lead between two lines. Hence the name leading. The leading is indicated in illustration **1** by the dark grey bar. Traditionally, the dimension of the leading is given in points. In photographic or digital typesetting, the distance from one baseline to the next is frequently used. This distance can be given in points or in millimetres. (This distance is frequently measured to indicate the size of type; however, there is no direct relation between the type size and the line space.)

There are problems when the sizes of printed characters need to be compared. Illustration **3** shows the possible varia tions in type size if the original vertical dimension needs to be measured. These variations are clearly not acceptable.

Measuring type size

At least two dimensions can be taken from type after it has been printed (illustration **4**).

- the x-height: that is the vertical dimension of the lower case x. This size determines to a large extent how large a typeface is perceived to be. The size of different typefaces can be directly compared when the x-height is used.
- the line space: that is the vertical dimension between two subsequent baselines. This size determines how far apart two lines appear to be.

These two dimensions, x-height and line space, can be used to specify type, as well as to measure type after it has been print ed. A second main advantage is that both measures can be given in millimetres, which avoids problems with the use of different kinds of points.

(Main references: Pavey, 1990; Boag, 1992)

Figure 3·2. A note about type size.

choose 11 point type; 40 per cent choose 12 point type and 30 per cent choose 13 point type (Boyce, 1981). They concluded that the most suitable type size for older people was 12 points. Ley investigated the recall of the content of an antibiotic leaflet by elderly people. The text was presented in three formats: all capitals, upper and lower case, and small type. It was expected that a text presented in capitals only would be harder to read, and thus lead to poorer recall, and that text in smaller type would be harder than text in larger type. Neither of these expectations was fulfilled. The subjects read and recalled the capitalized and small type texts just as well as the supposedly easier text. However, patient ratings on the anticipated difficulty of a text differed (Ley, 1988). The experimental materials were not reproduced, nor were any other details published. The results of this study are interesting because they show that graphic presentation does influence patients' ratings of perceived difficulty. I will mention this study again in section 4·4·2.

A study in Switzerland showed that 42 per cent of the interviewed patients (n=500) say that the type size is too small (Documed, 1988). Patients in the Netherlands frequently complained about the type size of texts in inserts while obtaining advice via a telephone helpline. In Belgian research (Stichele et al, 1991), 45 per cent of the patients (n=398) stated that the type size of inserts is too small. Rupf asked 100 patients to rate the type size in a package insert. Forty-one out of 46 patients who received an insert specifically for patients found the type size satisfactory or good. Nineteen out of 44 patients who received an insert for prescribers found the type size satisfactory or good (Rupf, 1991). The results of these studies are impossible to interpret, because the type size is not further described, and the test materials are not reproduced.

Line space.

Few studies in relation to package inserts have mentioned line space, but two articles do supply guidelines. Ralph (1982: p 49) pointed to the importance of line space for legibility, and specified four rules (these rules are quoted verbatim):

- one or two points of leading is recommended for 11 or 12 point or larger type
- four points of leading should never be used
- no less than two points of leading should used with smaller than 11 point type
- no more than two points of leading should be used with larger than 12 point type

The other guideline with regard to the line space is given by Raynor (1992). He specified space between lines as 'a quarter of the type size' (Raynor, 1992: p 181). Although both of these guidelines mention line space, which can be seen as positive, these recommendations seem rather odd as practical advice. The specification of line space in points, without reference to typeface or type size, is not sufficient.

Typeface, upper and lower case, and type weight.

Three more factors in relation to type are mentioned in the literature about inserts: the use of different typefaces, the use of upper and lower case, and the use of different type weights. Advice about these three is vague and frequently unhelpful. The advice about the choice of a typeface is frequently to use clear, legible typefaces such as Times or Helvetica (Raynor, 1992). Stone warns that novelty in typefaces should be avoided (Stone, 1991). A publication of the British Medical Association, aimed at doctors, states that the design of leaflets is important, and that different typefaces should be considered (Muir Gray, 1985). References for this 'advice' are not given.

The American NDMA states that a combination of upper and lower case letters is easier to read than all uppercase since people get their principal reading cues from the upper half of the characters of lower case type (NDMA, 1990b). That seems sound advice, and has been mentioned earlier (e.g. Spencer, 1969). However, this advice is difficult to follow in the USA because some regulations stipulate that warnings should be presented in all uppercase type.

Type weight has only been mentioned by the ABPI guidelines. The ABPI suggests that: 'Selective use of bold text will aid clarity' (ABPI, 1988). The typeface in the ABPI-guidelines example was described by Gibbs as: 'The typeface was bold and clear because many elderly patients have problems with failing eyesight which makes it difficult for them to read small typewritten instructions on medicine bottles' (Gibbs et al, 1987). In their sample insert (figure 3·1), this clarity caused by the use of bold type, is difficult to detect.

Line length.

The last factor that is mentioned in the literature about inserts in relation to the graphic presentation of text is the length of a line of text. Raynor suggests that the length of a line of text should be between 35 and 65 characters including spaces, or 10-12 words per line (Raynor, 1992). Ralph suggests that line width of 11 or 12

point type should not exceed 42 picas (7 inches) for a single column. When multiple columns are used, the columns should range between 18 and 28 picas (3-4.5 inches) (Ralph, 1982). The American NDMA suggests that a line length of 39 characters is close to the optimum. In the example supplied in the guidelines, the average line length is 33 characters (NDMA, 1990b). The advice of Muir Gray is to use columns in order to reduce the length of a line (Muir Gray, 1985). I have found inserts with an average line length of 23 characters (in a German insert about a hormone replacement therapy), as well as inserts with a line length exceeding 150 characters (in a French calcium supplement).

As a conclusion of section 3·1·3, it can be stated that existing regulations, guidelines and advice on how to make type legible are not sufficient. There are considerable variations in regulations and guidelines, and the advice is frequently unhelpful. This is partly due to problems with terminology, and partly due to a difficulty in describing and controlling the combination of all factors that have an influence on the legibility of text. However, some advice, as for example given by Spencer (1969), Hartley (1978), Reynolds and Simmonds (1982), British Standards (BS: 4884, 1983), and the Department of Trade and Industry (1988), could be followed to improve the legibility of inserts.

3·1·4 Pictograms.

Pictograms are suggested several times as an effective way of communicating information about specific medicines. However, a review of the literature shows that conclusions are difficult to draw. The regulations and guidelines have avoided a definition of a pictogram, and seem to refer to any schematic illustration as a pictogram. In this section, I review only those regulations, guidelines and investigations that mention the word pictogram. All other illustrative devices are discussed in section 3·1·5.

Article 3 of the EC-regulations state that: 'the inserts may include symbols and pictograms to clarify certain information' (Directive 92/27/EEC, 1992). Neither pictogram nor symbol are further defined. The difference between symbols and pictograms, and what kind of specific information could be clarified is not described either. A more constructive proposal for the use of pictograms was rejected. An amendment to the proposal of the EC-regulation, suggested that pictograms should be devised in connection with narcotics, any habit-forming and addictive medicines, and any performance enhancing medicine that is on the Olympic Committee list. Pictograms were also to be devised for inclusion on the outer packaging in relation to special user categories, in particular, children, pregnant or breast feeding women, the elderly or persons with specific pathological conditions (Official Journal of the European Communities, 1991). Although these suggestions were considered, these specific amendments on pictograms were not integrated into the final regulations.

The ABPI-guidelines suggest that: 'the use of approved and universally recognisable signs and symbols (like road traffic signs) and simple diagrams to aid comprehension' could be included (ABPI, 1987). The British and European consumers associations still think that the use of pictograms is a good idea, and have tried to make this point clear when proposals for the EC-regulations were made. For example *Which?*, a magazine of the Consumers Association, suggests the use of 'symbols or pictograms to clarify basic information and help with health education' on labels (Which?, 1991). The EC-guidelines state that the use of pictograms is controversial, despite the fact that results of several investigations have indicated a favourable response from patients (Joossens, 1993b).

Several investigators have tried to develop and test the effectiveness of pictograms in inserts. In 1988, the Royal Pharmaceutical Society started a research programme with the objective of developing pictograms. The working group reported that patients would need to pass an examination in pictograms in order to understand them. It was concluded that pictograms did not readily convey their meaning and the report of the working party has never been published (Stone, 1991).

In 1985, the organisation of French pharmaceutical industries cooperated with consumers organisations to develop pictograms for inserts. Six pictograms were designed; five of these are reproduced in **figure 3·3**. The pictogram 'protect against moisture' was correctly interpreted by 49 per cent of the subjects. However, 16 per cent of the subjects interpreted it as: 'do not place in water', or 'do not take with water'. Only 62 per cent of the subjects interpreted the drops in the pictogram as water. These responses are clearly not satisfactory (Joossens, 1990a).

In 1989, approximately 75 pictograms were developed and published by the United States Pharmacopoeial Convention. It is suggested that

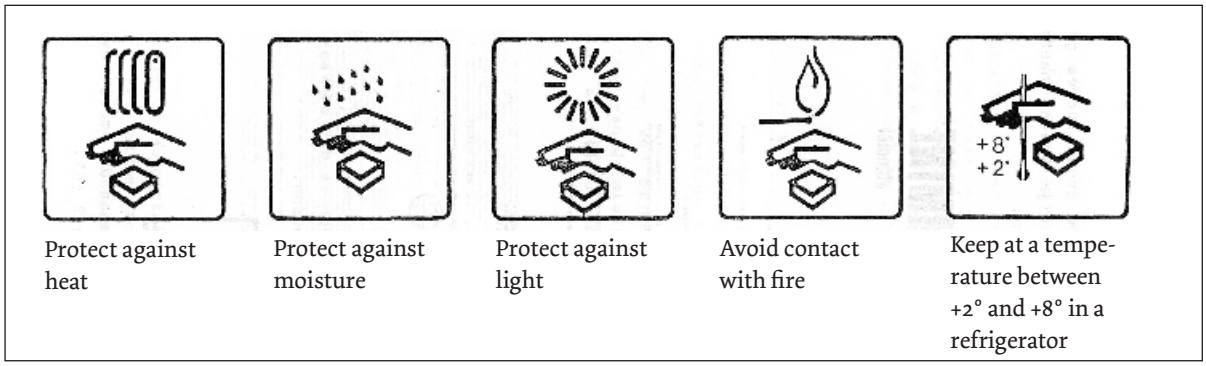


Figure 3·3. Pictograms developed in France (1985).

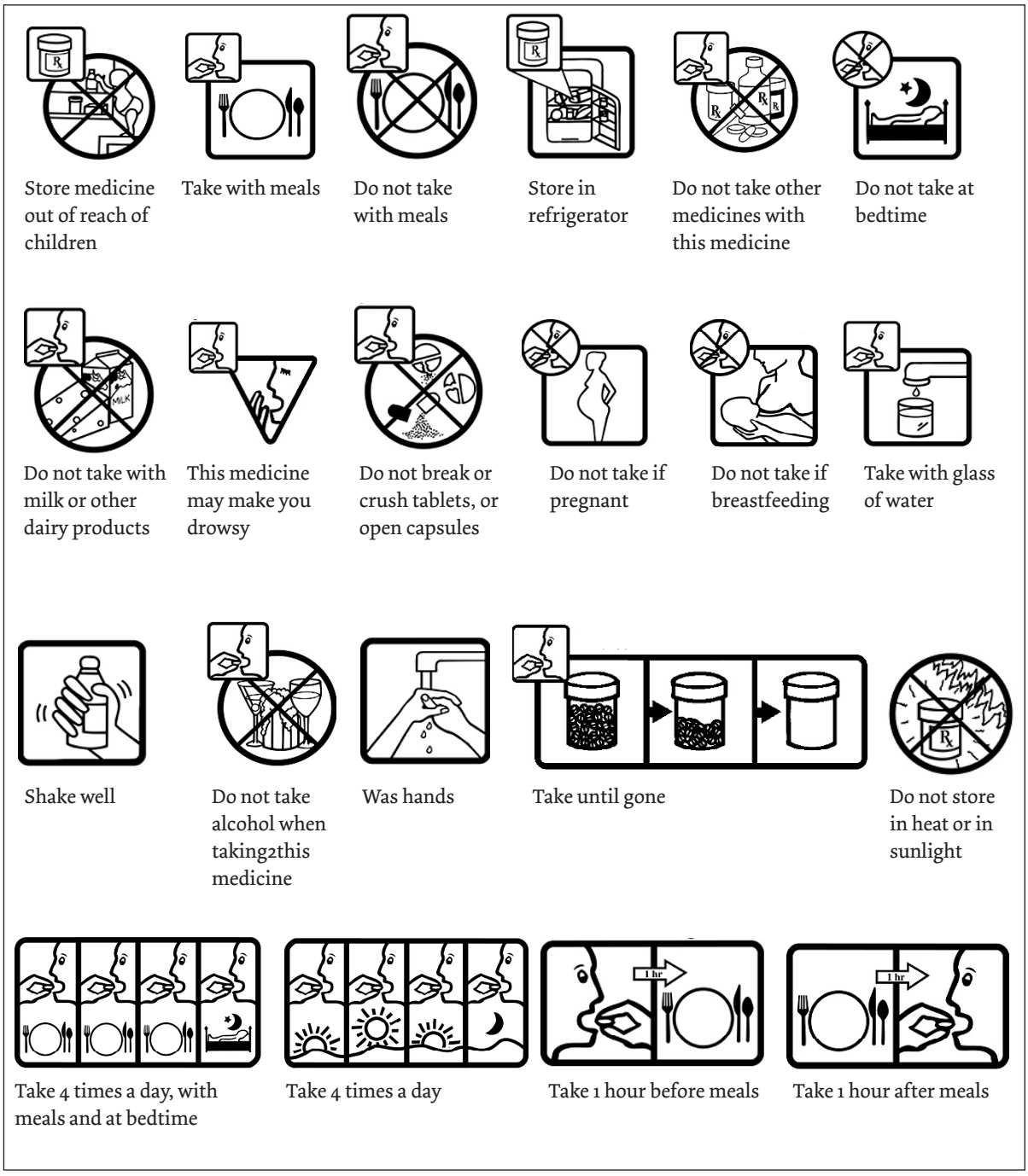


Figure 3·4. Pictograms developed by the United States Pharmacopoeia (USP) Drug Division in 1987 (selection).

'although some initial explanation may be needed, it is an effective, simple and quick communications mode' (Work, 1990: p156). However, most of these pictograms failed during comprehensibility tests. These pictograms are reproduced in **figure 3·4**. In Sweden, the understanding of five pictograms was tested on patients (n=516). Four were found difficult to understand. The only satisfactory pictogram was one which showed a bar through a full wine glass, and was understood by 79 per cent of the subjects (Joossens, 1993b).

It has been suggested that pictograms are especially helpful for illiterate patients. This was investigated in 1979 in Bombay and in London. The study in Bombay found that designers must put themselves in the position of the patient when a successful pictogram is to be devised. Solutions that were appropriate to the local situation were found most effective (Raw, 1979). The study in a London hospital compared the understanding of pictorial prescription labels by literate and illiterate patients. This study stated that 'the refined international conventional style of graphics is lost on patients; they are too complicated, inhuman and far too insensitive to be used in the medical field' and concluded that clear photographs should be used (Bratt, 1979).

Some investigators have tried to find out what patients thought about the inclusion of pictograms in inserts. In an investigation in 1985, 82 per cent of the patients found the pictograms useful (SOFEMA, 1989). In Belgium, 69 per cent of patients (n=398) said that not enough use was made of pictograms (Stichele et al, 1991). Recent research undertaken by Janssen Pharmaceuticals in Belgium related pictograms to headings of sections. Their research concluded that pictograms were helpful and well accepted by patients in Great Britain, Germany and France. However, their pictograms were only used in combination with an adjacent verbal heading. This makes the interpretation of the pictograms more precise (Joossens, 1993b).

At least two reasons can be stated why pictograms on their own should not be used in inserts:

- The International Standard Organisation (ISO) regards a pictogram as successful when 66 per cent of people can interpret the pictogram correctly (Foster, 1990). This level of understanding is clearly too low for information about medicines.
- The different interpretations of similar pictograms make a very careful design essential. The difference between: 'keep away from water' and 'take with water', or 'do not take during pregnancy' and 'this medicine will prevent pregnancy' is difficult to make. The use of pictograms seems problematic until these distinctions can be made clear to patients.

It seems that pictograms in inserts increase confusion, rather than contribute to understanding. Their inclusion in inserts might be useful, but there is simply insufficient evidence to make their use obligatory. Patients seem to like pictograms, but whether they have any positive effect on the understanding of information about medicines remains unclear. The combination of pictograms and text may help to make information sections more prominent. I will come back to the issue of prominence in section 4·3. However, the use of individual pictograms in inserts will not be pursued further in this thesis.

3·1·5 Illustrations.

There are no regulations referring to illustrations in inserts. However, this lack of regulation is also interpreted. In Great Britain, the content of the insert must conform to the content of the data sheet. Illustrations are not allowed in the data sheet, and the Medicines Control Agency initially decided that the use of illustrations in inserts is therefore not allowed in patient inserts either. For example, an illustration indicating the amount of a cream to apply, was initially refused, but at a later stage accepted, by the MCA for this reason (Higson, 1992). This illustration is reproduced in **figure 3·5**.

The ABPI guidelines state that it may be appropriate to include visuals to depict the actual product on the back of the insert (ABPI, 1988). More advice for the application of this guideline might be helpful. There are two main reasons for the use of

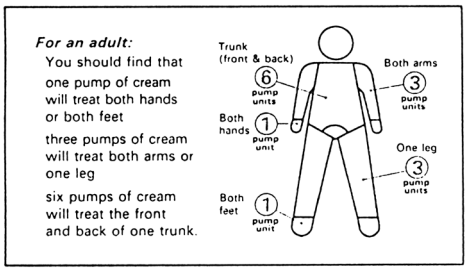


Figure 3·5. Illustration (detail) from a *Betnovate* cream pump dispenser insert. Glaxo, West Drayton, England (1992). Original in two colours.

illustrations according to Ley (1988). The first is that illustrations can be used to increase understanding. The second is to make the material more attractive and thus more likely to be read. However, there are three possible dangers in the use of illustrations in inserts (Ley, 1988). Firstly, illustrations might act as distractors and thus divert the attention from the text. However, I would claim that text and illustrations have different characteristics and can complement each other. Both text and illustration can be used in order to produce an effective insert. Secondly, Ley states that people often spontaneously develop images which help them comprehend and remember text. Illustrations in the text might in some cases be in conflict with these spontaneously produced images and thus reduce their effectiveness. However, Ley seems to overlook the fact that this spontaneous image may be wrong or inappropriate. An illustration could be helpful in developing an accurate image. Thirdly, Ley suggests that it is possible, in the case of medical information, that some illustrations might be anxiety provoking or aversive to some of those reading the inserts containing them. However, I have pointed out in section 2·2 that the text in an insert does not seem to provoke these reactions. Any such reactions can be prevented by careful consideration of the appropriateness of illustrations.

Research in Belgium undertaken in 1988 revealed that 69 per cent of the interviewed patients (n=398) would prefer more illustrations with the text (Stichele et al, 1991). Several investigators tried to find out whether the style of the illustration affects patients. Cartoon style illustrations did not make a significant difference in preferences of patients, when they were compared with realistic illustrations (Dirr & Katz, 1989; McDermott, 1989). Research in the Netherlands investigated the use of illustrations in printed information for patients. Because Moroccan and Turkish immigrants have a limited knowledge of the Dutch language, and might be helped by illustrations, illustrations were initially made by Moroccan and Turkish people. These initial illustrations were used as a basis for illustrations in inserts. In order to avoid confusion, the illustrations were accompanied by text. The illustrations proved successful on preference and comprehension measures (Hattum, Apituley & Paes, 1991).

I have found illustrations in inserts in the following information sections.

- name of the product
- pharmaceutical form
- therapeutic indication
- warnings
- method of administration
- frequency of administration
- storage requirements

This list cannot be complete because there is no complete collection of inserts available at the moment. This list is only meant to indicate in which of the information sections, described in figure 2·1, illustrations are currently used. Two additional topics are sometimes illustrated: an illustration can indicate how the package should be opened, and an illustration can show a safe method of disposal.

Concluding this section, it can be stated that the inclusion of illustrations in inserts can be beneficial. Clear regulations or guidelines seem necessary, but only after there is some consensus about the purpose of illustrations in inserts.

3·1·6 Concluding.

In the final part of this section, conclusions about the current graphic presentation of inserts are drawn. Two conclusions are clear:

- The regulations are not sufficient to produce an adequate graphic presentation. The existing regulations are clearly not specific enough to be of much help. Patients, producers and the regulatory authorities have complained about these deficiencies.
- The guidelines, aimed at producers of inserts, are not always applied, are sometimes inappropriate, or may not be specific enough.

Three reasons can be suggested for this situation. The first is that there has been little communication between producers of information about medicines for patients, and graphic designers as developers of the graphic presentation of this information.

The second reason is a difference in experimental approach. The scientific rigour of medical investigations has rarely been applied to investigating features of the graphic presentation. These first two reasons lead to discrepancies between opinions as to the importance of the graphic presentation. Two examples might make this clear.

In 1982, an investigation was undertaken in the Department of Pharmacy, Aston University, on the discrimination and understanding of the labelling of pharmaceutical packaging by elderly patients. All labels were handwritten and the conclusion was that these handwritten labels were inadequate and inefficient. Medical staff had to read labels several times and elderly

patients had to identify their drugs by means other than the label (Veitch & Wright, 1982). Very similar research had been undertaken 15 years earlier by Hailstone and Foster in the School of Advanced studies of the Manchester College of Art and Design. They concluded in 1967 that typewritten labels were discriminated more readily than handwritten ones (Hailstone & Foster, 1967). The reasons why handwritten labels were still in use in 1982, 15 years after an investigation had shown their inadequacy, can be seen as an illustration of the lack of communication.

The second example is supplied by Ley in 1988. Ley is a psychologist who has undertaken a large number of studies into the communication between health carers and patients. He describes research on 'the physical packaging of written information' and cites Tinker (1963), Poulton (1969), Wright (1977, 1978), Hartley (1980), and Felker (1980), and summarizes by using a list of points devised by Poulton, Warren and Bond (1970). Ley is one of the few researchers who has referred to this literature and concludes that: 'the conditions under which graphical aids will be effective are not known with any certainty' (Ley, 1988). The Poulton, Warren and Bond article is still an appropriate reference, but by quoting guidelines in 1988 from 1970, Ley seems to ignore the developments in the intermediate period.

In spite of these problems, the medical profession in Great Britain has become increasingly interested in graphic presentation since the early eighties. This led to several investigations on how to produce graphic information for patients. An editorial in the *British Medical Journal* stated that: 'the design of the leaflet is all-important, and too many are overlong, overcomplex and incomprehensible to many patients. The size of the leaflet, the language used, the typeface, lay out, illustrations and the explicitness and specificity of the contents are all vitally important, and a deficiency in one aspect may render the leaflet useless' (BMJ, 1980). Other editorials in *The Lancet*, and in the *British Medical Journal*, emphasize the importance of graphic presentation (Lancet, 1989; Smith, 1992). It seems clear that health carers realize the need for an effective graphic presentation, when printed information is supplied to patients. The reasons why the graphic design profession has not paid much attention to these needs remain unclear.

A third reason for the absence of appropriate regulations and guidelines is most likely related to the problem of describing graphic presentation. Though there are several frameworks to discuss, analyse and investigate graphic presentation, none of these seems specifically applicable to the issues I would like to address in relation to inserts. The four groups of features of the graphic presentation, as described in this section illustrate this problem. This issue will be further discussed in sections 4·1, 4·2, and 4·3.

These three reasons provide the justification for the study of the graphic presentation of information in inserts. The next section describes the use of inserts by patients. Section 3·3 describes the combination of the different types of use and the graphic presentation.

3·2 The use of documents.

In sections 2·2 and 2·4 the patients' requirements and the producers' aims for supplying inserts were described. It was concluded that, in order to achieve the producers' aims and to fulfil the patients' requirements, it is essential that patients use inserts. In this section, some aspects of the use of inserts are described. In previous sections, investigators studied *preferences* of patients for type sizes, *opinions* of patients about illustrations, *recall* of information, and *understanding* of pictograms. It is obvious that the use of inserts can vary in other aspects as well. Reading skills, attitudes, beliefs, motivation, experience, prior knowledge, and preferences will all have some influence on document use. These aspects of use do not seem to be related to each other and the results of the studies are therefore difficult to compare. The main purpose of this section is to see whether it is possible to place these aspects of the use of inserts in some sort of frame. Because little research has been undertaken on the use of inserts by patients, the generic terms 'users' and 'documents' are used in this section.

Section 3·2·1 defines the term 'use of inserts' by patients. Section 3·2·2 provides a general description of the use of documents and looks at reasons for using a document, and possible reading strategies. This is a first way to break document use into separate parts. A second way is described in section 3·2·3, in which document use is divided into three fields. Section 3·3 relates both divisions of the use of inserts with graphic presentation.

3·2·1 A definition of use of inserts by patients.

An initial definition of *use* could be: all the activities of patients that are related to information in inserts. This includes all the activities during which the insert is unfolded, looked at, and discarded, as well as all the mental activities that may occur during and after the encounter. This is a very broad definition, but I hope to show in this section that only certain activities of patients can be influenced by graphic presentation. It is only possible to talk about use when a patient undertakes the physical action of looking at an insert. And when a patient looks at an insert in order to extract information, graphic presentation is unavoidable; patients depend on (in the sense of not being able to do without) graphic presentation. The patient has no alternative but to look at graphic presentation of information in an insert, in order to extract information. It seems important to state this, although it is rather obvious.

The above definition of use is closely related to common definitions of *reading*. However, the term reading seems too narrow. Reading can be briefly defined as 'the extraction of information from print', or more elaborately as 'the perception of graphic symbols and the formation of concepts, thus allowing the meaningful interpretation of text'. Reading often seems to refer to the extraction of information from text only, but illustrations, pictograms and other graphic marks such as rules, diagrams and bullets also need to be considered when inserts are investigated. Looking at other types of graphic marks is traditionally not seen as part of the reading process. Reading also implies a continuous and sequential use of text. However, the user can start, stop and re-start at any point in a document at any point in time. In several circumstances, a user might locate specific information, or compare information in a sequence that does not seem to be contained in the term reading. The word use seems to describe the extraction of information from printed documents more precisely. Most investigations and publications have not made this distinction. In order to discuss these investigations, the meaning of the term reading is extended to integrate the above mentioned activities. However, the term use is preferred.

There is one type of activity that has to be considered, and that is a patient's decision not to use a document. It could be argued that this decision should also be part of the use of documents. For example, Wright suggests that there is an urgent need for a theory of NOT-reading; that is a theory describing users who intentionally ignore information. The decision not to read may be based on several reasons, such as previous poor experiences with similar printed information sources, a shortage of time or a poor interest in the information itself (Wright, 1988). Wright's decision making model for users is reproduced on the left in **figure 3·6**. Although this model is based on users of computer screens, it seems appropriate to printed documents as well. Hatt (1976) mentions a similar issue when he states that one of the stages of the use of a document is that: 'a reader finds a text'. This implies that readers sometimes cannot find a text. However, as far as inserts go, the group of patients who decide not to use an insert, or cannot find an insert, is between 20 and 25 per cent, as was shown in figure 2·2.

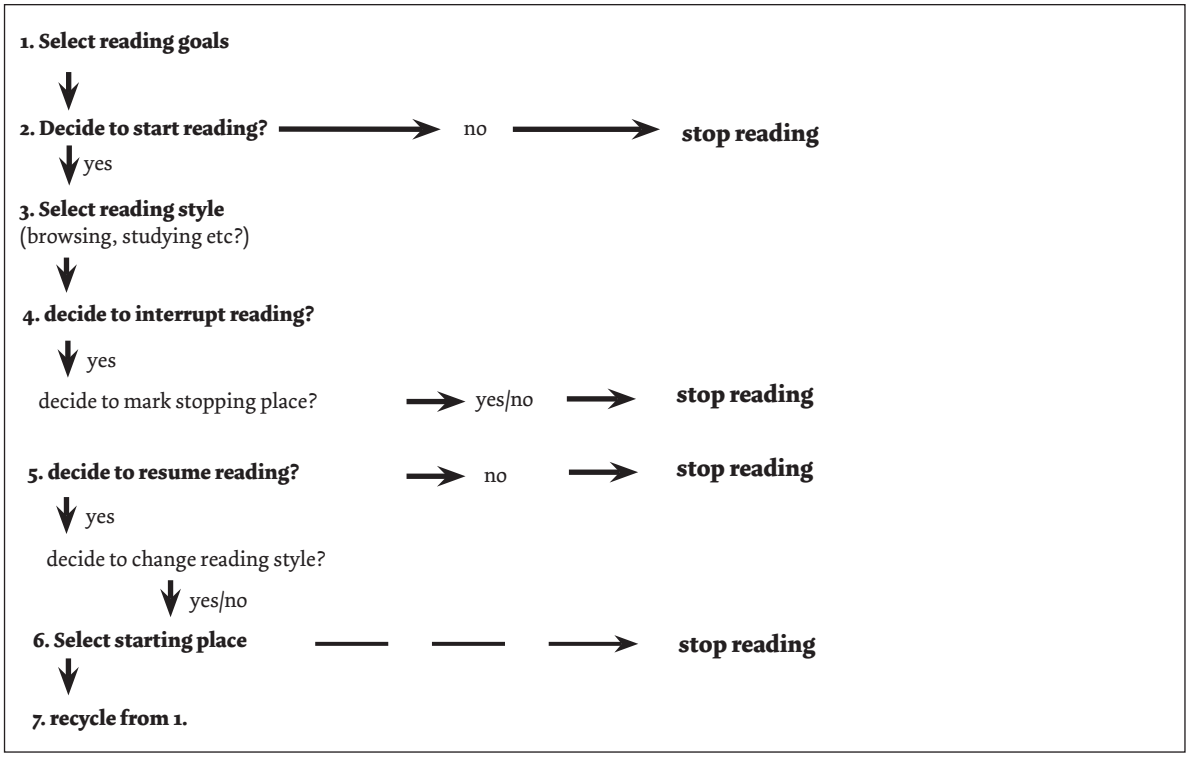


Figure 3·6. Readers' decision making to stop reading. According to Wright (1988).

For the rest of this thesis, I will ignore these groups of non-users.

A rather primitive model of the use of inserts was described in 1979 by Krug. He described an intended sequence - what is supposed to happen - when a patient uses an insert. This sequence is illustrated on the opposite page in **figure 3·7**. Although his approach, which describes an insert as an integral part of a larger situation, is followed in this thesis, his suggested sequence of the use of inserts is too optimistic. It is optimistic in that it does not take into account the large percentage of cases in which things can go wrong. In particular, the direct relation between the supply of information and the consequent satisfaction and behaviour of a patient does seem too simplistic. This relation was described in section 2·2, and experimental evidence for this direct relation has not been found. It is, however, worth mentioning his approach, because he is one of the few investigators who has considered the use of inserts by patients.

3·2·2 A description of use.

There are several issues involved in the investigation of the use of inserts. Several theories, such as theories of visual perception, reading, information processing, and research fields such as psychology, linguistics, philosophy, and ergonomics need to be taken into account. An overview of these areas would clearly be too extensive to do, and too superficial to be of any

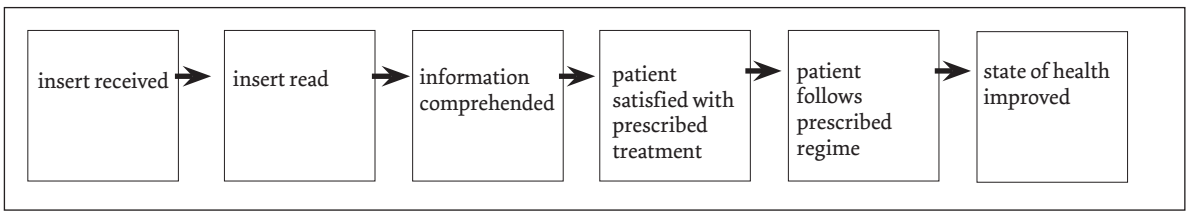


Figure 3·7. Patient rationale-intended sequence (Utopia version). According to Krug (1979).

help. I have tried to summarize some of the existing theoretical models relating to some general characteristics of users. I have used a pragmatic approach and described only those models which seem to be related to the way patients use inserts and that might be applicable to the study of graphic presentation. These approaches stem mainly from psychology and linguistic science. I have made some speculative connections between the theories and the use of inserts.

Two approaches to document use are described. The first approach looks at reasons and purposes for using a document, and at strategies that could be applied by users to achieve these purposes. The second description divides document use into three fields: visual perception, information processing, and the affective field. This is described in section 3·2·3.

Reasons for using a document.

A general reason for using a document can be defined as: 'to extract information from a document'. The extraction takes place during the interaction of the user with a document and results in the acquisition of knowledge, experience or information (Guthrie, 1988). This general reason can be subdivided into several types. Two reasons were initially distinguished: 'reading to learn' and 'reading to do' (Sticht, 1977).

In *reading to learn*, the user relates and stores the information in long-term memory so that it is available for later use. It is possible to subdivide this 'reading to learn'. For example, several types of types of learning have been distinguished, such as learning by understanding (meaningful learning) and learning by memorising (rote learning) (Mayer, 1987).

In the second type of use, *reading to do*, the user processes the information for immediate application to a given task and typically does not require long-term retention of the information. 'Reading to do' can include reading to perform each step immediately after a step has been read, or to read through a whole procedure and remember it long enough to perform it immediately afterwards, or it can include reading to memorize the procedure for a future performance (Bovair & Kieras, 1991). This last reason for using a document has been called *reading to learn to do.* This is the case in for example tutorials of computer programs (Redish, 1989). Users can also *read to assess.* In this case, a user determines whether a document will be useful for a later task or for another person (Diehl & Mikulecky, 1981).

Three of these reasons for using a document seem to be directly related to reasons that patients have for using inserts. These reasons were described in section 2·4. The 'reading to do' relates to the need to follow the instructions for taking a medicine. The 'reading to learn' relates to the need to know more about the medicine and the therapeutic indications. The 'reading to learn to do' relates to the actions that might have to be undertaken if side effects occur.

Reading strategies.

Following on from the reasons for using a document, is the approach used in reading a document, that is the ways users go about to achieve their purpose. At least five approaches, or strategies, can be distinguished (Pugh, 1979): skimming, scanning, search reading, receptive reading, and critical reading. Although not all aspects of document use can be classified as reading, these reading strategies can be applied to document use as follows:

- skimming: to use a document in such a way that a general overview of the document can be constructed
- scanning: to use a document in such a way that specific information can be found. The user knows the kind of information that is needed, but this information can appear anywhere in a document
- search reading: to use a document in such a way that the meaning of specific items can be found. In search processes, the search for information is selective: it is not necessary to inspect the whole document. The purpose of using documents at home is often to locate specific facts rather than to acquire or recall knowledge as usually demanded in classrooms. Guthrie proposed that locating information in documents warrants a unique process model which is more closely related to analytical reasoning, than to visual search or language processing (Guthrie, 1988)
- receptive reading: to use a document in such a way that the use results in a thorough comprehension of the information. The user tries to uncover what the producer of the document wants to convey
- critical reading: to use a document in such a way that an accurate assessment about the text can be made

All five strategies might be applied by patients when an insert is used, and it is also possible that patients change their reading strategy during the use of an insert. Most of the research in this area has been undertaken in educational, or occupational environments. Very little research has been done on the use of documents in the domestic environment.

3·2·3 A division of document use.

A second division of the use of documents can be made. This second division categorizes aspects of the use of documents into three broad fields: the field of visual perception, the information processing field, and the affective field. Aspects that are categorized in the field of visual perception are related to the looking at documents. The information processing field encompasses all the aspects of the use that are related to understanding of information in documents, and the aspects related to the preferences and opinions can be classified in the affective field. This division of document use is a simplification, but it offers a practical way to describe, and categorize, some specific aspects of document use. Some issues related to these fields are discussed below.

The field of visual perception.
It is obvious that the use of printed documents would not be possible without visual perception. The limitations and possibilities of the human visual system need to be taken into account when the influence of the graphic presentation on the use is investigated. Several theories of visual perception exist (Gordon, 1989). One main point needs to be made and that is that visual perception can be subdivided into several aspects. For example, Bertin (1981) distinguishes between four aspects of visual perception:

- associative perception groups components that have something in common
- selective perception distinguishes components
- ordered perception compares the hierarchical order of components
- quantitative perception compares the size of components

These four types of visual perception can be described as comparative perception. A fifth aspect of visual perception can be described as sequential. This aspects of the visual perception sequences the succession in which components are perceived. Both these groups of aspects seem to be important when the influence of graphic presentation is investigated.

The information processing field.
The second field document use can be categorized as the information processing field. This is a vast area and it is doubtful whether an elaborate description would be beneficial for this investigation. However, in order to be able to describe some of the experiments in section 4·4, it seems important to mention a few aspects in this field.

In a model of the human information processing system, four different types of memory can be separated: sensory memory, short term memory, working memory, and long term memory (Mayer, 1984; 1987). Although this model was used to investigate the conditions for meaningful learning from expository prose, it seems appropriate for the following description. This model is represented diagrammatically in **figure 3·8**. A similar model is used to describe the acquisition of procedures from text (Bovair & Kieras, 1991). Several other theories of reading comprehension processes have been developed. These theories are sufficiently elaborate, and have been compared in enough detail, that they can be used as comprehensive descriptions of the processes that the reader must perform in order to comprehend text (Kintsch & Dijk, 1978; Thibadeau et al, 1982; Dijk & Kintsch, 1983). Most of the models of reading comprehension processes divide these processes into different

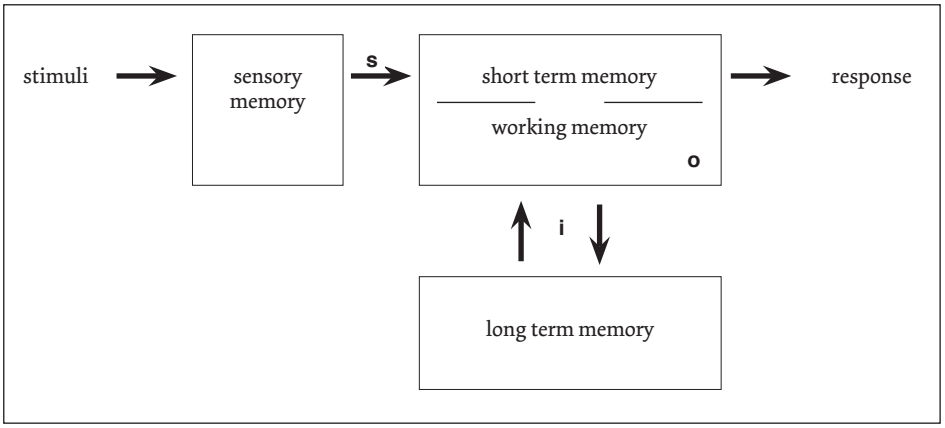


Figure 3·8. Human information processing system. According to Mayer (1987).
s = selection; **i** = integration; **o** = organisation.

stages, and suggest several strategies to progress from one stage to another. These descriptions of stages frequently overlap, and the user can alternate between these stages in several directions. I will come back to some of these theories when experiments are discussed in section 4·4.

The affective field.
The affective field is the third field of document use. The preferences and opinions of users about features of graphic presentation fall into this field. It seems important to include this field because preferences of patients are frequently investigated. The influence of preferences of subjects on document use are not clear, but it is suggested that these affect the willingness of a subject to use a document (Reynolds, 1984).

Two issues need to be addressed. In the first place, relationships between these three fields needs to be mentioned. It seems that visual perception and information processing are closely related, and are difficult to separate. The relationship between these two fields, with particular reference to graphic presentation, has been investigated by Rivlin (1987). It is clear that both these fields interact. The influence of the preferences on initial visual processing and information processing is not clear, but it can be argued that these preferences will influence document use. This division into three fields is not an attempt to categorize all the activities that might go on, but a convenient frame to discuss document use, and experiments related to the graphic presentation of information in documents.

The second issue that needs to be addressed is the relationship between both divisions of document use. On the one hand, there is a division into purposes and strategies, and on the other hand a division into three fields. These two divisions are both mentioned in the literature about document use, as it was briefly reviewed in this section. However, these two divisions are rarely combined and several interesting questions can be formulated by a combination of these divisions. These are, however, beyond the scope of this investigation.

3·2·4 Concluding.
The description of some theoretical models in the previous part could easily be extended. However, the aim of this section was to subdivide document use into several aspects. Two divisions were made. The first divided document use according to the reading purpose and the strategies for using a document. A direct relation between this division and the use of inserts is suggested. The second division distinguished three main fields: visual perception, information processing, and the affective field. The relation between this second division and the use of inserts is less straightforward, but it seems to offer a stronger relation with theories of information processing. Other divisions are possible, but these two seem to offer convenient frames to discuss some aspects of the use of documents. The next section will relate these divisions to graphic presentation.

3·3 Relations between graphic presentation and use.

Section 3·3·1, discusses the relation between the graphic presentation and the use of inserts. The conclusions of section 3·1 and 3·2 are combined in order to find those areas in which the influence of the graphic presentation on the use of inserts can be detected. The second section describes the relation between graphic presentation of information in inserts, and the aims of inserts as mentioned in section 2·2·1. Section 3·3·3 summarizes this chapter.

3·3·1 A matrix.

In the previous two sections, I have described graphic presentation of inserts, and document use. The graphic presentation was divided into four features: overall graphic presentation, graphic presentation of text, pictograms, and illustrations. This division was based on current regulations, guidelines, and opinions of producers and patients about graphic presentation. Section 3·2 described two ways in which document use can be divided. The first division was according to the reasons and strategies of patients to use a document, the second divided the use into visual perception, information processing, and affective fields. In order to investigate the influence of graphic presentation on the use of inserts, it is necessary to see whether these four features of graphic presentation affect different aspects.

One way of investigating this, is to combine each feature of graphic presentation with every aspect of the use. This relationship could be visualized as a matrix. The columns of the matrix are formed by aspects of the use. The rows are formed by the four features of the graphic presentation. **Figures 3·9** and **3·10** show two possibilities. These figures are based on the description of graphic presentation in section 3·1, and on the two descriptions of the use in section 3·2. As was stated in section 3·2, the aspects of the use are not clearly separable, and frequently overlap. In figure 3·9, the purpose for using a document will influence the strategy of the use of a document. In figure 3·10, the three fields — visual perception, information processing, and the affective field — will influence each other. This is indicated by the use of dotted lines in the figures.

These matrices provide a dissection of the main research question of this thesis into specific parts. The matrix identifies the possible areas that could be investigated in order to detect the influence of graphic presentation on the use of insert. Some cells in this matrix have already been investigated. For example, the investigation into the preferences of patients for illustrations in inserts (Dirr & Katz, 1989) could be placed in the cell in the affective column and the illustration row in figure 3·10.

Both matrices could be applicable for this investigation. However, as it will become clear in section 4·4 where the experiments are discussed, the most appropriate matrix for this investigation is the matrix of figure 3·10.

The division of graphic presentation into four rows in the matrix is not very precise. Although this division was used to review current regulations, guidelines and opinions, it does not include all features of graphic presentation. For example, the relation between text and illustrations, or the use of space are not mentioned. It is necessary to look at the description of graphic presentation in more detail to see if these rows can be made more specific. Section 4·2 looks specifically at frameworks that have divided graphic presentation into several, more detailed features. Section 4·3 describes a modification of existing frameworks, and this description will alter the row-headings of the matrix. The matrix, as represented in figures 3·9 and 3·10, is therefore not the final version but needs to be seen as an intermediate stage.

3·3·2 Concordance and suitability.

The main point that needs to be discussed in this section is the relation between graphic presentation and the aims for the supply of inserts to patients. In order to find out whether graphic presentation in inserts influences the use of inserts, it needs to be related to the aims of the supply of inserts. The following discussion applies the distinction between the producers' domain and the patients' domain as it was introduced in section 2·5. This section relates graphic presentation to the producers' aims and the patients' requirements.

The producers' domain is discussed first. The aim of the development process of the graphic presentation of information is twofold. The first aim is to create a graphic presentation that represents the information. The content of this information is described in section 2·3. The appropriateness of features of the graphic presentation as a representation of the topic will be called *concordance*. The development process aims for a high concordance between the graphic presentation

	Document use.							
	Reading purpose			Reading strategies				
	reading to do	reading to learn	reading to learn to do	reading to assess	skimming	scanning	search reading	receptive reading	critical reading
Graphic presentation								
1 Overall graphic presentation								
2 Text								
3 Pictograms								
4 Illustrations								

Figure 3·9. Document-use matrix 1.

	Document use.		
	Visual perception	Information processing	Affective
	comparative, sequential	knowledge, memory	preferences
Graphic presentation			
1 Overall graphic presentation			
2 Text			
3 Pictograms			
4 Illustrations			

Figure 3·10. Document-use matrix 2.

and the information content (the topic). This term was used by Rivlin (1987) to indicate the same principle. Zachrisson (1965) called the same principle 'congeniality'.

The second aim of the development of the graphic presentation is to present information in such a way that a patient can use this information. The requirements of patients with regard to graphic presentation of information are not known, and these requirements have to be assumed during the development. This line of argument is similar to the description of the investigations into the patients' requirements for information. In section 2.5, it is mentioned that the only way to find out whether information fulfils the requirements of patients is to involve patients in experiments. It is therefore necessary to involve patients in experiments that investigate the patients' requirements with regard to the graphic presentation of information.

The patients' domain describes whether the graphic presentation fulfils the requirements of patients in relation to the graphic presentation of information. The appropriateness of features of the graphic presentation for specific aspects of the use will be called *suitability*. Rivlin (1987) has used this term in his study, while Adams (1989) called this principle 'compatibility'. The suitability of the graphic presentation describes the appropriateness of its features for specific aspects of the use.

The development process of the graphic presentation aims to make it both concordant and suitable. A concordant graphic presentation represents the information content appropriately; a suitable graphic presentation fulfils the requirements of patients. The requirements of patients relate specific features of the graphic presentation to specific aspects of the use of inserts. In order to ascertain the requirements of patients regarding the graphic presentation of information, it is essential to conduct experiments. The results of these experiments can be incorporated in the development of the graphic presentation in order to make the graphic presentation more suitable. Several types of experiments can be undertaken. These will be further discussed in section 4.4.

3.3.3 Summary chapter 3.

In this chapter the current graphic presentation of information in inserts is described. This description divided the graphic presentation into four groups: overall graphic presentation, text, illustrations and pictograms. These four groups were a convenient way for describing the regulations, guidelines and opinions about the graphic presentation. However, these four do not encompass all the features of the graphic presentation, and it is necessary to find a more satisfactory way to describe graphic presentation.

The second section of this chapter described two ways of subdividing document use. The first way described some reasons for using documents, and strategies that could be applied by users. The second way described three fields: perceptual, information processing, and affective. Neither of these ways is completely satisfactory. However, both ways seem to be sufficient for this investigation.

The features of graphic presentation and document use can be combined in a matrix. Two matrices were illustrated. These matrices provide a dissection of the main research question of this thesis into specific parts. Each cell in these matrices can be investigated in order to ascertain whether the graphic presentation does influence the use of patient package inserts by patients.

Two conclusions can be drawn. The first conclusion is that there is a need for a more satisfactory way to describe graphic presentation. The second conclusion is that it is necessary to make a choice as to which cells in the matrix would be the most beneficial for this study to investigate.

4 Graphic presentation: analysis and evaluation.

Chapter four describes two major issues. The first part investigates ways of analysing and describing graphic presentation. Section 3·1 concludes that a division of graphic presentation according to four features (overall graphic presentation, text, pictograms, and illustrations) was unsatisfactory. This division is appropriate to describe the current regulations, guidelines, and opinions, but is not detailed enough for this investigation. Several frameworks have been developed to describe features of graphic presentation. Section 4·1 defines an approach to describe existing frameworks. Section 4·2 describes eleven frameworks, and considers their possible application to the description of the graphic presentation in inserts. A modification of existing frameworks is proposed in section 4·3.

Section 4·4 reviews investigations that have been undertaken to investigate influences of graphic presentation on document use. These investigations are reviewed in order to find out what has been investigated before, and which evaluation techniques would be the most appropriate for this investigation.

In other words, the matrix structure introduced in section 3·3 is further refined in this section. Sections 4·1, 4·2 and 4·3 describe different proposals for row headings of the matrix. Section 4·4 reviews several experiments that fall within the different cells of the matrix, and compares evaluation techniques that could be applied to experiments into the suitability of graphic presentation.

4·1 Approach to the analysis of graphic presentation.

Section 3·1 concluded that the description and division of graphic presentation into overall presentation, text, illustrations and pictograms is not satisfactory for this investigation. It is necessary to find a more precise way to identify and describe features of the graphic presentation. This more precise description can than be used to analyse graphic presentation. Several other ways to describe features of graphic presentation have been developed. I will use the word 'framework' to describe any method, model, or technique, that attempts to describe or analyse features of graphic presentation. Some of these existing frameworks are fairly elaborate models, while others consist of a single linear scale only. This section outlines an approach to the description of these frameworks.

Three reasons for the necessity to review existing frameworks can be given. The first reason is that it is necessary to describe features of graphic presentation, before an influence of these features on the use of inserts can be investigated. Therefore, existing frameworks are reviewed with special attention to their approach to describing features of graphic presentation. It might be possible to apply parts of these frameworks as row headings of the document-use matrix of figure 3·10. The second reason for looking at existing frameworks, is to find a way to compare the graphic presentation of inserts with the graphic presentation of other types of documents. In order to compare empirical research results, some sort of framework seems essential. A third reason to describe graphic presentation – which is not directly related to this thesis, but is interesting to keep in mind – is related to regulations. If it is possible to describe some characteristic features of graphic presentation, then it may be possible to regulate and control these features. This is especially relevant for inserts because a large number of different inserts need to be developed and controlled.

Two issues need to be mentioned at the start of a comparison of different frameworks. The first issue is the purpose of the description, the second issue is the approach to the description.

At least three purposes for describing graphic presentation can be distinguished. A first purpose is in the producers' domain. A topic can be represented graphically in a variety of ways. In relation to inserts, topic refers to all the information about a specific medicine that needs to be included in a patient package insert. This information is described in section 2·3. The purpose of the description of features of graphic presentation is to analyse relations between the topic (information content) and graphic presentation. This type of analysis will be called *concordance analysis*. The concordance between the topic and the graphic presentation is introduced in section 3·3·2.

A second purpose of describing features of graphic presentation is to analyse the graphic presentation of a document independent from the producers' domain or the patients' domain. The main purpose is either to describe a specific feature of graphic presentation, or to develop a taxonomy of some features of it. This purpose of analysis will be called *independent analysis*. This type of description can be used to show the scope of graphic options for the development of graphic presentation in documents.

A third purpose for analysing graphic presentation is to identify relations between the graphic presentation and document use. This type of analysis is in the patients' domain, and it tries to describe and analyse the relations between the graphic presentation and the use of inserts by patients. This type of analysis will be called *suitability analysis*. The suitability of a graphic presentation was introduced in section 3·3·2. The following section will specifically look at the application of existing frameworks to this type of analysis.

The second issue is the approach to the description of the different frameworks. Most frameworks describe the graphic presentation as a collection of objects. Some frameworks focus on the description of specific objects. Other frameworks focus in particular on the relations between these objects. In the next section, the smallest objects of graphic presentation are discussed first. The frameworks that discuss the relations between these objects are described in section 4·2·2.

4·2 Analysing graphic presentation.

This section describes some of the different ways of analysing features of graphic presentation. The specific aim of this section is to find a way to analyse the suitability of graphic presentation. It is not an attempt to provide a complete overview of all available frameworks.

In the description of some frameworks, I have indicated why certain parts of these frameworks seem more appropriate for this study than others. Section 4·2·1 starts with the description of frameworks that attempt to analyse the individual graphic components. Section 4·2·2 deals with frameworks that have analysed combinations of graphic components. Section 4·2·3 concludes by describing five conditions for a framework that could be used to analyse the suitability of the graphic presentation of information in inserts. A modified framework is introduced in section 4·3.

4·2·1 Analysing the smallest objects.

Frameworks that describe structured documents often represent a document as consisting of a collection of objects. It seems appropriate to concentrate on the definition of these objects. The lowest or smallest (atomic) level of objects in different frameworks can be compared. Three types of objects on this atomic level can be distinguished. In the first place a *topic element*. The topic element is the smallest bit of information that needs to be presented. The second smallest object is a *graphic component*. A graphic component is a mark (or group of marks) which is specified during the development of a document by one specific set of variables. A graphic component represents a topic element. The relation between a topic element and a graphic component determines part of the concordance of the graphic presentation. A graphic component is distinguished from other graphic components when the set of variables that is used to specify the component is different. The specification of only one variable in this set needs to be different to form a separate graphic component. The smallest atomic level in the patients' domain is the *user unit*. Definitions of these three smallest objects are presented in **figure 4·1**. The relation between the user unit and the graphic component is part of the suitability relation. The user unit will be discussed in section 4·3·2.

In order to investigate the influence of graphic presentation on use, it seems clear that the description of the smallest object should start with a description of graphic components. This description of graphic components can be related to user units in order to see whether there is a connection between graphic components and user units. This description of graphic components can also be related to topic elements. This relationship, the concordance, falls in the producers' domain. The study of topic elements would lead further into linguistic sciences and philosophy, and is therefore not pursued in this thesis.

Several types of graphic components can be distinguished. For example, Twyman distinguishes between four modes of symbolization: verbal/numerical, pictorial & verbal/numerical, pictorial, and schematic (Twyman, 1979; 1982). Twyman mentions that this breakdown is fairly crude, but it seems an appropriate division between types of graphic components. Mosenthal (1985) describes three types of 'representation', and separates linguistic, pictorial, and mathematical representations. In the following description, four types of graphic component are described: verbal components, pictorial components, schematic components, and composite components. The division into these four types of components should make it easier to discuss some features of the graphic presentation in inserts. These four types of

- **Topic element:**
  The smallest bit of information that needs to be presented in an insert.
- **Graphic component:**
  A mark or group of marks which is specified during the development of an insert by one particular set of graphic variables.
- **User unit:**
  An area of an insert on which a patient decides to focus in order to extract information.

Figure 4·1. The smallest objects of patient package inserts.

graphic components could be used to form row headings of the matrix in section 3·3. Verbal graphic components, pictorial graphic components and schematic graphic components are all specified by a single set of graphic variables. Composite graphic components consist of any combination of verbal, pictorial, and schematic components, and these are therefore specified by several sets of graphic variables.

Verbal components.

At least three different definitions of verbal components can be given. A definition of a verbal component could be that a verbal component epitomizes a given phenomenon using a word or some combination of words. A description of the choice of words and the way in which these words appear on paper defines a verbal component. A second definition could define verbal components as consisting of all characters that are directly accessible on an ASCII keyboard, or all the words that appear in a dictionary. A third definition of a verbal component could state that verbal components include all graphic marks that can be pronounced. However, the boundaries of verbal components are not clear in any of these three definitions. For example, it is not clear whether some punctuation marks can be seen as verbal components.

The major approaches describing verbal components are based on linguistic theories; only a few are based on graphic presentation or on a combination of both. Some of the text analysis methods were mentioned in section 2·3·3. These methods rarely involve graphic presentation in their analysis, and are therefore not directly applicable to this study. There are ways to analyse verbal components based on their graphic presentation. Several different frameworks for the analysis and description of the large number of available type faces have been proposed (e.g. Vox, 1955; Noordzij, 1981). The variety of typefaces that are applied in inserts can be analysed according to these frameworks. However, it remains doubtful whether these differences between typefaces are noticed by patients. Another type of description of verbal components is to measure some features of these components. For example, the '20 line measure', the x-height, the line space, and the capital height of verbal components can be measured and used to describe verbal components in inserts. These measures would describe the size of the verbal components without reference to the topic, or the patient, and can therefore be seen as frameworks for an independent analysis.

Pictorial components.

A pictorial component is a graphic mark or group of marks that relates, however distantly, to the appearance or structure of a real or imagined thing (Twyman, 1985). Several taxonomies and frameworks for analysing and describing pictorial components have been developed. Three frameworks for the analysis of pictorial components should be mentioned here. Ashwin (1979) described a framework for the analysis of illustrations which clarified the notion of style. Alesandrini (1984) produced a classification for instructional pictures based on the way in which pictures convey their meaning. He distinguished three types: representational, analogical, and arbitrary. Goldsmith (1984) developed an analysis identifying twelve elements that could be used to analyse pictorial components. These twelve elements are formed by a matrix that combines four factors (unity, location, emphasis and text parallels) on three levels (syntactic, semantic and pragmatic). Illustrations can be evaluated within this matrix structure in terms of their information accessibility.

The use of pictorial components in inserts has been described in sections 3·1·5. These three descriptive frameworks could be applied to inserts. However, the infrequent use of this type of graphic component in inserts, does not warrant a further analysis.

Schematic components.

The third type of graphic component is the schematic component. Every graphic component that is specified by a single set of graphic variables, and cannot be seen as a verbal component or as a pictorial component, can be classified as a schematic component. Examples of schematic components are the diamond, the asterisk, the rules and the bullets in figure 3·1. Schematic components are nearly always used in combination with other components. The relations between components will be further discussed in section 4·2·2. Some descriptive frameworks for schematic components have been developed. For example, Bertin (1983) distinguished seven variables (shape, orientation, colour, texture, value and size) that can be applied during the development of the schematic graphic components. However, this distinction is no more than a way to identify schematic components.

Composite components.

A fourth type of graphic component can be distinguished, to be called *composite components*. A composite component is a group or cluster of graphic

marks, that cannot be further separated, but can consist of any combination of verbal, pictorial and schematic components. Examples of composite components are a photograph depicting several items, a diagram, or an illustration representing several topic elements. Several composite components are used in inserts. Two examples are given in **figure 4·2**.

One special type of composite component is the diagram. Taxonomies for this type of composite component have been suggested by Bertin (1981, 1983) and Rankin (1990). One way to analyse this type of diagram is proposed by Tufte. Tufte states (1983: p 51) that: 'graphical excellence is that which gives the viewer the greatest number of ideas in the shortest time with the least ink in the smallest space'. This is called later the *data-ink ratio*. The ideal ratio of data to ink is one to one: every mark should represent at least one bit of information, and every mark should provoke the greatest number of ideas. How this greatest number of ideas can be investigated, or how the number of data can be identified is not discussed further. The use of this ratio is not empirically verified either. The application of this framework to analyse composite components in inserts seems therefore limited.

As a conclusion for the description of these four types of graphic components, it can be stated that, in spite of the usefulness of having a crude description of types of graphic components, it does not seem essential for the analysis of the graphic presentation in inserts to make an exact distinction between these four types. These four types of components can indeed be distinguished, but it should be realized that some graphic components can be described as a combination of two or more types.

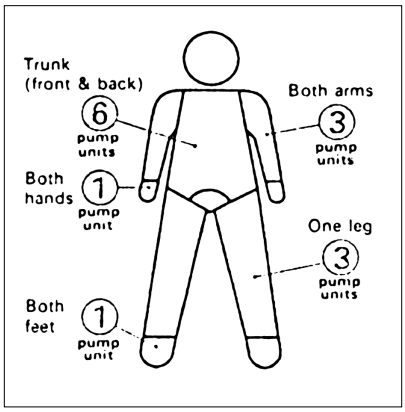
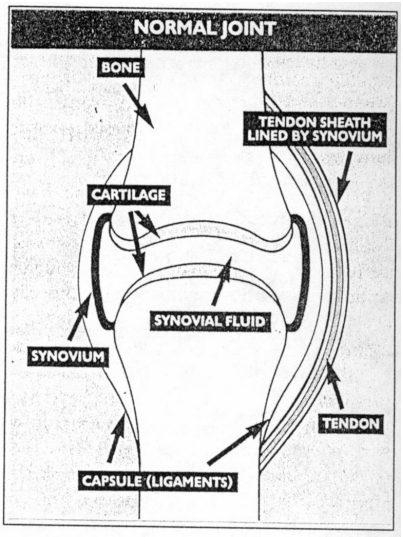


Figure 4·2. Examples of composite graphic components. *Left:* Betnovate cream pump dispenser insert (Glaxo, 1992). *Right:* Rheumatoid Arthritis handbook for patients (The Arthritis and Rheumatism Council, 1990).

4·2·2 Analysing the overall graphic presentation.

This section consists of a description of eleven frameworks that describe features of the overall graphic presentation. These frameworks are only discussed in so far as they can be made applicable to the analysis of graphic presentation in inserts, and in particular to a suitability analysis. Parts of these eleven frameworks will be used in the description of a modified framework in section 4·3, and in the review of empirical research in section 4·4. A description of several different frameworks is always a slightly daunting task. Most frameworks have been developed and described for different reasons, and their application to a specific type of document, such as inserts, could be inappropriate. There is therefore no point in comparing them. However, the description below seems a way of finding out whether it is possible to provide a more helpful division of features of the graphic presentation.

Although the eleven frameworks are unrelated, three categories can be distinguished in order to create some sequence through them. The categorization of these frameworks is based on their intention, and not on the possible application of these frameworks to this investigation. The first category describes the frameworks of Bonsiepe (1968) and Horn (1989). In the context of this thesis, these two frameworks fall in the producers' domain, because they analyse graphic presentation with the purpose of developing and improving the graphic presentation. The second category contains frameworks developed by Walker (1982), Norrish (1987a), and Rivlin (1987). These three frameworks fall in the patients' domain, because these frameworks could be used to analyse the graphic presentation from a patients' point of view. The third



category contains six frameworks. These six frameworks have been developed by Hartley (1978), Twyman (1979), Bernhardt (1985), Waller (1987), Southall (1989), and Kirsch and Mosenthal (1990). These six frameworks involve both the producers' domain, and the patients' domain. Although, other frameworks, such as the approaches by Bertin (1983) for composite components, and by Goldsmith (1984) for pictorial components could be developed to encompass the overall graphic presentation, such adaptations are beyond the scope of this thesis and will not be pursued here.

Bonsiepe.

The first framework that could be used to analyse the graphic presentation is described by Bonsiepe (1968). He suggested a method of comparing the degree of graphic order of documents. Bonsiepe regarded all typographic items as elements, and placed these elements in rectangular shapes. The dimensions and position of the rectangles were used as starting points for an analysis. Bonsiepe suggested that there are two types of order. The first type of order is the order of the system. This order is indicated by the dimensional relationships (sizes of the rectangular shapes) of the elements, and the frequency with which these sizes occur. The second type of order is the relation between the elements. The distribution of these elements on a page is a function of the alignment of these elements with horizontal and vertical reference lines. The number of alignments can also give a numerical value to the order. Both numbers can be used to compare the *orderliness* of two pages.

This approach is interesting for two reasons. If this analytic framework is reliable, than it can be applied to compare the 'orderliness' of the graphic presentation of different inserts. The analysis can also be used to see whether patients are influenced by the orderliness of the graphic presentation.

However, at least three reasons against the application of this mathematical-empirical approach to inserts can be stated. The first reason is that the measure is crude. It will not identify differences in orderliness *within* rectangles. The size of these rectangles seem to be arbitrary as well. The illustrations of the catalogue that were analysed in the publication showed that several different graphic components were placed in a single rectangle. The size of the elements (the rectangles) in this framework does not therefore seem to be very precise. The second reason is the lack of experimental evidence. It is assumed that pages with the fewest alignments are the most aesthetically pleasing and the most efficient, but this assumption is not verified empirically. The third reason is that in order to score high on the orderliness-scale, the rectangles need to be of approximately similar dimensions. If the different information sections are not similar in size, the level of orderliness will be reduced. Especially this last point reduces the usefulness of this framework to this study of inserts.

Horn.

The second framework in this category is called Information Mapping (Horn, 1989). Information Mapping is a method for analyzing, organizing, writing, sequencing and formatting information with the aim of improving communication. This framework is mainly aimed at the analysis of the information content, and is used to develop a graphic presentation. The smallest element in this method is an information block. Such a block consists of a specific kind of information with a label. Information maps are a collection of information blocks about a specific topic. Four principles generate information blocks and maps: chunking (group all information into small manageable units), relevance (include only information that relates to one main point), consistency (use similar words, labels etc for similar matter) and labelling (give every block and map a label). Seven different types of information are distinguished (procedure, process, structure, concept, fact, classification, principle). This Information Mapping method could be applied to analyse the information in inserts. All four principles, and all seven types of information can be identified in the information sections that need to be included in inserts.

Although this framework is mainly aimed at the analysis of the information content, it could equally well be applied to an analysis of the graphic presentation. The four principles for generating information blocks can be used to see whether graphic components are related to the information content. This type of analysis falls into the producers' domain, because it could be used to analyse the concordance of the graphic presentation with the information content. However, the analysis of the graphic presentation of the information content could also be applied to studying the responses of patients. In particular, the influence of the application of the four principles (chunking, relevance, consistency and labelling) on the responses of patients could be studied.

The frameworks by Bonsiepe and Horn provide a

way of analysing and evaluating features of the graphic presentation. However, both these approaches can be categorized as belonging to the producers' domain, and could only with substantial modifications be applied to a suitability analysis. The following three frameworks provide ways to analyse graphic presentation by approaching the features of the graphic presentation from a users' point of view. These three frameworks can therefore be placed in the patients' domain.

Walker.

This framework described by Walker (1982) is mainly aimed at describing graphic organization (overall graphic presentation) of verbal graphic language. The framework describes the results of the production of verbal graphic language by lay people. The main subject of analysis was letters written by children. Although this framework investigates only verbal components, the relations between these components are of particular interest, and should be valuable for the task at hand.

Walker tried out a taxonomic method for describing typographical features on a physical, spatial and graphic level. Several features at each level are listed. Features on a 'spatial level' are for example word spacing, line increments and margins. These features are broken down into states, which describe specific possibilities. For example, states within the feature of 'margins' are negligible, narrow, medium, wide, and uneven. The person who is analysing verbal graphic language has to make a choice into which state a typographical item falls. The states are recorded. The description of these states is comparable with the analysis of verbal graphic components, as mentioned in section 4·2·1. By comparing the levels, features and states of different documents, the graphic presentations can be compared. This is a framework that provides a practical approach to the analysis of graphic presentation.

It is possible to apply this framework directly to inserts. However, the levels, features, and states should be made specific to those characteristics of the graphic presentation that are used in inserts. This is necessary in order to find those levels, features, and states that could be investigated.

Norrish.

In order to describe the graphic presentation of brochures and scientific journals, Norrish (1987a) identified several structures in the graphic presentation. Norrish stated that 'structures were recognized by looking at the document for visual signals and cues which alert the reader to something different happening in the text' (Norrish 1987b). She further suggested that changes in the graphic presentation signalled that something different was happening in the text. She recorded these changes in the graphic presentation in relative terms. This record was made in order to 'try to document what the reader sees'. Two types of structure were initially recognized: a topic structure, and an access structure. Both structures were represented in tree diagrams. These tree diagrams are representations of the structure of the graphic presentation in a document, and show the relations between graphic components. However, Norrish stated that the representation of the topic structure and the access structures in the tree diagrams duplicated much of the detail and served no particular purpose (1987b: p 10), and she therefore combined both. By doing this, the assumption is made that the graphic presentation accurately represented the topic structure, and that both structures could be analysed together.

Norrish's approach clearly illustrates the difference between concordance and suitability. The assumption was made that the structure of the graphic presentation is equal to the topic structure. This is the definition of a concordant graphic presentation. However, it was recognized that there were differences between the topic structure and the access structure (graphic presentation) in several examples. These differences were ignored by combining both structures, but could easily have been indicated in the tree diagrams. However, these differences are a clear indication that the concordance of the graphic presentation in the examples was not optimal.

The graphic presentation was analysed by recording visual signals and cues which alert the reader that something is happening. These decisions as to where 'changes' occurred were made by a single observer. This assumes that a single observer will notice the differences between graphic components in a way similar to the users. The application of this framework to inserts seems possible. The identification of the graphic components, and the description of the relations between those components in tree diagrams can be used for the study of inserts. However, it seems important that patients should be asked to identify these graphic components. I will come back to this point in section 4·4.

Rivlin.

This is a third framework that combines the

development of 'typographic organisation' and 'the psychology of visual perception'. Rivlin distinguishes three fundamental functions of typographic organization: association (relations of unity and distinction), succession (relations of order) and attention (relations of importance). He concludes that 'these three functions constitute the main structural relations between the components of a printed message. They therefore provide a framework within which the relationship between typographic organization and visual perception can be examined' (Rivlin, 1987; p 162). These typographic functions are realized by the user through three perceptual principles: grouping, sequencing and emphasising.

Several comments need to be made if this framework is applied to the analysis of the graphic presentation in inserts. This framework states that emphasis is a perceptual principle. This does not seem to be correct because a reader, or user of a document cannot emphasize parts of the graphic presentation by looking at it. Rather, a user perceives the prominence, or salience, of some graphic components. A second comment is that Rivlin states that 'the principles of perceptual grouping constitute the chief visual means by which textual components may be associated and dissociated, thereby indicating the structure of the message' (Rivlin, 1987; p 38). Rivlin showed that these associations were investigated in experiments. However, the ways in which these associations are interpreted by users of documents was not discussed. Despite these deficiencies, the direct relation between typographic functions and initial visual perception seems a useful starting point for an analysis of the graphic presentation. The three fundamental functions of typography need to be refined, in order to be applicable to the analysis of the graphic presentation of information in inserts.

The three frameworks of Walker, Norrish, and Rivlin show that it is possible to divide the graphic presentation into several features. All three based their divisions on those features that could be identified by users. This is the main reason for placing these three frameworks in the patients' domain.

The third category contains six frameworks. All six frameworks describe graphic presentation in such a way that the description could be applied in the producers' domain, as well as in the patients' domain.

Hartley.

The fourth approach which directly relates the producers' domain and the patients' domain is suggested by Hartley (1978; 1987). Hartley suggests that two main decisions will make texts easier to understand. These decisions need to be made during the development of a document. The first decision, which is directly related to the purpose of the reader to use a document, is to determine the format of a document. The use of standard page sizes, as specified by the International Standard Organisation, is preferred. The second decision affects the choice of graphic features and spatial features. It is argued that especially the consistent use of space (rational spacing) can help to convey the structure of instructional text. The spatial arrangement needs to reflect the underlying organization of the text, and to match readers' expectations (Hartley, 1987). From a producers' point of view, this consistent use of space requires clarity of thought.

Three reasons are supplied why spacing is useful from a user's point of view. The spacing can help users to perceive redundancies in the text; spacing can help to perceive the nominal and effective stimuli easier; and spacing can aid the perception of the structure of the document as a whole (Hartley, 1984). Two types of spacing are separated: horizontal and vertical spacing. Horizontal spacing can be used to group functionally related parts together (for example: words, phrases). Vertical spacing can be manipulated to group and separate the functionally related parts of a piece of text (for example: headings, paragraphs).

This approach of rational spacing can very well be applied to the study of inserts. Space can convey a topic structure (in the producers' domain), and it can help readers to know how to proceed through a text (in the patients' domain). However, the emphasis on spatial relations seems to reduce the attention to several other aspects of graphic presentation such as differences between types of components.

Twyman.

Twyman (1979) proposed a schema presenting a number of theoretical possibilities in relation to the analysis and development of graphic presentation. The following approach is an elaborate framework in the sense that it tries to embrace all graphic language. The proposed matrix could be used to guide the development (as a template of advice), and as an independent description (for the discussion of graphic language). The matrix is reproduced in **figure 4.3**. The column headings describe methods of configuration. These configurations describe the spatial organisation of graphic components. Seven headings are selected to

show a shift from pure linearity on the left to extreme non-linearity on the right. The row headings describe the modes of symbolisation. Three of these modes were discussed earlier in this section.

The matrix seeks to identify the principal options open to anyone using graphic language. This can be directly related to concordance: the matrix suggests different configurations and modes to represent a topic. Two reasons can be given why this matrix can be helpful for an analysis of the graphic presentation of inserts. The first reason is that the matrix can be used to analyse the graphic presentation for research purposes. The matrix might also be considered as an aid for reviewing empirical research in the field of graphic language. The second reason is to consider the influence of the graphic presentation on reading/viewing strategies and cognitive processes of the user. Especially this second reason could be applied to the investigation into the suitability of graphic presentation in inserts. However, the matrix seems to be less appropriate for this type of analysis. When features of the graphic presentation of inserts are placed in the cells of this matrix, the majority of inserts will be positioned in cell number 2. Some parts of inserts could be placed in cell numbers 3, 5, and 9. Most cells will remain empty. In order to investigate the influence of the graphic presentation on the use of inserts, different, or more applicable headings seem necessary.

Bernhardt.

An interesting framework, consisting of a single linear scale, is proposed by Bernhardt (1985). Four different documents, all about a similar topic, were discussed in terms of their text structure and graphic presentation. These four documents were a research report, a legal act, a brochure, and a fact sheet. Bernhardt suggests that documents can range from visually informative to non-visually informative. Visually informative documents rely heavily on a combination of graphic features to signal the organization of a text. Non-visually informative documents make relatively little use of graphic signals of textual organisation. The recognition of boundaries within a text (topic elements) and the highlighting of these boundaries by visual cues (graphic components) frees the reader from the necessity of reading in a linear fashion, and allows the reader to direct attention to various locales within the

		Method of configuration						
		Pure linear	Linear interrupted	List	Linear branching	Matrix	Non-linear directed viewing	Non-linear most options open
Mode of symbolization	Verbal/ numerical	1	2	3	4	5	6	7
	Pictorial & verbal numerical	8	9	10	11	12	13	14
	Pictorial	15	16	17	18	19	20	21
	Schematic	22	23	24	25	26	27	28

Figure 4·3. Twyman's matrix for the study of graphic language (Twyman, 1979).

text. Bernhardt also showed that reasons for developing a visually informative document, or a non-visually informative document, are not dependent on the content, but on the intended users.

Applying this scale of visual organization to inserts, it seems that inserts can be placed in several positions on the scale. Some inserts are highly visually informative, others are non-visually informative. The importance of Bernhardt's framework in this context is that it compares the supply of similar information to different users with reference to the different graphic presentations. This comparison is very similar to the situation in which information must be supplied to prescribers and to patients.

This framework also illustrates the difference between concordance and suitability. The graphic presentation in all four documents is concordant with the topic (the level of visual informativeness represents the information content). The differences in the graphic presentation between the documents indicate that the suitability depends on the user of the document (the level of visual informativeness helps the user to direct attention).

Waller.

Waller set out to 'suggest a framework within which typography can be discussed and criticized' (Waller, 1979; 1987). He developed a largely theoretical distinction between topic, artefact and access structure. The main purpose of this distinction is 'to form the basis for describing genres of typographically-organised documents' (Waller, 1987: p 180). Topic structure simply refers to anything the author wants to talk about. Artefact structure refers to the constraints and possibilities of the physical nature and production constraints of a document. Access structures are devices that help the reader gain access to the text, and to read it in a variety of ways. They can use both spatial and typographic cues to group relatively large chunks of text, and to sequence them appropriately (Waller, 1979).

The three structures (topic, artefact, and access structure) underlie the fourth structure. This fourth structure is called conventional structure or genre. However, Waller suggests that it is more likely that the actual recognition of a genre is by more obvious and typical physical characteristics than by these three underlying structures. A second approach for the description of genres is therefore described. Four areas are identified which define the genre structure: the typical context of use, the typical format and configuration, the typical treatment of verbal language and the typical treatment of visual elements. The relation between these four areas and the previously mentioned three structures, however, remains a bit vague.

The direct practical application of these four structures (topic, artefact, access, and genre structures) to inserts is difficult. These structures frequently overlap substantially in inserts. However, inserts seem to belong to a specific genre of their own. From a theoretical point of view, this framework is helpful, because it distinguishes between the topic structure and the access structure. The topic structure can be related to the concordance between the information content and the graphic presentation, and the access structure can be related to the suitability of the graphic presentation.

Southall.

The fifth framework that provides an approach for the analysis of the graphic presentation is described by Southall (1989). Southall makes a distinction between the graphic structure and the visual structure. The graphic structure of a document consists of marks, or groups of marks, and the metric relationships between them. These features are directly measurable. The attributes of these graphic marks, interpreted by the human visual system give the marks their visual attributes. These attributes (aspects of the use) are user dependent and cannot be measured directly. The visual structure of an actual document should reflect the logical structure of the text that the document realizes. This is important because an understanding of the logical structure of a text is essential for the comprehension of a text by users. Southall distinguishes three characteristics of logical relationships: hierarchy, containment and sequence.

- hierarchy: ranks can be assigned to the elements of the structure. The visual attributes of the graphic object that realize the elements of the text should make clear which levels in the logical hierarchy each element belongs to
- containment: higher-ranking elements contain lower-ranking elements. The visual relationships between the graphic objects should reflect the containment relationships between logical elements
- sequence: elements of equal rank follow one another in the text. The sequence in which graphic objects are

perceived should reflect the sequence of the logical elements

These three relationships need to be clearly expressed to make understanding of the text by readers possible. Graphic designers have three tools for expressing these logical relationships: space, size, and typographic colour, or style.

Two arguments can be mentioned to explain why Southall's approach can be appropriate to the study of inserts. The information sections in inserts could be hierarchically ordered. The information sections contain several topic elements and the sequence of the information sections is determined by regulations. These three types of topic relations (Southall's logical relations) can be represented in the graphic presentation. The distinction between the graphic presentation and the visual presentation is useful, and is in agreement with the distinction between concordance and suitability.

However, there are also two points that raise problems with the application of this approach to this study of inserts. The understanding of the logical structure by the user is seen as essential by Southall, but how this understanding is related to the visual structure remains unclear. Southall states that we do not know enough about how the human visual system perceives a visual structure, and he suggests studying the development of graphic presentation. The reason for studying this is to determine the rules by which graphic designers develop documents. However, it seems more useful to study users of documents in order to ascertain whether the application of these rules has any influence on the user.

Kirsch and Mosenthal.

Kirsch and Mosenthal (1990) proposed an analysis of the usability of documents based on three variables: document variables, task variables, and process variables. Document variables are based on the structure and complexity of the document. Task variables are based on the structural relation between the document and the accompanying question or directive. Process variables are based on strategies used to relate information in the question or directive to information in the document. These variables were initially applied in a Young Adult Literacy study in the United States.

A grammar, which can be seen as an analytical framework, was developed to analyse the structure of documents. This grammar was used to examine the documents, tasks, and process variables. Kirsch and Mosenthal found that the combination of these three variables accounted for 89 per cent of the variance in the performance of young adults. An explanatory model based on these findings was developed that could account for the constructs underlying document processing. Kirsch and Mosenthal state that this model could be used by document designers in improving the usability of documents.

The analysis of document variables is particularly interesting for the study of inserts, although the graphic presentation of information was not mentioned. The analysis consists of three levels: semantic features, specific information and the organizing category. These three levels seem to be directly related to the graphic presentation of the information in the examples provided by Kirsch and Mosenthal. These examples were a label from a medicine bottle and a bar chart. An inclusion of the graphic presentation as an integrated part of this framework could be used to investigate the suitability of the graphic presentation in inserts.

4·2·3 Concluding.

A conclusion for this section about different analytical frameworks can be that none of these frameworks is directly applicable to the study of the influence of the graphic presentation on the use of inserts by patients. However, several ideas can be applied. At least four conclusions can be drawn from this review of frameworks.

The first conclusion is that the division into the producers' domain and the patients' domain can be recognized in several of the frameworks. The frameworks of Hartley (1978), Twyman (1979), Southall (1987), Norrish (1987a), Waller (1987), Kirsch and Mosenthal (1990) all specifically mention both domains. The other frameworks do not contravene this division.

A second conclusion is that an analysis for a suitability investigation assumes that every noticeable difference in graphic presentation has a purpose. There are two sides to this conclusion. In the producers' domain, this indicates that linguistic features must be incorporated in an analysis of the graphic presentation. This integration of the graphic presentation into a linguistic analysis has been suggested by Bernhardt (1985) and Waller (1987). In the patients' domain, patients must use what they see as a basis for reasoning about the structure of a topic. The graphic presentation must therefore represent a topic (concordance) when the suitability of the graphic presentation is

investigated. Without this assumption, a discordant graphic presentation (that is, a graphic presentation that does not represent a topic) could be analysed. The analysis of the suitability of a discordant graphic presentation would be erroneous. The analytic frameworks of Norrish (1987a) and Walker (1982) applied this notion that every noticeable difference does have a purpose. In order to identify noticeable differences, they employed an observer to make decisions. The frameworks of Bonsiepe (1968) and Bernhardt (1985) and the analysis of the method of configuration of Twyman (1979) could be applied to documents in which the relation between topic and graphic presentation is not considered. I will come back to this point in section 4·4 when experiments investigating the suitability are discussed.

A third conclusion is that a suitability analysis should take features of the human visual processing system into account, and therefore test patients' perceptions. The framework of Rivlin (1987) points towards this conclusion.

A fourth conclusion is that it seems useful to separate the analysis of the graphic components from the analysis of the relations between these components. Several frameworks suggest that the graphic presentation should be directly related to the topic elements and the topic structure (Hartley, 1979; Waller, 1987; Horn, 1989; Southall, 1989). An analysis should make a division between graphic components as representing topic elements, and graphic relations as representing relations between topic elements.

The following section will start with these conclusions as a basis for a modified framework that could be used to analyse the suitability of the graphic presentation in inserts.

4·3 Proposal for a modified framework.

This section introduces a framework that can be used as a tool to analyse the graphic presentation of inserts. This analysis can be used to investigate the influence of graphic presentation on the use of inserts by patients. The framework tries to avoid some of the deficiencies of existing frameworks for this type of analysis as mentioned in the previous section.

Section 4·3·1 outlines an approach for the selection of some features of existing frameworks. Section 4·3·2 describes a way in which the smallest components can be approached. The next section, 4·3·3, describes four possible relations between graphic components, and section 4·3·4 describes the overall graphic presentation. Section 4·3·5 describes some advantages and disadvantages of this modification.

4·3·1 An approach to the modification.

The previous section concludes that existing frameworks are not directly applicable to an investigation of the influence of graphic presentation on the use of inserts by patients. The conclusions drawn can be used as starting points for a modification of existing frameworks. Three points need to be mentioned here. The first two points are related to the smallest objects that need to be analysed. The third point relates to the largest features of graphic presentation that need to be analysed.

Several frameworks have started from the smallest object. For example the frameworks by Bonsiepe (1968), Walker (1982), Horn (1989), and Kirsch and Mosenthal (1990) all start their analysis on the most detailed level. The size of a single object of the graphic presentation that could have an influence on the use must be described. In the context of this thesis, a single object of the graphic presentation is a graphic component. These were introduced in section 4·2, and shown in figure 4·1. The size of a graphic component can range from relatively small (a single letter or numeral) to relatively large (an information section in an insert). A framework for analysing the suitability of graphic presentation in inserts needs to include this smallest level of analysis. These boundaries of the smallest objects were either not clearly defined, or not addressed at all in the frameworks of Twyman (1979), Rivlin (1987) and Waller (1987).

It is essential to consider the human visual processing system when the smallest object of a

graphic presentation needs to be described. This was suggested by Rivlin (1987). Without this inclusion, features of graphic presentation that could not possibly be noticed by users might be analysed. The combination of the dimensions of the smallest object of the graphic presentation (that is a graphic component), and aspects of the human visual processing system leads to investigations into the smallest noticeable difference. The smallest noticeable difference can be experimentally defined. This approach is part of the domain of the study of psychophysics (Stevens, 1975). It seems doubtful whether the smallest noticeable difference of graphic components needs to be analysed when the influence of graphic presentation is investigated. I will come back to some experiments that have tried to relate the smallest noticeable difference to specific graphic components in section 4·4.

A third point that needs to be made refers to the largest scale of an analysis. Section 3·1·2 described the overall graphic presentation. Horn (1989) mentioned the consistency of the use of graphic components, Hartley (1978) mentioned the document size. It seems necessary to include this level into a modified framework in order to describe those features of the graphic presentation that are related to the complete insert.

In the following section, 4·3·2, the modified framework is described. This framework is based on the conclusions of section 4·2·3 and the points mentioned above. The framework consists therefore of three levels:

- the first level describes graphic components
- the second level of the framework describes relations between graphic components
- the third level describes the overall graphic presentation

4·3·2 The relation between use and graphic presentation.

Section 4·3·1 distinguishes between three levels of analysis of graphic presentation. In section 4·2·1 and in figure 4·1, the *user unit* is mentioned as the smallest object in the patients' domain. This section sets out to describe the user unit, and relate the user unit to the three levels of analysis that are mentioned above. This description is necessary in order to investigate the patients' requirements with regard to the graphic presentation of information.

On the first level of analysis, a patient can look at graphic components that represent a topic element. This is essential when a patient wants to understand the topic element. The second level of analysis looks at relations between graphic components. The interpretation of these graphic relations is essential for the patient in order to understand relations between topic elements. The third level of analysis looks at the overall graphic presentation. The overall graphic presentation provides the patient with an impression of the whole topic. These three statements are crucial for this investigation.

The definition of the user unit is based on the requirements of a patient. A user unit is an area of an insert on which a patient decides to focus. A user unit can be described as 'whatever feature of the graphic presentation the patient wants to pay attention to in order to understand the information content'. A user unit can therefore be similar in size to a graphic component as, for example a patient looks at a pictogram. A user unit can encompass more than one graphic component, when a patient looks at a group of graphic components. A user unit can also incorporate the overall graphic presentation. However, a user unit cannot be smaller than a graphic component. A patient can of course pay attention to a detail of a graphic component, but, in order to understand a topic element, it is essential for a patient to look at a complete graphic component.

This description provides a direct relation between the use (as described in user units) and the graphic presentation (as described in graphic components).

Identifying user units and graphic components

In order to use this three-level analysis, it is necessary to show that graphic components can be described reliably. As was mentioned before, the frameworks of Bonsiepe (1968), Walker (1982), Norrish (1987b), and Kirsch and Mosenthal (1990) used observers. Norrish (1987b: p 11) stated that graphic components were separated 'by looking at the parts of text which were differentiated'. Kirsch and Mosenthal trained a person to separate elements and came to an agreement of 89 per cent between themselves and the third person. Although the framework of Kirsch and Mosenthal did not directly incorporate graphic presentation, the separation of elements seemed to follow the graphic presentation accurately. This seems to indicate that graphic components can be reliably separated by

trained observers.

User units are more difficult to identify. It is essential to involve users of documents in these judgements, because they define the user units. This difference between the graphic presentation, described in graphic components, and the interpretation of this graphic presentation by the human visual system, in user units, was mentioned in the framework of Southall (1989). Experiment 1 was set up to identify ways to investigate user units, and section 5·1 reports this experiment.

4·3·3 The relations between graphic components.

At least two points need to be mentioned before the relations between graphic components can be discussed. In the first place, all the topic elements in a topic structure are somehow related to each other. In a concordant graphic presentation, the relations between graphic components represent the relations between topic elements in a topic structure. The graphic components in a concordant graphic presentation are therefore always related to each other.

In the second place, the relations between graphic components can be considered on different scales. As was indicated in section 4·3·2, the user unit can vary from a detail to totality. Relations on a detailed scale are those relations between graphic components that are adjacent. Relations between graphic components on a larger scale are between components which are not adjacent. In order to accommodate this variety, relations between graphic components need to be applicable on a detailed scale as well as on the total scale.

At least four types of relations between graphic components can be described:
- proximity/distance
- similarity/difference
- prominence
- sequence

These four are mentioned in several of the frameworks that are discussed in section 4·2, but they have not been combined. These four relations can be applied in the producers' domain, in order to describe the relation between the graphic presentation and the topic. These four relations can also be applied in the patients' domain in order to describe the relation between the graphic presentation and the interpretation of the graphic presentation. The following description mentions in which frameworks these four relations between graphic components have been described.

Proximity relations.
The distance between graphic components can be varied during the development of the graphic presentation. This distance between graphic components can be used to indicate the connection between topic elements. Graphic components are placed close together when there is a strong relation between topic elements. Components are placed further apart when there is a weak relation between topic elements. In a concordant graphic presentation, the strength of the relation can be represented by the distance separating the graphic components. This proximity relationship between the topic and the graphic presentation has been mentioned in the analytic frameworks by Hartley (1978) and Walker (1982). In these two frameworks, the use of space to separate graphic components is mentioned. A similar principle is mentioned by Rivlin (1987) and Horn (1989), who suggest grouping graphic components by placing them close together.

The proximity relation can be linked with theories of visual processing. The relation seems similar to the Gestalt principle of proximity, which states that things that are close together are seen as groups. The grouping of closely placed elements has been experimentally investigated. This type of experiment has been undertaken by Pomerantz and Garner (1973), and Pomerantz and Schwaitzberg (1975). Most of these studies have used abstract stimuli. The interpretation of this relation by users of documents has also been experimentally investigated. I will review some of these experiments in section 4·4.

Similarity relations.
The second relation between graphic components can be described as the similarity relation. Each variable in the set of graphic variables that specifies a graphic component can be modified during the development in order to make graphic components look similar. The similarity of graphic components indicates a similarity between the status of the topic elements in the topic structure. A difference can indicate a difference in status between topic elements in the topic structure. The similarity relation between graphic components was indicated in the frameworks of Horn (1989), and Southall (1989). Horn mentioned the consistency in the

specification of graphic components, and Southall stated that the hierarchical rank of a topic element should be made clear by the graphic presentation.

The similarity of graphic components according to the visual perception theories depends very much on the feature of the graphic component that is compared. A recent review has discussed the main issues in relation to the concept of similarity (Medin, Goldstone, Gentner, 1993). Several experiments have investigated the interpretation of the similarity relations between graphic components. I will review some of these experiments in section 4·4.

Prominence relations.

The third relation between graphic components can be analysed in terms of prominence differences. The status of a topic element can be described as the hierarchical rank of an element in the topic structure. Prominence differences of graphic components indicate the amount of difference between the status of topic elements. These status differences can be interpreted by patients by comparing the prominence differences of graphic components. The status difference can be represented in the graphic presentation by varying the level of emphasis. This prominence relation was mentioned in the analytic framework of Rivlin (1987). However, Rivlin described these status relations between graphic components as 'attention', and defined emphasis as a perceptual principle. It is important to distinguish between emphasis and prominence. Emphasis is a particular specification of graphic variables, and this is used by a developer to represent the difference in status between topic elements. Emphasis falls therefore in the producers' domain. The interpretation of this difference in status, that is the comparison of the prominence of graphic components, is done by the patient. Prominence falls therefore in the patients' domain.

This distinction between emphasis and prominence is rather artificial. However, it is necessary to describe the amount of difference between the status of topic elements in the producers' domain as well as in the patients' domain. The terms emphasis, conspicuousness, attention and prominence could all have been used. The term 'prominence' seems most appropriate in the patients' domain, but it should be realized that it is used in a specific way. Some experiments investigating whether users interpret these prominence differences are discussed in section 4·4.

Sequential relations.

The fourth relation between graphic components is the sequential relation. Graphic components can be presented in a succession which is chosen by the producer. This succession reflects the sequence of topic elements. Topic elements in expository texts are rarely all sequential. Some topic elements are concurrent, overlapping, circular or simply do not have a relation to each other at all. The two-dimensional format of the insert limits the number of ways the sequential relations can be presented. Therefore, the sequence of the graphic components does not necessarily represent the sequential relationship between topic elements. Sequence was mentioned in the frameworks of Twyman (1979), Rivlin (1987), and Southall (1989). Some experiments have investigated the interpretation of a sequence of graphic components by users. These experiments are discussed in section 4·4.

4·3·4 The overall graphic presentation.

The third level of analysis looks at the graphic presentation of all the graphic components in a document. The overall graphic presentation has been mentioned in section 3·1·2. This is the largest level of analysis. For example, the format of the document, the use of graphic components as decoration, and the paper quality would fall into this third level. Waller (1987) posed four questions that could analyse graphic presentation of complete documents. These four questions are:

- what is the typical context of use?
- what is the typical treatment of verbal language?
- what is the typical format and configuration?
- what is the typical treatment of visual elements?

The answers to these four questions for different inserts would provide similar answers, and inserts can therefore be seen as a genre. The responses of patients to features of the overall graphic presentation of inserts has been discussed in section 3·1·2.

The complete framework, as described in sections 4·3·2, 4·3·3, and 4·3·4 is illustrated in **figure 4·4**.

4·3·5 Why is this modified framework useful?

The relation between graphic components (as presented by the producer in a document) and user units (as these graphic components are seen by patients) is the central point of this thesis. The influence of the graphic presentation on the use is directly related to the relation between graphic components and user units.

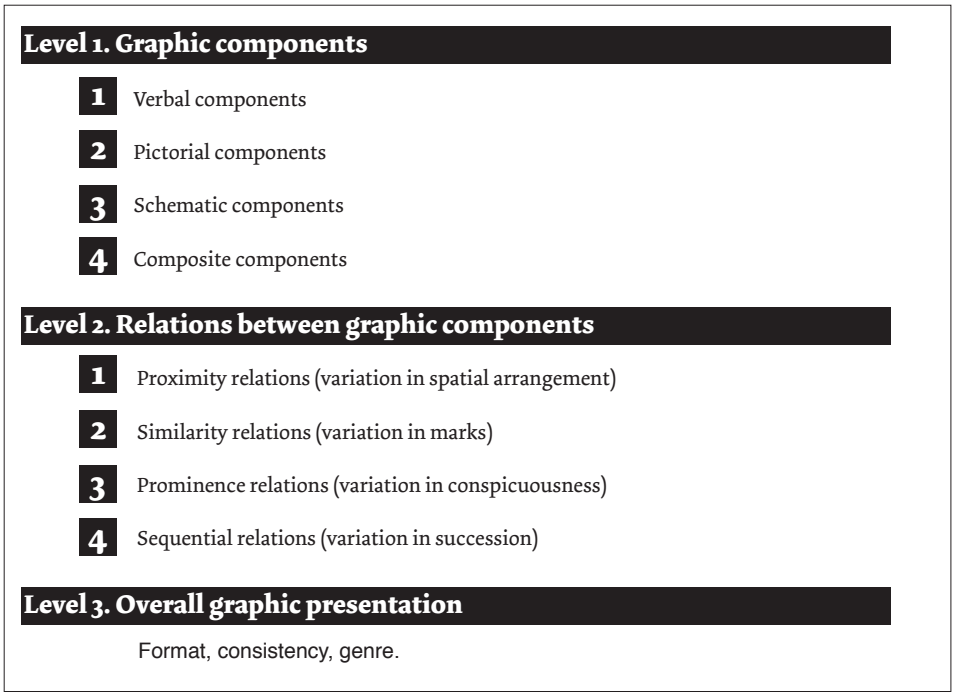


Figure 4·4. Modified framework for the analysis of graphic presentation.

The division of an analysis of the graphic presentation into three levels makes an investigation into the suitability of the graphic presentation feasible. The suitability of each individual component can be investigated, and the suitability of different types of components (verbal, pictorial, schematic or composite) can be compared. The second level of the framework describes the relations between graphic components. Although these relations frequently interact, they can give an indication as to whether the user can relate the topic elements according to the graphic relations. This combination is essential for an understanding of the topic by the user. The third level describes the overall graphic presentation. The suitability of the overall graphic presentation can be investigated.

This framework also makes it possible to describe the row headings of the matrix which are suggested in section 3·3·1. The column headings are discussed in section 3·2. The complete matrix is represented in **figure 4·5**. Only the column headings as they were discussed in section 3·2·3, and represented in figure 3·10, are illustrated in figure 4·5. These column headings seem more appropriate for this investigation, and will be used in the review of some experiments in section 4·4. However, it is realized that both matrices could be applicable to an investigation into the use of graphic presentation. The dotted lines between the columns of the matrix indicate that the visual perceptual, information processing, and the affective field cannot be strictly separated, and could overlap.

4·3·6 Concluding.

In this section, the connection between graphic presentation and use was made. It was found that, at least in theory, it is important to look at the relationship between graphic components and user units. A framework makes the analysis of the graphic presentation of an insert feasible. The framework for analysis of features of graphic presentation, and aspects of use as they were discussed in section 3·2, can be combined in a matrix. The matrix illustrates the connections between features of the graphic presentation and aspects of the use of documents. This fulfils the theoretical aim of this thesis. The next section will look at different experiments that have tried to investigate the use of the graphic presentation. Section 4·4 will therefore look at some experiments that have investigated specific cells in the matrix.

	Document use.		
	Visual perception comparative, sequential	**Information processing** knowledge, memory	**Affective** preferences
Graphic presentation			
Level 1			
1 Verbal components			
2 Pictorial components			
3 Schematic components			
4 Composite components			
Level 2.			
1 Proximity relations			
2 Similarity relations			
3 Prominence relations			
4 Sequential relations			
Level 3. Format, consistency, genre			

Figure 4·5. A matrix combining a framework for the analysis of graphic presentation and some aspects of document use.

4·4 Evaluation of the graphic presentation.

In the previous two sections, several ways of analysing and describing a graphic presentation were discussed. In this section, some evaluation techniques that attempt to investigate the suitability of the graphic presentation are discussed. Two main questions need to be answered.

- Which evaluation techniques have been applied to investigate the suitability of graphic presentation, and what are the conditions and assumptions?
- Could these techniques be applied to investigate the suitability of the graphic presentation of inserts?

This section looks therefore at techniques that have been used to attempt to investigate specific cells in the matrix of figure 4·5.

Section 4·4·1 describes the purpose of a suitability evaluation. Section 4·4·2 discusses some experiments that indicate that graphic presentation does influence the use of documents. These experiments have used a wide variety of different types of documents and methods. Their methods could be used for an investigation into the influence of graphic presentation on insert use. Section 4·4·3 looks at four points (techniques, materials, subjects and measures), and discusses how these could be specified for a suitability evaluation. Section 4·4·4 summarizes the main points of this section.

Several overviews about evaluation techniques have been published (Schumacher & Waller, 1985; Wright, 1985; Schriver, 1989). These overviews emphasize that the evaluation of a document should be seen as an integral part of the development process. The overviews focus on methods of evaluating the usability of documents and distinguish between evaluation techniques that involve users, and techniques that do not. One of the aims of a usability evaluation is to find out how well a user can work with a document. A suitability evaluation is smaller in scale and is specifically aimed at investigating the influence of graphic presentation on document use. A suitability evaluation can therefore be seen as part of a usability evaluation.

4·4·1 Purpose of evaluating graphic presentation.

The purpose of a suitability evaluation is to investigate the relation between graphic presentation and document use. Two main types of results can be distinguished when a suitability evaluation is conducted. The first type of evaluation investigates the appropriateness of features of the graphic presentation for specific aspects of the use of a specific document. The results of this type of suitability evaluation can be used to improve the graphic presentation of that document. The results of this type of evaluation are only applicable to a specific document. The second type of evaluation attempts to find results that could be generalized. The results of this type of evaluation can then be applied to other documents. Schumacher and Waller (1985) mentioned both types, and state that the validity of results of the first type of evaluation is restricted to a specific document. However, they noticed that developers 'cannot help but generalize from it' (Schumacher & Waller, 1985; p 379).

The division between these types of results of a suitability evaluation is important for this investigation. The strict division seems difficult to maintain, when the suitability of graphic presentation of inserts is investigated. One of the questions that should therefore be asked for any suitability evaluation is the extent to which the results of an evaluation are applicable to the graphic presentation of other inserts.

4·4·2 A review of some experimental studies.

This selective review of empirical studies mentions only those experiments that have investigated the influence of graphic presentation on the use of printed documents. There are three main reasons to review these experiments. The first reason is to show that several studies have been undertaken, and that they have provided evidence that graphic presentation does have an influence on a document's use. The second reason for reviewing these experiments is to determine experimental techniques, experimental materials, and measures that could be applied to this investigation of inserts. The review looks therefore specifically at experiments that have been undertaken in some cells of the matrix of figure 4·5. The third reason for reviewing these experiments is to find cells in the matrix that would be useful for this investigation into the graphic presentation of inserts.

I have used the row headings of the matrix of figure 4·5 to structure the review. The description of experiments follows the sequence of the rows of the matrix, and indicates in some cases in which columns these experiments could be placed. The first part describes some studies investigating the suitability of graphic components, the second part looks at studies

that have investigated relations between components, and the third part looks at studies that have investigated the overall graphic presentation.

Evaluation of the suitability of graphic components. This part describes experiments that have investigated features of graphic presentation on the first level of the framework, i.e. verbal components, the pictorial components, the schematic components, and the composite components.

Several experiments have been carried out to determine whether the graphic presentation of verbal components influences the responses of subjects. These investigations into the influence of variations of verbal components are traditionally classified as legibility research. Extensive bibliographies have been compiled on the influence of the graphic presentation on reading (Tinker, 1965; Zachrisson, 1965; Spencer, 1969). Tinker, and his colleague Patterson published a large number of legibility studies between 1929 and 1965. The specifications of the graphic presentation of verbal components were varied in these experiments. Some of these experiments indicated that the graphic presentation of verbal components does have an influence on the reading speed of subjects. These experiments could be therefore be placed in the visual perception column of the matrix.

The research of Tinker has been criticised for at least two reasons. The first is its lack of practical application. The experiments did not add any surprising results, and merely confirmed existing practices. The second criticism suggests that evaluations which modify and monitor the influence of a single variable are inappropriate for the study of graphic presentation because graphic variables interact.

Several other experiments have been conducted to evaluate the influence of the graphic presentation on the use of verbal components. Seven studies are mentioned below. One of the very few studies that has investigated the influence of the graphic presentation of verbal components on patients was undertaken by Ley (1988). This study was mentioned in section 3·1·3. In this study, patients' ratings of the difficulty of a text were influenced by the graphic presentation. A second study investigating the opinions of subjects about verbal graphic components was conducted by Rowe (1982). He asked students (n=24) to mark characteristics of a typeface on six semantically different scales, such as . It was found that different typefaces provoked different semantic responses. These two experiments could be placed in the affective column of the matrix. However, it is clear that aspects of visual perception and information processing are involved in both experiments.

Bartz (1970) found that map searching tasks are executed significantly faster by students (n=300) when the search word is presented in a similar typeface as the typeface in which it appears on the map. Seymour and Jack (1978) found that the differentiation between uppercase and lower case characters for familiar abbreviations was essential for the recognition of these abbreviations by sixth-form students (n=16). Jacoby and Hayman (1987) undertook an investigation to discover whether the prior presentation of a word is helpful to its later perceptual identification. The responses (n=24) confirmed that memory for visual details plays a role in identification of words. Rivlin investigated the presentation of verbal components using a tachistoscope for a word detection task (Rivlin, 1987). Five different graphic variables were used to differentiate a word in a string of 12 letters. Twenty four students reacted to a short exposure of the string of twelve letters by indicating if the target word was separated. Each target word that was separated by different graphic variables (colour, alignment, weight, size, and typeface) was accurately recognised by students. Although the differentiation of a word by a different typeface was the least successful, it was still recognized faster than the control group in which a word was not differentiated. A study by Lewis and Walker (1989) investigated relations between different typefaces and reaction times. Qualities, such as heavy/light and fast/slow, of different typefaces and of different animals were rated by subjects. The name of an animal was presented in a typeface that was congruent or conflicting with its rated qualities. It was found that responses (n=18) to conflicting attributes of typefaces and names of animals were significantly slower than the responses to congruent combinations. This indicates that the graphic presentation of verbal components has a direct effect on the reaction times. These five studies could be placed in the visual perception column of the matrix.

These seven studies illustrate that the influence of the graphic presentation of verbal components has been investigated. Understanding, searching, identification, recognition, and differentiation were used as aspects of the use. These aspects were placed in the different columns of the document-use matrix. This

positioning is open to debate, because the visual processing, information processing, and affective field interact.

The main measures for the investigations mentioned above were the speed and accuracy of the execution of a task. In addition, three studies, by Rowe (1982), Lewis and Walker (1989), and Ley (1988), used a rating technique to investigate responses of subjects. These investigation techniques, and the measures could be applied to the investigation of inserts.

The second group of components encompasses the pictorial components. Several experiments have been undertaken to evaluate the comprehension of this type of components. An extensive overview of the experiments in this group is given by Goldsmith (1984). Some researchers have investigated the use of different pictorial components in inserts. These studies have been mentioned in section 3·1·5. Several other experiments have investigated the influence of pictorial components on aspects of the use. For example Peeck and Zwarts (1983) investigated the recognition and memory performance for pictures of birds of 50 students (16 with a high knowledge of birds, 16 with a low knowledge and 18 with no knowledge of birds). The students were shown slides of European birds and American birds for 3 seconds and were asked to compare the illustrations afterwards. The high knowledge students and low knowledge students recognized the illustrations more accurately. The high and low knowledge students also described the illustrations in a significantly different way. This experiment used the accuracy of recognition, and a written description of pictorial components as a measure of the suitability of pictorial components. A similar experiment was undertaken by Lowe (1993). He evaluated the difference between the mental representation of weather maps between experts (meteorologists) and novices. He found that experts and novices pay attention to different areas of the map. These results are interesting for the suitability of pictorial components in inserts because they indicate that different types of users may use pictorial components in a different way. Both these experiments can be placed in the information processing column of the matrix.

A suitability evaluation of schematic components is difficult, because schematic components are nearly always used in combination with other types of graphic components. One of the reasons is that individual schematic components cannot represent a topic element. However, some suitability evaluations have been undertaken on schematic components. Adams (1989) investigated size ratios of three schematic components: circles, squares and bars. This empirical investigation (n=22) was based on diagrams by Bertin (1983). Bertin stated that the ratio between the area of symbols must be at least 1.122 in order to be perceptible. Adams found that, in order to distinguish between symbols, this size ratio is too small. This is an interesting example of an investigation into the smallest noticeable difference of schematic components. Many other studies have investigated the smallest noticeable difference of schematic components in a psychological context, but the application of their results into the graphic presentation is uncommon. This experiment could be placed in the visual perception column of the matrix of figure 4·5.

Various experiments have been undertaken to investigate the suitability of the graphic presentation of composite components. Several experiments have used maps and matrix like structures as test material. Although these composite components are rarely used in the graphic presentation of inserts, the experimental methods investigating the usability of these components might be applicable for a suitability evaluation. For example Barker, Hailstone and Simmonds (1986) evaluated the influence of the graphic presentation on map searching tasks (n=8). They concluded that variations in the graphic presentation, especially the figure-ground contrast, significantly influenced the location time. Wright, Lickorish and Hull (1990) evaluated the usability of a hand-held map in a hospital. They found that several changes in the graphic presentation needed to be made. These improvements were based on the comments of six subjects and could be classified into two groups: assumptions of users, and interpretation of graphic presentation. A modified map took notice of these comments, was re-tested (n=12), and proved to be more successful. The success was evaluated according to the number of difficulties in using the map, the number of confusions and the number of errors. It seems that the speed and accuracy of use of a composite component are indications of the suitability of the graphic presentation.

A few points can be made to summarize this overview of experiments investigating the suitability of different types of graphic components. In the experiments described, subjects were asked to 'look at' a

graphic component. This 'looking at' was defined in section 3·2·1 as use of a document. These experiments have shown that the graphic presentation of components does influence the use of these components. Investigations have been undertaken in each column of the document use-matrix on the first level of the graphic presentation. Methods, materials and subjects vary, but it seems to be possible to group six experimental tasks.

- recognition (seen it before?)
- location (where is it?)
- identification (what is it?)
- differentiation (is it different?)
- recall (what was it?)
- preference (do you like it?)

With the exception of preference, the speed and the accuracy of the use of graphic components in the first five groups may provide a measure of the suitability of the graphic presentation of components. For preferences, the agreement between the subjects about a specific feature of the graphic presentation can be seen as an indication of the suitability.

Evaluation of the suitability of relations between components.

Four relations between graphic components (proximity, similarity, prominence and sequence) were distinguished in section 4·3. The discussion below categorizes some experiments according to those four relations. The majority of experiments have tested materials that show a combination of these four relations. The arrangement of the investigations in these four groups of relations between graphic components is therefore open for discussion.

The first type of relation between graphic components is the grouping of graphic components by proximity. The proximity relation describes the distance between graphic components. The spacing between phrases has been frequently investigated (for example North & Jenkins, 1951; Frase & Schwartz, 1979; Keenan, 1984). These studies found that extra space between chunks facilitated reading when it was measured by reading speed, a search task or a comprehension test. These findings were not confirmed in several other experiments (Klare et al, 1957; Carver, 1970; Hartley, 1980). The inconclusiveness of these findings were discussed by Keenan (1984) who suggested that other interactions between graphic components could be the cause. Hartley, Davies and Burnhill (1978) showed that the retrieval of information from a document might be aided by the use of a line space between paragraphs. The adding of space between paragraphs does provoke a response in students, as was shown by Hartley (1980). He asked 65 sixth-formers to compare paragraphs and rate how easy they thought the paragraphs were to read. The results showed that a document with additional space between paragraphs was judged more readable. A similar result was found by Shebilske and Rotondo (1981) who separated, among other things, ideas in a text by an additional line space. A clear majority of the students who used the special format thought that it helped both during reading and during recall. However, the results of paraphrastic recall and a multiple choice test did not show significantly improved recall scores. In an experiment on 30 school children, Hartley (1992) provided 15 children with a 'chunked format' text, in which information that belonged together was grouped closely together, and 15 with the same text in continuous prose. Hartley showed that the 'chunked text' improved the recall, improved delayed recall, and affected the format of the recall.

Very few studies have investigated the proximity relation between types of graphic components. Investigation into the proximity relation between verbal components and pictorial components, or between verbal components and schematic components has rarely been undertaken.

The second type of relation between components is the grouping of graphic components by their similarity. Several investigations have tried to identify whether a difference in the graphic presentation produces an increase in knowledge of subjects. For example, Herschberger and Terry (1965) varied the graphic presentation of several categories of the content in a history lesson. The differences in importance of the content category were indicated by two categories of cues (red and black text, all lower case), or by five categories of cues (full caps red, lower case red with red underlining, lower case red, lower case black with red underlining, and lower case black). A control group received a text without these differentiations. The main result was that the subjects who received the text with two types of cues learned more important (cued) material.

The following two experiments could be classified in the prominence relation as well. They investigate a rank order of the difference between typefaces. However, the amount of difference is not further applied, and these studies are therefore placed in the

similarity group. An investigation by the Readability of Print Research Unit of the Royal College of Art aimed to compare the effectiveness of variations in type weight and type style for distinguishing topic elements (Spencer, Reynolds & Coe, 1973). These differences in the graphic presentation did not represent a topic (non-context situation), because the knowledge of subjects about the topic might have influenced the outcome of the rating. A rank order of different weights, typefaces and styles was established. The results of this experiment were confirmed in an experiment by Garofalo (1988). Garofalo used this rank order to indicate different hierarchical levels of an American History textbook. The influence of this differentiation on recall was tested on 80 students. The results suggested that the differences in the graphic presentation, as a representation of the differences in the topic, affects learning. These results were not very convincing (Hartley, 1989), but the results confirm that a differentiation of a topic by different typefaces influences the responses of subjects.

The third type of relation is the prominence-difference between graphic components. These are studies investigating whether subjects notice the amount of difference between graphic components. Warning labels is one type of document in which experiments have been undertaken. A study on 94 students investigated the prominence of warning notices on labels for chemical bottles. The level of subject compliance with the warning label and an assessment as to whether or not the label was read were reported. Perception of danger was measured with a questionnaire. It was found that some combinations of colours, shapes and wording are more prominent than others, and that these results could be ranked (Rodriguez, 1991). Although this comparison of the prominence of graphic components in this study was not within a single document, the results show that prominence differences are noticed by subjects, and that they are interpreted as indicating the amount of difference in the topic. More prominent was in this experiment interpreted as more dangerous.

The fourth relation between graphic components is the sequence of these components. Several investigations have been undertaken to investigate the influence of this sequence on the use of documents. Schumacher and Waller (1985) used two different ways of registering macro-eye movements to find out which of these two methods would be the most appropriate to ascertain how subjects (n=32) proceed through a seven page document. The results of the use of a video recorder registering eye movements and a light pen recorder recording the movements of a subject in a document were compared. The time spend on a graphic component (which are called sub-blocks) and the accuracy of responses was investigated in a retention test. The results of the investigation were not mentioned in the original publication, but it was stated that both techniques provided reliable sets of data. Burnhill, Hartley and Young (1976) investigated the effects of the placing of tables and illustrations in a single or double column page layout. The test was conducted on 340 secondary school pupils who were asked to scan a page, locate a phrase and write down a missing word from that phrase. It was found that single column format was scanned significantly faster. The main reason was that the reader was confused where to resume reading in the two column layout, because the sequence was not clear.

Two points can be mentioned as a conclusion to this sketchy review of experiments into the suitability of relations between graphic components. In the first place, there are very few experiments conducted in each specific group of relations between graphic components. The four different relations between graphic components are rarely separated in experiments. Although these four different relations are frequently mentioned in the descriptive frameworks, described in section 4·2, it seems rather more difficult to clearly separate these in an experimental situation. Secondly, the influence of these four relations on a specific aspect of the use has clearly been shown. However, the categorization of these specific aspects in one of the fields of document use — visual perception, information processing, or the affective field — is rather more difficult.

Evaluation of the suitability of the overall graphic presentation.

The third level of framework describes the overall graphic presentation. Several experiments have been undertaken to investigate responses of users of documents in relation to the overall graphic presentation. There are a few studies which have investigated the opinions of patients on the overall graphic presentation of inserts (Documed, 1988; Rupf, 1991). These studies were mentioned in section 3·1·2. Zachrisson (1965) investigated if there is a relation between graphic presentation and its topic or message. The graphic presentation of two types of invitations,

two different advertisements and two different title pages were used as test materials. All six documents varied the typeface (sans-serif and a serif) and the configuration (symmetrical or asymmetrical). The hypothesis was that experts and non-experts would rank the congeniality (suitability) of these four variations of 6 types of documents different from non-experts. This proved not to be the case. It was concluded that some formats are more suitable for some types of documents. Zachrisson suggested that this might be caused by learning or habit.

Several investigations have asked subjects to state their preferences for a complete document. For example Wright, Lickorish and Hull (1990) carried out a survey (n=60) and found that the preference for hand-held maps or mounted maps depended on whether the map was to be used for an exhibition, a hospital, or a shopping precinct. The use of a section of physics textbooks was investigated by Wendt (1982). He found that responses of students (n=346) lead to the conclusion that the wording of a document improves the recall scores, and that the graphic presentation increases the reading speed and affects preferences. This last group of experiments seems to suggest that preferences, time to locate information, and accuracy of using a document can be used as measures to investigate the suitability of the overall graphic presentation.

It can be stated, as a main conclusion of this section, that several investigations have provided evidence that the graphic presentation does influence responses of document users. This was one of the three reasons to undertake this review. This overview also indicated that there are several evaluation techniques that can detect these influences. The placing of the experiments in the matrix, however, proved problematic, since most experiments could be placed in several cells. This can be seen as an indication that the division of the rows and columns is too detailed for an overview of experiments. The following section looks specifically at the evaluation techniques, materials, subjects, and measures.

4·4·3 Evaluation methods.

The previous section provided an overview of some experiments which covered most cells of the document-use matrix. This section describes some experimental methods that could be applied to the suitability investigation of the graphic presentation of inserts. The appropriateness of the techniques, experimental materials, subjects, and measures for a suitability analysis of inserts need to be discussed. However, these points are interrelated and cannot be seen as independent. They are discussed individually in order to make the assumptions and conditions for a suitability evaluation of inserts clear. Three exploratory experiments, which apply the methods that are described in this section, are described in chapter 5.

The techniques.

This section describes several experimental techniques that could be used to investigate the suitability of the graphic presentation of information in inserts. At least three techniques can be used to investigate the suitability of graphic presentation. There are two main ways to collect results when these three techniques are applied. Results can be obtained during the interaction of the subject with the documents, or results can be obtained after the use.

The first technique compares different sets of test materials. The graphic presentation of a topic in each set is made different. Each set of materials is given to a different subject group, and the groups are given an identical task. The responses of the groups are compared. An example of this evaluation technique is described by Duffy, Curran and Sass (1983).

A second technique also compares the graphic presentation of several documents, but asks subjects to do the comparing. This technique has been applied by Scerbo and Fisk (1990).

The third technique evaluates a single document. Two types can be distinguished. The first is the 'before and after' approach. In this type of experiment, subjects respond to a task before they have received a document. A document is supplied, and the same task is undertaken. The difference in responses is monitored. The second type is the approach by which half of the subject group receives a document, and the other half does not. The differences between the responses of both subject groups can be monitored. Both these techniques have been mentioned in the research into the information requirements of patients, as it is described in section 2·2.

Section 2·2·6 concluded, after reviewing several studies investigating the effects of the supply of printed information to patients, that interviewing patients would be a reliable experimental technique. However, it should be realized that it is difficult to obtain responses about the graphic presentation from users. Rivlin's informal tests for his second experiment showed that subjects have problems talking about graphic features

(Rivlin, 1987; p 119). This issue has frequently been mentioned and has received some attention in relation to experimental techniques (Paivio, 1975; Lowe, 1993). Despite this objection, subjects can be asked to comment on the graphic presentation.

These three types of evaluation could all be applied to an investigation into the suitability of the graphic presentation. All combinations of these three techniques are possible. In the experiments, which are described in chapter 5, a combination of these techniques is applied.

The experimental materials.

Schumacher and Waller (1985) mention that there are two kinds of documents that can be selected for evaluation: either particularly important ones for which there are substantial safety or financial implications, or documents that are seen as typical of their kind. Patient package inserts fall into both categories. Three points need to be mentioned. The first point is related to the experimental materials that have been used in most studies. These materials have tended to be educational materials or continuous text. Non-educational materials, and non-continuous text have received much less attention. Although inserts contain some information that could be classified as educational material, the majority of topics included in an insert have to do with procedural instructions, warnings and advice. The experimental techniques that have been applied to investigate educational materials, or continuous text might not be applicable to the suitability evaluation of the graphic presentation of inserts. A careful reconsideration of the appropriateness of the technique in relation to the experimental materials seems essential.

A second point in relation to the testing material is that the graphic presentation of the test material must be concordant with the topic. This point was made in section 4·2·3. Patients must use what they see as a basis for understanding a topic. When the graphic presentation does not represent a topic, as it is for example the case in the insert presented in figure 1·0, than the topic is more difficult to grasp for patients. It is therefore preferable to use inserts with a concordant graphic presentation for experiments.

A third point is that it seems essential to use the actual printed inserts in the experiments. Several experiments have shown printed documents on slide or on computer screens (for example Rivlin, 1987; Lowe, 1993). Although the results of these experiments were reliable, the ecological validity remains debatable.

Two standard difficulties of describing experimental research into graphic presentation will be solved. In the first place, there is the problem of describing variations of the graphic presentation. This problem has for example been mentioned by Wright (1980). The descriptive framework of figure 4·4 will be used to describe the test materials of the experiments. The second standard problem is that test materials are rarely reproduced in publications. This problem has been mentioned by MacDonald-Ross and Waller (1975), and all inserts that are used in experiments reported in this thesis are therefore reproduced.

It seems clear that a suitability evaluation of inserts must use an existing insert in which the graphic presentation represents the information sections as they are mentioned in section 2·3. In the second place, the variation of the graphic presentation needs to be described, and the inserts need to be reproduced.

The subjects.

The majority of the investigations into the suitability of graphic presentation have used students or children as subjects. This is appropriate if educational materials are tested, but for the study of the suitability of inserts, it seems more appropriate to use patients as subjects.

At least two options are open for the recruitment of patients to participate in experiments. The first option is to approach patients in cooperation with a pharmacist or prescriber. The pharmaceutical and medical investigations, as mentioned in the earlier sections of this thesis, frequently apply this option. Examples of the application of this option are the studies by Gibbs (1990), Rupf (1991), and Haecht (1992). A group of patients using a specific type of medicines can be approached in this way. This option provides an accurate match between the subject and the test material. The second option to approach subjects who can be seen as representative for patients.

The measures.

The description of the choice of an appropriate measure for a suitability analysis is the last of the four points that needs to be discussed. Many different measures could be taken to give an indication of the way in which a document could be used. These measures can be divided into two groups: those that can be obtained without the involvement of subjects, and those that are obtained with the assistance of subjects. Readability formulas, computer-based stylistic analysis programs,

and checklists can be used as measures of documents, that can be acquired without the involvement of subjects. These measures are not appropriate for this study, because they do not give an indication of the re-lation between graphic presentation and use of inserts.

The other type of measures can apply for example Cloze tests, eye movement protocols, user edits, or several types of performance tests such as memorability, recall or paraphrase tests. Although these measures indicate that using a document involves more than comprehension alone, it seems clear that the influence of graphic presentation on any of these measures is difficult to establish. Several studies have specifically investigated the influence of graphic presentation on a change in knowledge. The results of these studies are frequently inconclusive. A review by Bartram (1982) of Foster's bibliography on legibility research suggested that graphic presentation does not seem to have a measurable effect on any sensible index of comprehension. An investigation into the second column of the matrix of figure 4·5 is therefore not appropriate for this investigation. It seems therefore more beneficial to concentrate on initial visual processing and preferences.

The results of at least five tasks can be used as indicators of the suitability of the graphic presentation of a document. Whether the results of these tasks are valid measures of suitability remains to be seen. These five tasks, which were mentioned in section 4·4·2, are:

- recognition
- location
- identification
- differentiation
- preferences

The accuracy and time taken to complete the first four tasks can be recorded as an indication of the suitability of graphic presentation.

Several types of data seem especially relevant as a suitability measure. The responses of individual subjects should be recorded. This gives an indication as to whether a specific aspect of the use is influenced by a specific feature of the graphic presentation. A high response, that is when a large proportion of subjects reacts to a feature of graphic presentation, is an indication of the extent of the influence. The average response quantifies this extent. A second measure is the variation in the responses, or the level of agreement between subjects. This agreement provides a measure of those aspects of the use that are influenced in a similar way. A high agreement in the responses is an indication of a highly suitable graphic presentation. This agreement is important when the effectiveness of a feature of the graphic presentation is discussed.

4·4·4 Summary chapter 4.

Chapter 4 set out to investigate frameworks that could describe graphic presentation, and evaluation techniques that could investigate graphic presentation. In section 4·2, several ways to analyse graphic presentation are described. This description is used as a basis for a modified framework. This modified framework is introduced in section 4·3, and consists of three levels. The first level describes four types of graphic components: verbal, pictorial, schematic and composite. The second level describes four relations between graphic components: proximity, similarity, prominence, and sequence. The third level of the framework describes the overall graphic presentation. This framework is used in section 4·3 to review several experiments reported in the literature. Two conclusions are drawn. In the first place, the results of experiments clearly show that some features of graphic presentation influence document use. However, the results are scattered over a large range of different types of documents. Whether these results are applicable to patient package inserts remains to be seen. Secondly, the matrix is useful to describe some of the issues relating to experiments.

The experiments have mainly focussed on the influence of individual graphic components on specific aspects of the use, or the influence of the overall graphic presentation on aspects of the use of a complete document. The specific relations between components, level 2 of figure 4·4, has received less attention. Most experiments have employed verbal components in continuous texts or educational material, and used students or children as subjects.

In reviewing some of the available evaluation methods, it became apparent that there are several methods that could be applied to investigating the suitability of graphic presentation in inserts. Interviewing patients seems an appropriate technique to obtain responses. Inserts with a concordant graphic presentation should be used as test material. The agreement between patients about a specific feature of graphic presentation could be used as a measure of the suitability.

5 Experiments investigating suitability.

This chapter describes three exploratory experiments into the suitability of the graphic presentation of inserts. These experiments have been conducted in order to look for some experimental evidence for the assertions in the previous four chapters. A second reason to conduct these experiments is to find out to what extent the descriptive framework of figure 4.3 can be useful in analysing and describing the graphic presentation of inserts.

The word *experiment* has been used for the activities in this chapter, although it is realized that these explorations can, strictly spoken, not be classified as experiments. However, the word experiment was preferred above *tests* (which in this thesis refers to pilot tests) and *trials* (which has a specific meaning in pharmacological research).

The first two experiments used an adaptation of an existing insert for an eye preparation as test material. The first experiment asked patients to separate and rank units according to their prominence and according to their importance. The test insert was modified according to the results of experiment 1, and experiment 2 repeated the procedure of experiment 1. The third experiment used an insert that was developed as a sample to illustrate the application of a proposal for European regulations. This experiment investigated the preferences of patients for 4 alternative graphic presentations. Section 5·1, 5·2, and 5·3 in this chapter describe one experiment each. Section 5·4 discusses some of the issues raised by the experiments.

Approval from the University Ethics and Research Committee (dated 12-8-1992) and from the West Berkshire Health Authority Ethics and Research Committee (applied 23-6-1992; ratified 3-8-1992) was obtained in order to execute the following experiments.

5·1 Experiment 1.

The first experiment is an exploration into a technique for a suitability evaluation of the graphic presentation of information in inserts.

5·1·1 Objectives and method.

The first experiment had three main objectives:
- to find out whether patients can identify graphic components, and if there is a difference between user units and graphic components
- to find out whether patients can rank user units in terms of importance and in terms of prominence
- to determine if there is a relation between importance and prominence of graphic components

Rationale.

In order to use an insert, it is essential for a patient to look at the graphic presentation. As a first step to finding out if the graphic presentation has any influence on the use of inserts, it is worthwhile to investigate whether patients identify graphic components, and if and how patients group graphic components. This objective initiates an investigation into the differences between user units and graphic components in a specific insert. A patient may group several graphic components together, a patient may focus on a specific graphic component, or a patient may look at a detail of a graphic component. The grouping and separating of graphic components might give an indication of the relation between user units and graphic components.

The second objective attempts to focus on the suitability of the graphic presentation. Differences in the graphic presentation must be interpreted by users in order to understand a topic. This has been argued by Norrish (1987b), Rivlin (1987), and Southall (1989) and is discussed in section 4·3. Two labels, importance and prominence were chosen. Importance was defined as 'having the largest effect on the use of a medicine'. It was hoped that importance differences between user units could be distinguished by patients, and that 'importance' would be related to the content. Prominence was defined for patients as 'attracting attention'. It was hoped that prominence differences could be identified by patients to distinguish between user units, and that 'prominence' would be related to the graphic presentation.

The second objective is incorporated in this experiment to find out whether there is an agreement between patients about the importance, and about the prominence of user units. It was hoped that patients would be able to rank user units systematically into a sequence. Two different rank orders, from the most important to the least important, and from the most prominent to the least prominent therefore had to be obtained. A low agreement in either rank order, that is when patient's ranks vary widely, can be seen as an indication that the graphic presentation can be interpreted in different ways, or that subjects respond randomly. In that case, there is a large variance in the ways that patients extract information from an insert and the graphic presentation is not the most efficient in fulfilling requirements of these patients. A high agreement between the responses of patients within the importance group, and between the responses of patients within the prominence group, might indicate that the graphic presentation is more effective. However, a high agreement n either group is not an indication that the information is appropriate for each patient. In other words, a low agreement in the ranking of user units indicates a low suitability of the graphic presentation. A high agreement indicates that the graphic presentation is more suitable, but it is not an indication as to whether the information is useful for patients. This measure of 'useful for patients' was discussed in section 2·4.

The third objective was included to find out if there is a relation between importance of a graphic component and prominence of a graphic component in a specific insert. In section 4·3, it was suggested that prominence differences between graphic components are one of the four types of relation between graphic components. In order to investigate the suitability of graphic presentation, it is worthwhile investigating prominence differences in relation to document use. This third objective aims to relate the patient's perception of the prominence of a graphic component, with the patient's awareness of the importance of the information in a graphic component.

It is necessary to emphasize this point because it might cause confusion. The experiment sets out especially to ask opinions of patients on how important a user unit is and how prominent a user unit is. These opinions might not be similar to the opinions of the developer of the insert. The third objective was set to investigate whether patients interpret these prominence differences in the graphic presentation. The relation between the prominence of a graphic

component and the importance of a graphic component is a fundamental relation for the concordance as well as for a suitability evaluation. This will be further discussed in section 5·4.

Tasks and data collection.
An experimental technique had to be found that could record the following responses of subjects:
• the identification of graphic components
• ranking of graphic components
These results had to be ascertained in both an importance and in a prominence subject group.

Several pilot tests were undertaken to find an appropriate technique for recording whether subjects identified graphic components. During several pilot tests, subjects were asked to encircle areas of inserts. Questions like 'please encircle as many units as possible', 'please encircle the most prominent section', and 'choose the most prominent part of the insert and encircle it' were tried. The results of these pilot tests were too diverse to analyse. However, these results showed that the borders of the 'units' were determined by graphic components. Other pilot tests asked subjects to cut 'units' of an insert with a pair of scissors. The results of these tests proved to be analysable. Subjects cut carefully round graphic components. It became clear during these pilot tests that subjects responded more to the word 'unit' than to 'bit', 'area', or 'section'. 'Parts of a unit' was accepted without any problem. The ranking of units seemed to provide reliable results in both the encircling tests as well as in the cutting tests.

Two reasons seem to be causing the difference between encircling and cutting. In the first place, cutting forces subjects to decide which graphic components to group in a unit, and therefore how to separate different units. Adding marks to the insert by encircling seems to make this task more difficult. Secondly, separated units are physically removed from the remaining insert. This makes it more difficult to compare the separated units directly with the units on the remaining insert. Units on the remaining insert can therefore more easily be compared with each other. The ranking of separated pieces of paper proved to be easier for subjects as well.

These pilot tests resulted in the formulation of three tasks: cutting, underlining, and ranking. **Figure 5·1a** and **5·1b** show the task cards for both the importance and the prominence subject group. These task cards were tested again, and the results seemed to provide appropriate responses. The underlining task

1 Please cut out the most important unit.
This is the unit that will have the largest effect on you when you want to take your medicine.
Give this unit number 1.

Please cut out the next most important unit.
Give this unit number 2.

Go on until all bits of paper consist of one unit, and they are all numbered.

2 Please look at each bit of paper separately.
There may be parts on each bit of paper that are more important.
Please underline these important parts in each unit.

Figure 5·1a. Task card for the importance group. 60 per cent reduced

1 Please cut out the most prominent unit.
This is the unit that attracts your attention first.
Give this unit number 1.

Please cut out the next most prominent unit.
Give this unit number 2.

Go on until all bits of paper consist of one unit, and they are all numbered.

2 Please look at each bit of paper separately.
There may be parts on each bit of paper that are more prominent
Please underline these prominent parts in each unit.

Figure 5·1b. Task card for the prominence group. 60 per cent reduced

was added, despite failing in the pilot tests, to investigate whether more detail in the separation task could be ascertained. The execution of these tasks by subjects resulted in several numbered pieces of paper which together formed a complete insert. Some of those pieces will contain pen marks.

5·1·2 Test conditions, subjects, test insert.

In order to follow the conclusions of section 4·4·4 and to make the evaluation ecologically valid, patients were approached to execute these tasks. This experiment was conducted in the waiting room of the hospital pharmacy of the Royal Berkshire Hospital in Reading. Out-patients were approached during three consecutive Thursday mornings (July 30th, August 6th, and August 13th 1992). This might have influenced the sample towards a clinical direction, such as eye-clinic

attendants or diabetic patients. However, it was found that the majority of the subjects came specially for the pharmacy.

A small table and several chairs were placed in the waiting room of the hospital pharmacy. As soon as patients had handed in their prescription forms, and had been told that the dispensing could take approximately ten minutes, they were approached and asked if they would like to participate in a small experiment. An information sheet/consent form was handed over, and the patient was asked to sign it. **Figure 5·2** shows such a form. This procedure was required by the University of Reading Ethics and Research Committee, and the West Berkshire Health Authority Local Research Ethics Committee. This consent form gave patients the option not to participate. The form has also identified some patients with visual disorders or patients who could not read English sufficiently. If there was a severe doubt about the ability of a patient to participate on these grounds, the results, if any, were discarded.

Forty two patients were asked, forty agreed to participate. Eleven patients who came into the pharmacy were not asked or interviewed for two reasons. Three left the pharmacy immediately after they handed in the prescription. Eight patients entered the pharmacy during an experiment. This last group of patients was not asked to participate, because the remaining waiting time would have been too short to execute a complete experiment. Patients who participated were handed a test insert and a task card (**figure 5·1a** or **5·1b**, and **figure 5·3**). The tasks were allocated to patients alternately. Several pens and pairs of scissors were available. Each subject took between five and ten minutes to complete the tasks.

Information for patients

I am trying to find out what patients think about patient package inserts. These inserts are sometimes included in medicine boxes.

Several small experiments will be carried out. I would be grateful if you would help me with one of these experiments.

Your medical treatment will not be affected and your name will not be used in any way. You can withdraw from the experiment at any stage.

If you would like to know more about the research, or would like to know the results, please contact me on the address below.

I need your signature to show that you have voluntarily agreed to help me.

This experiment asks you to cut a piece of paper and number the pieces.

Thank you for your co-operation.

Signature:

Karel van der Waarde
University of Reading
Department of Typography & Graphic communication
2 Earley Gate, Whiteknights
PO Box 239, Reading RG6 2AU
Tel: (0734) 875123 ext 7217
Fax: (0734) 351680

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July 1992

Figure 5·2. Consent form/ information sheet. 75 per cent reduced

Test insert.

The front of an existing insert for aqueous eye drops was selected as a test insert (aqueous = like water). The original name and contents of the product were altered to avoid copyright infringements. These eye drops are a prescription-only medicine for the treatment of some allergic forms of inflammation of the eyeball or inner eyelid. The test insert can be seen as an example of any eye drop preparation. This product can be prescribed for any patient, and is therefore appropriate to use as a test insert.

The test insert includes verbal components, a pictorial component and some schematic components such as the rule and the registered trademark (®) sign. The test insert is shown in figure 5·3, and the graphic components have been identified and numbered.

The division of the graphic presentation into graphic components was based on the description of a graphic component in section 4·2·1. Two points need to be made. The majority of the graphic components do not seem to be difficult to distinguish. Informal discussion revealed a large agreement between several observers. However, several graphic components can be added when the use of capitals is considered. The words 'Farnilon, Aqueous, Sodium, Cromoglycate, BP, INN,

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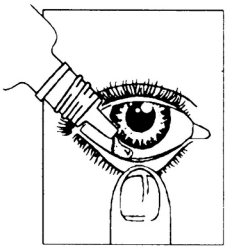
How to use Farnilon® Aqueous eye drops

It is vital to use Farnilon Aqueous eye drops **regularly, every day.** This is to prevent further symptoms from occurring when your eye condition is controlled.



To use, place one or two drops into each eye, four times a day or as directed by your doctor.

Sit down in front of a mirror, so that you can see what you are doing. Pull the lower eyelid gently, and then carefully place one or two drops in the gap between the eye and lower eyelid.

Now release the lower eyelid, and blink a few times to make sure the whole of the eye is covered by the liquid.

After you have used Farnilon Aqueous, store the bottle below 30°C and keep it away from direct sunlight.

Name of product Farnilon® Aqueous eye drops.

Presentation A clear colourless aqueous solution of Sodium Cromoglycate BP 2% w/v (INN Cromoglicic acid) with benzalkonium chloride 0.01% w/v.

Figure 5·3. Test insert 1 with graphic component numbers.

Cromoglicic' could be distinguished as separate graphic components on that basis. However, it was felt that the inconsistent use of capitals (benzalkonium and chloride are not capitalized) did not warrant listing any of these words as separate graphic components. A second point is the letter spacing in the line starting with the word 'presentation'. The characters in this line are clearly further apart than characters in other verbal components. For this reason, this line could have been listed as a separate graphic component. It was decided not to label this as a graphic component, because the additional letter spacing did not seem to represent a different topic element.

5·1·3 Results.

The following discussion of the results is divided into three sections. The first section describes the results related to graphic components and user units, the second section describes the ranking of user units, and the third section describes the relation between importance and prominence of user units.

Identifying and grouping of graphic components. The results of the separation and underlining tasks are presented in **figure 5·4** and **5·5**. The subjects in the importance group separated 144 user units (n=20; mean 7.2; SD=1.24), the subjects in the prominence group separated 115 user units (n=20; mean 5.75; SD=1.68). This difference in means is significant (t-test: t=3.10, d*f*=38, p<0.01). This is just an indication that there is a significant difference between the two groups, and that the words 'importance' and 'prominence' cause different responses. The prominence group separated more different units (P=31) than the importance group (I=22).

The experiment tried a technique to find out whether patients can identify graphic components, and how these graphic components are separated and grouped. **Figure 5·6** presents the number of times that a graphic component has been identified. This figure combines the results that have been represented in **figures 5·4** and **5·5**. There are two ways in which the responses are analysed to see whether a patient has identified a graphic component. The first is when a user unit contains exactly one graphic component. In this case, a patient has cut round a graphic component to separate it from other components. The second way is when a graphic component is completely underlined by a patient. The user units (the pieces of paper) were

Separated/grouped (graphic component number)	**i.**	**p.**
1+2	-	1
1+2+3	1	4
1+2+3+4	11	12
1+2+3+4+5	4	-
1+2+3+4+5+6+7	3	1
1+2+3+4+6+7	-	1
1+2+3+4+6+7+8	-	1
1+2+3+4+8+12+13+14+15+16	1	-
3+4+6+8+9+10+11+13+14+16	-	1
4+5	1	1
4+6+7	-	1
4+6+8+9+10+11+13+14+16	-	1
4+6+8+9+10+11+14+15+16	-	1
5	8	18
5+6+7	1	-
5+8	1	-
5+9+10	2	-
6+7	15	10
6+7+8	1	-
6+7+8+9+10+11+12+13+14+15+16	-	1
6+7+8+9+10+11+12+13+14	-	1
6+8+9+10+11+13+14+16	-	1
7	-	4
8	17	5
8+9+10	-	1
8+9+10+11	-	5
8+9+10+11+12+13+14+15+16	-	2
9	16	6
9+10	2	-
10	16	6
11	18	4
11+12+13+14	1	-
11+12+13+14+15+16	1	3
12	-	3
12+13	-	1
12+13+14	6	6
12+13+14+15+16	11	3
15	-	3
15+16	7	7

Figure 5·4. Number of subjects that separated and grouped units. **i** = importance, **p** = prominence.

(component number)	Part of graphic component that was underlined	i.	p.
1	(whole unit)	-	1
1	How to use	1	-
1	Optikron Aqueous	-	1
5	(whole unit)	1	1
5	Pupil of illustration encircled/underlined	-	6
6	when your eye condition is controlled	-	1
6+7	drops regularly, every day,	2	-
7	(whole unit)	9	9
8	place one or two drops into each eye	-	1
8	one or two drops into each eye	1	-
8	one or two drops into each eye, four	1	-
8	one or two drops	2	-
8	two drops	-	2
8	four times a day	2	1
8	directed by your doctor	1	-
8	as directed by your doctor	2	-
8	or as directed by your doctor	1	-
9	Sit down in front of a mirror	2	-
9	so that you can see what you are doing	1	-
9	what you are	-	1
9	Pull the lower eyelid gently	-	1
9	lower	-	1
9	gently	1	-
9	place one or two drops into the gap between the eye and the lower eyelid.	2	-
9	carefully, place one or two drops into the gap between the eye and the lower eyelid.	1	-
9	carefully, place one or two drops	-	1
9	one or two drops	1	-
9	two drops	-	1
10	now	-	1
10	and blink a few	1	-
10	blink a few	-	1
10	blink a few times	2	1
10	and blink a few times to make sure the	2	-
10	to make sure the whole of the eye is covered by the liquid.	1	-
10	blink a few times to make sure the whole of the eye is covered by the liquid.	-	1
10	whole of the eye is covered by the liquid. 2	-	
11	(whole unit)	1	1
11	store the bottle below 30° C	7	-
11	the bottle below 30 ° C	1	-
11	below 30 ° C	1	1
11	and keep it away from direct sunlight	4	1
11	keep it away	-	1
11	away from direct sunlight	1	-
12	(whole unit)	-	7
12+13+14	(whole unit)	1	-
13+14	Optikron®	-	2
14	(whole unit)	1	-
15	(whole unit)	-	6
15+16	(whole unit)	1	-
16	Sodium Cromoglycate BP 2 % w/v (INN Cromoglicic acid) with benzalkonium chloride 0.01 % w/v.	1	-
16	(INN Cromoglicic acid)	-	1

Figure 5·5. Underlining graphic components.
i = importance, **p** = prominence.

Component number	Separated			Underlined (whole component)			Noticed	Underlined (part of component)		
	i	p	total	i	p	total		i	p	total
1	-	-	-	-	1	1	1	1	1	2
2	-	-	-	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-	-
5	8	18	26	1	1	2	28	-	6	6
6	-	-	-	-	-	-	-	2	1	3
7	-	4	4	9	9	18	22	-	-	-
8	17	5	22	-	-	-	22	10	4	14
9	16	6	22	-	-	-	22	8	5	13
10	16	6	22	-	-	-	22	8	4	12
11	18	4	22	1	1	2	22	14	3	17
12	-	3	3	-	7	7	10	-	-	-
13	-	-	-	-	-	-	-	-	-	-
14	-	-	-	1	-	1	1	-	1	1
15	-	3	3	-	6	6	9	-	-	-
16	-	-	-	-	-	-	-	1	1	2
1+2+3+4	11	12	23	-	-	-	23	-	-	-
6+7	15	10	25	-	-	-	25	2	-	2
12+13+14	6	6	12	1	-	1	13	-	-	-
12+13+14+15+16	7	7	14	-	-	-	14	-	-	-
15+16	11	3	14	1	-	1	15	-	-	-

Figure 5·6. Noticing graphic components.

therefore categorized according to the graphic components they contained. The importance group identified 87 graphic components in total. The prominence group identified 73 graphic components.

Several user units, containing more than one graphic component, were separated. For example

a user unit including graphic components 1, 2, 3, and 4 (I=11, P=12); a user unit including components 6 and 7 (I=15, P=10); a user unit including component 12, 13, 14 (I=6, P=6); a user unit including components 15 and 16 (I=7, P=7); and a user unit including components 12, 13, 14, 15 and 16 (I=11, P=3).

The results of the underlining task seem to be difficult to interpret because of the large variation between the responses. The only graphic components that were clearly distinguished were components 7, 12 and 15. Component 7 was underlined eighteen times (I=9, P=9). This differs substantially from components 12 (I=0, P=7) and 15 (I=0, P=6), although components 12 and 15 are specified by the same set of graphic variables as component 7. The use of bold makes these three graphic components prominent, but graphic components 12 and 15 are not considered to be important. This might indicate that subjects distinguish component 7 for different reasons. I will come back to this point in section 5·2·2.

Three parts of graphic components were underlined more often than other parts of components; 'one or two drops' was mentioned twice in the insert and was underlined 10 times in total (I=8, P=2); 'blink a few' was underlined 9 times (I=6, P=3) and 'below 30° C' was underlined 10 times (I=9, P=1). The results of the underlining task indicate that patients perceive differences in importance within graphic components. These differences are not represented by a different graphic component. This might reveal that the suitability of the graphic presentation of these specific graphic components is not optimal. The variation between the responses of patients in the rest of the results of the underlining task does not seem to warrant further analysis. It seems that the underlining task asks for too much detail.

Special attention to several user units seems worthwhile. In the first place the illustration (graphic component number 5) which was separated by 8 subjects in terms of importance and by 18 subjects in

terms of prominence. Six subjects in the prominence group underlined a part of the illustration. All six underlined or encircled the area around the end of the nozzle. This difference between the results of the subjects in the importance group and the results of the subjects in the prominence group seems to indicate that there is a large difference in prominence between the illustration and other graphic components, and a small difference in importance between the illustration and other components. Four subjects cut through the illustration (I=4, P=0) in a similar way. All four subjects looked at the division of the information in text paragraphs only and disregarded the other components. A possible explanation might be that 'units' in the importance group were interpreted as referring to text only. This is further supported by four subjects who clearly separated the text from other components by grouping component 5 with the first four components (I=4, P=0). In total, eight subjects in the importance group disregarded the illustration by either cutting it in half or by combining it with component 1, 2, 3, and 4. Eight other subjects in the importance group separated the illustration. These results seem to point to a split within the importance group whether to see the illustration as a unit or not.

A second user unit demanding some attention consists of the graphic components 8, 9, 10, and 11. These graphic components are clearly separated by the subjects in the importance group (I=17, I=16, I=16, I=18 respectively). The prominence group combined these graphic components more often (P=15, P=14, P=14, P=16 respectively). This indicates a discrepancy between the opinion of patients about the importance differences of these graphic components and the prominence differences of these graphic components. Some subjects commented that these components looked very similar but represented different types of information. The comparison of the importance of these graphic components was therefore difficult. The majority of the underlining was done within these four graphic components. The underlining in graphic component 11 in the importance group is particularly remarkable. Fourteen out of 20 patients felt that there were importance differences within this graphic component.

A third user unit that was frequently separated consists of graphic components 11 to 16. Fourteen subjects combined components 12, 13, 14, 15, and 16 in a unit (I=11, P=3). Fourteen subjects separated components 15 and 16 as one unit. These fourteen subjects were equally divided over the importance group and the prominence group (I=7, P=7). The prominence group included components 15 and 16 in larger units (figure 5·4). This result seems to indicate that there is some doubt in both groups of subjects whether to combine graphic components 12, 13 and 14 from graphic components 15 and 16, or to separate them.

Several remarks can be made at the end of this first part of the results section. It seems that subjects identify graphic components, and are able to separate and group graphic components. The division of the graphic presentation of the test insert into graphic components, as it is illustrated in figure 5·3 was used as a starting point. The separation and underlining tasks showed that:

- nearly all patients separated user units according to the boundaries of graphic components. Only 4 subjects cut through a graphic component
- most graphic components were identified by patients, although not all components were identified by all patients
- graphic components 2, 3, 4, 6, 13 and 16 were not individually separated or underlined. These graphic components were always combined with other graphic components
- subjects in the importance group separated more units than subjects in the prominence group. It might also be the case that there are more importance differences in this insert than there are prominence differences
- subjects in the importance group agreed more about the separation of units. It might be the case that importance differences are easier to distinguish than prominence differences. These results will be further discussed in section 5·2·2.

Ranking of graphic components.

A second task for patients was to rank the pieces of paper (user units) according to their prominence, or according to their importance. Patients frequently cut out all user units first and numbered them afterwards. The results of the rankings are presented in figure 5·7. All graphic components within a user unit received the same ranking number. The following method to assign ranks was used. This method of ranking has been suggested by Wilcoxon (1945). When two or more scores are tied at the same rank, the rank assigned is the average of the tied ranks which would have been assigned if the scores had differed (Siegel & Castellan, 1988). For example, subject 1 in the importance group combined components 6 and 7 in one unit, and gave this unit rank number 4. Component 6 and 7 are

Importance ranking:

subject number:	component number: 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	8.5	8.5	8.5	8.5	3	4.5	4.5	1	2	6	11	13	13	13	15.5	15.5
3	3	3	3	3	3	7.5	7.5	6	9	10	11	13	13	13	15.5	15.5
5	4	4	4	1.5	1.5	12.5	12.5	10	9	11	14	7	7	7	15.5	15.5
7	3.5	3.5	3.5	3.5	1	6.5	6.5	8	9.5	9.5	11	14	14	14	14	14
9	2.5	2.5	2.5	2.5	10	11.5	11.5	7	8	9	14.5	14.5	14.5	14.5	5.5	5.5
11	7	7	7	7	7	7	7	1	2	3	11	15	15	15	12.5	12.5
13	3	3	3	3	3	10.5	10.5	6	7	8	9	14	14	14	14	14
15	14.5	14.5	14.5	14.5	2	5	5	5	2	2	7	10	10	10	10	10
17	7	7	7	7	7	7	7	11	12	13	14	2	2	2	15.5	15.5
19	3.5	3.5	3.5	3.5	10	6.5	6.5	1	8.5	8.5	13.5	13.5	13.5	13.5	13.5	13.5
21	9	9	9	9	9	1.5	1.5	3	4	6	5	14	14	14	14	14
23	14.5	14.5	14.5	14.5	7	4.5	4.5	3	1	2	6	11	11	11	8.5	8.5
25	5	5	5	5	5	5	5	1	9	11	10	14	14	14	14	14
27	3.5	3.5	3.5	3.5	1	7.5	7.5	6	9	11	10	14	14	14	14	14
29	2.5	2.5	2.5	2.5	10	6.5	6.5	5	9	11	8	14	14	14	14	14
31	11.5	11.5	11.5	11.5	2	5.5	5.5	11.5	2	2	4	11.5	11.5	11.5	11.5	11.5
33	14	14	14	14	14	1.5	1.5	3	4	5	6	9	9	9	9	9
35	9.5	9.5	9.5	9.5	5.5	3.5	3.5	5.5	1	2	7	14	14	14	14	14
37	9.5	9.5	9.5	9.5	2	4.5	4.5	1	7	3	6	14	14	14	14	14
39	2.5	2.5	2.5	2.5	7	7	7	5	10	11	9	14	14	14	14	14
Total:	138	138	138	135.5	110	125.5	125.5	100	125	144	187	245.5	245.5	245.5	258.5	258.5
Mean:	6.9	6.9	6.9	6.8	5.5	6.3	6.3	5	6.2	7.2	9.3	12.3	12.3	12.3	13	13
Rank:	**7.5**	**7.5**	**7.5**	**7.5**	**2**	**4**	**4**	**1**	**4**	**10**	**11**	**13**	**13**	**13**	**15.5**	**15.5**

Prominence ranking:

subject number:	component number: 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
2	6	6	6	6	6	6	6	1	10	2	13.5	13.5	13.5	13.5	13.5	13.5
4	3.5	3.5	3.5	3.5	1	11	11	11	11	11	11	11	11	11	11	11
6	14.5	14.5	14.5	14.5	6	1.5	1.5	10.5	10.5	10.5	10.5	4	4	4	7.5	7.5
8	14.5	14.5	14.5	14.5	12	1.5	1.5	5	4	3	6	10	10	10	7.5	7.5
10	2.5	2.5	11.5	11.5	1	11.5	4	11.5	11.5	11.5	11.5	5	11.5	11.5	6	11.5
12	3.5	3.5	3.5	3.5	1	12	12	12	12	12	12	12	12	12	6.5	6.5
14	2.5	2.5	2.5	2.5	5	6.5	6.5	9	8	10	11	14	14	14	14	14
16	14.5	14.5	14.5	14.5	4	5.5	5.5	1	2	3	7	10	10	10	10	10
18	2	2	2	6	4	6	6	14.5	14.5	14.5	14.5	9	9	9	11.5	11.5
20	2.5	2.5	2.5	2.5	7	5.5	5.5	16	14	13	15	11	11	11	8.5	8.5
22	2.5	2.5	2.5	2.5	5	11.5	11.5	14.5	14.5	14.5	14.5	7	7	7	9.5	9.5
24	2	2	2	12	4	12	5	12	12	12	12	6	12	12	7	12
26	3.5	3.5	3.5	3.5	1	9.5	9.5	14.5	14.5	14.5	14.5	7	7	7	11.5	11.5
28	4.5	4.5	4.5	4.5	1	4.5	4.5	9	9	9	13.5	13.5	13.5	13.5	13.5	13.5
30	6	6	6	12	1	12	2	12	12	12	12	3.5	12	3.5	12	12
32	13	13	13	13	1	13	13	13	9	2	5.5	5.5	5.5	5.5	5.5	5.5
34	3.5	3.5	3.5	3.5	1	6.5	6.5	12	12	12	12	12	12	12	12	12
36	2.5	2.5	2.5	2.5	6	12.5	5	12.5	12.5	12.5	12.5	7	12.5	12.5	8	12.5
38	2	2	2	5	12	5	5	14.5	14.5	14.5	14.5	9	9	9	9	9
40	2.5	2.5	2.5	2.5	5	6.5	6.5	12	12	12	12	12	12	12	12	12
Total:	108	108	117	140	84	160	128	217.5	219.5	205.5	235	182	208.5	200	196	211
Mean:	5.4	5.4	5.9	7	4.2	8	6.4	10.9	11	10.3	11.8	9.1	10.4	10	9.8	10.5
Rank:	**2.5**	**2.5**	**4**	**6**	**1**	**7**	**5**	**14.5**	**14.5**	**12**	**16**	**8**	**12**	**10**	**9**	**12**

Figure 5.7. The above numbers present the ranks of the graphic components for 40 subjects.

therefore tied at the same rank. If component 6 and 7 had been separated, they would have been ranked 4 and 5. The average of these two ranks (4+5=9/2=4.5) is the rank number of component 6 and 7.

If a graphic component was cut in half, as the illustration was, than the rank of the component is tied with the unit that has the lowest ranking. For example, subject 11 cut through the illustration to separate graphic components 1, 2, 3, 4, 6, and 7, from component 8. Because component 8 was ranked higher, the illustration was tied with the unit with the lower rank, that is with components 1, 2, 3, 4, 6, and 7. The rationale for this choice is that the subject did not find the illustration important enough to separate it, and a combination with the higher rank would therefore not be appropriate.

The Kendall Coefficient of Concordance for the importance group is W=0.41 ($p<0.001$), and for the prominence group W=0.30 ($p<0.001$). The coefficient of concordance is measured on a scale varying from 0 to 1. The coefficient indicates the degree of agreement between subjects about ranks of graphic components. The concordance of the results of the ranking task within the importance group and within the prominence group are highly significant. These scores therefore indicate that subjects in each group agreed with each other to a significant extent.

In order to see if any of the subjects had influenced the total of the ranking task too much, the deviation of each subject from the total rank in the importance group and in the prominence group was calculated. The Kendall Rank Correlation Coefficient was calculated for each subject. Graphic components 1, 2, 3, and 4 and graphic components 6, 7, and 9 were grouped in the same total rank in the importance group, because the differences in means were very small. In the prominence group, graphic components 8 and 9, and graphic components 10, 13 and 16 were given the same rank for the same reason. **Figure 5·8** presents the outcome of these rank correlation calculations. There is no significant difference in the rank correlation coefficients in both groups of subjects (n=20; mean 0.477; SD=0.2325 in the importance group, n=20, mean 0.4805; SD=0.4104 in the prominence group).

Figure 5·8 also shows that there are four subjects in the prominence group with a negative rank correlation coefficient. However, if these four subjects are excluded, the total rank of the prominence group does not change. The subjects in the prominence group, with a negative rank correlation coefficient were compared with the total rank of the importance group. This was done in order to see if these subjects had interpreted prominence to indicate importance. For one subject (prominence no 16, $\tau = -0.38$) this appeared to be the case. The rank correlation coefficient for this subject in the prominence group with the total rank of the importance group was $\tau = 0.33$. However, this coefficient is not significant. For the other three subjects in the prominence group, this was not the case. This might suggest that these three subjects had difficulties with the task.

Figure 5·9 illustrates the ranks of the graphic components. The most striking difference between the importance rank and the prominence rank in figure 5·9 is the dispersion of the graphic components in the prominence rank and the grouping of components in the importance rank. The three groups in the importance rank (components 1-10, component 11, and components 12-16) follow the sequence of these components from the top of the insert to the bottom of the insert. It looks as if this sequence does influence the importance ranking graphic components by patients.

It can be concluded that subjects can reliably rank units according to importance and according to

Importance		**Prominence**	
subject	τ	subject	τ
1	.88	2	.26˙
3	.67	4	.66
5	.19˙	6	-.05˙
7	.61	8	-.40
9	.13˙	10	.65
11	.62	12	.61
13	.51	14	.84
15	.27˙	16	-.38˙
17	.07˙	18	.82
19	.56	20	.70
21	.63	22	.60
23	.18˙	24	.74
25	.73	26	.74
27	.64	28	.61
29	.49˙	30	.53
31	.37˙	32	-.26˙
33	.18˙	34	.80
35	.59	36	.75
37	.71	38	.68
39	.51	40	.71

Figure 5·8. Rank correlation coefficient (t) of each subject when compared with the mean of the importance and prominence group.
(˙ denotes not statistically significant, $p>0.01$)

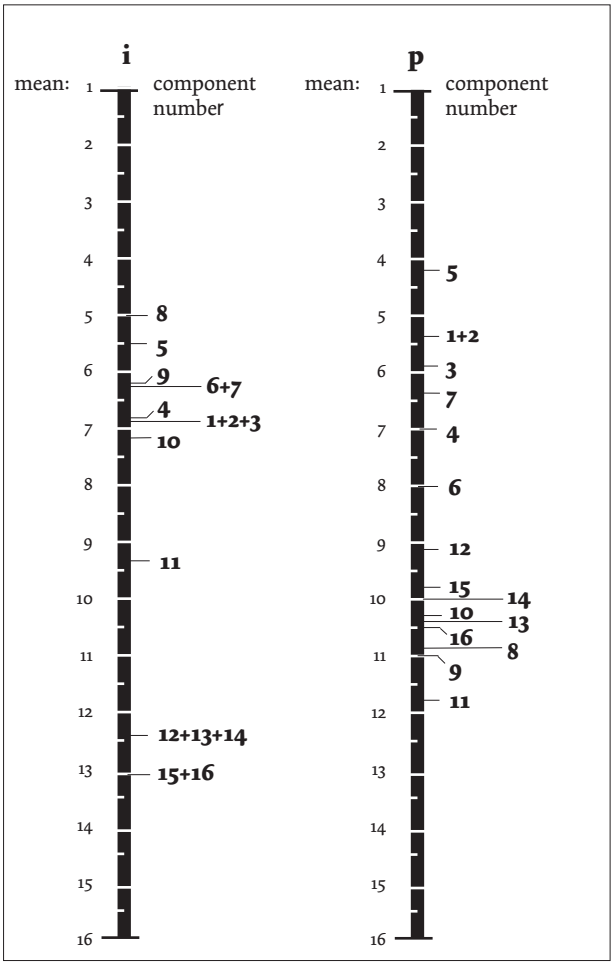


Figure 5·9. Comparison of the means of the ranks per graphic component in the importance and prominence group.

prominence. This result fulfils objective 2 of this experiment. The importance ranking task has a higher concordance than the prominence ranking task, which indicates that there is a larger variation in the results of the prominence group. The results of the separation task support this.

The relation between importance and prominence. One of the three objectives of this experiment was to find out if there is a relation between the importance of units and the prominence of units. The first point to mention is that the results of the importance and the prominence groups differ. Three reasons can support this. There is a significant difference ($p<0.001$) between the number of units that are separated by the subjects according to the prominence and according to the importance. In the second place the subjects in the prominence group separated more different units (I=22, P=31). And in the third place, there is no significant rank correlation between the importance rank and the prominence rank ($\tau = 0.26$, $p=0.081$).

The differences between the means of the importance and prominence ranks can be used to indicate relations between the importance of graphic components and between the prominence of graphic components. However, they cannot be seen as absolute measures, and can only be used in comparisons. A comparison of the means of the ranks of the graphic components is presented in **figure 5·10.** This figure illustrates that there is a clear difference between the means of the importance ranks and the means of the prominence ranks. For graphic components number 8, 9, 10, 11, and 6, the mean of the importance rank is larger than the mean of the prominence rank. For component 4 and 7 these ranks are about equal. For graphic components 3, 5, 2, 1, 13, 14, 16, 15, 12 the means of the prominence ranks are higher than the means of the importance ranks. These differences illustrate the relative differences in the opinion of patients between 'the importance of a graphic component' and 'the prominence of a graphic component'. Again, these comparisons cannot be seen as absolute measures, but are only used to illustrate the differences between the means of the importance and the means of the prominence ranking. Looking at these differences, it is clearly not the case that the most important graphic component (8) is the most prominent graphic component. Or the other way around, that the most prominent component is ranked as the most important. There does not seem to be a direct relation between importance and prominence in this insert. It might therefore be more useful to look at the differences in the ranking between importance and prominence for individual graphic components. This will be done in section 5·2·2.

5·1·4 Discussion.

The results of this experiment were obtained with a novel investigation technique and should therefore be carefully interpreted. Although some results are statistically significant and point towards conclusions, several similar experiments need to be conducted to test the reliability of this technique. The discussion of the results of this first experiment will follow the description of the second experiment. The results of both experiments are compared in section 5·2·4. However, it is possible to describe some of the advantages and disadvantages of this technique.

The first point that needs to be mentioned is the

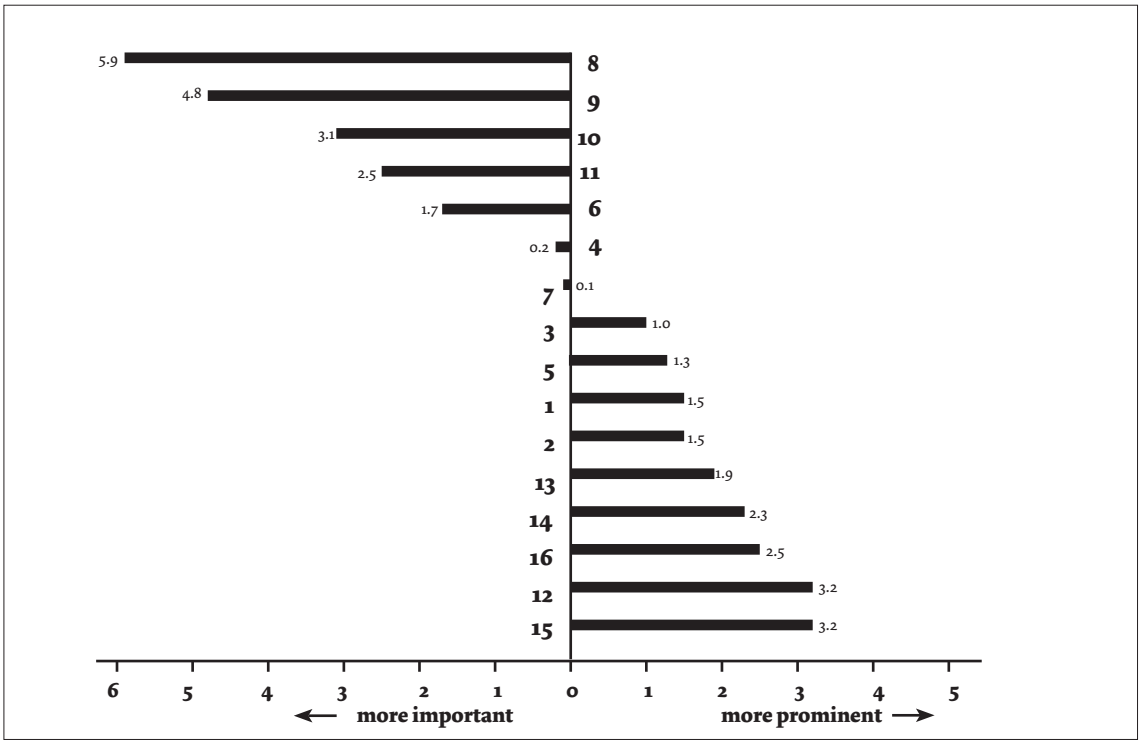


Figure 5·10 Difference of the mean of the importance and prominence per component. The component numbers are in bold.

relation between subjects and test insert. As was suggested in the conclusions of the previous chapter, patients (rather than students), and an existing insert (rather than a mock up) were used in this experiment. However, these two factors still do not guarantee an optimal combination of test material and subjects. The information in the eye drop insert would not have been appropriate to all subjects in the experiment. Therefore, although the ecological validity of this experiment seems high, there is still room for an inappropriate match between test materials and subjects.

A second point that needs to be made is related to the technique. The anticipated problem that only adjacent graphic components could be combined in identifying user units, was not confirmed in this experiment. Several patients separated user units and gave them identical ranks afterwards. Although this was rare (only 2 patients gave separated units the same rank), it is an indication that the opportunity was there. The main advantage of the cutting technique was that it is a practical way of ascertaining differences between graphic components and user units. Although cutting seems a rather crude technique, it clearly identified that there is a difference. This was the case in the importance group, as well as in the prominence group. The combinations of graphic components into user units was highly consistent within the importance group, and within the prominence group.

One of the defects of this cutting technique is that only one side of an insert can be evaluated. When an insert is printed on both sides, the experiment needs to be repeated in some way. A second defect of the cutting technique is that graphic components that are hardly noticed, can be placed high in the rank order. Graphic components that are combined in a single user unit will receive the same rank. The differences, in importance or in prominence, between these graphic components in the same user unit are therefore ignored.

The underlining task was least successful. There was a poor agreement between subjects about the parts of user units that were underlined in either group. This might have been due to the fact that underlining requires a more detailed analysis of the contents in the case of the importance group, or a more detailed visual judgement in the prominence group.

The main results of this first experiment can be summarized as follows. These points are related to the objectives.

- most, but not all, graphic components in the test insert are identified by patients

- graphic components can be separated and grouped. There is agreement between subjects about the graphic components that are combined into units
- the ranking of units is consistent. There is a significant concordance between the responses of the subjects within the importance group, and between the responses of the subjects within the prominence group
- it seems that the relation between prominence and importance is not consistent over all components. It might be more beneficial to investigate this relation for individual components

Section 5·2 describes the second experiment. The results of the first and the second experiment will be discussed in section 5·2·4.

5·2 Experiment 2.

Experiment 2 modified the graphic presentation of the test insert according to the results of experiment 1. The main reason to undertake this second experiment was to find out whether differences in the graphic presentation cause different reactions of patients.

5·2·1 Objectives, method.

Two objectives were set for the second experiment:
- to determine if the differences in the graphic presentation cause different reactions
- to determine whether it is possible to improve the suitability of the graphic presentation in an insert

Rationale.

The first objective can be divided into three areas. The first area is related to the grouping and separation task. The question is whether a modification of graphic presentation does influence the grouping/separation of graphic components. The second area is queried by asking whether a modification of graphic presentation influences importance rankings and prominence rankings of subjects. And the third area is investigated by asking whether the relationship between importance of a graphic component and prominence of a graphic component can be modified. It was hoped that answers to these three questions could be obtained by comparing the results of the second experiment with the results of the first experiment. The differences between the results of the first experiment and the results of the second experiment are an indication of the influence of a modification of the graphic presentation on subjects. The comparison of the results can be interpreted in relation to the second objective.

Tasks and data collection.

The same procedures as in the first experiment were applied in the second experiment. The same task cards, information sheet/consent form and experimental arrangement were used. However, the underlining task was deleted, because it was felt that the results of this task in the first experiment varied too much to be of use. The main reason to include underlining in the first experiment was to find out if patients could subdivide user units in order to identify graphic components. The separation task clearly indicated that this was the case, and it was not necessary to go into as much detail with the second experiment to prove this again.

5·2·2 Test conditions.

Twenty two patients participated in the second experiment. Eleven patients executed the importance tasks, and eleven executed the prominence tasks. The patients were interviewed on June 17th, June 24th and July 1st 1993.

Test insert.

The test insert was modified according to some of the results of the first experiment. Three results of experiment 1 were that:
- subjects in the importance group as a whole identified more units than subjects in the prominence group, and subjects in the prominence group as a whole separated more different units
- the agreement within the importance group and within the prominence group is highly significant. For the importance group the Kendall Coefficient of Concordance is W=0.41, and for the prominence group, this Coefficient is W=0.30
- there is no rank correlation between the ranks of the importance group and the ranks of the prominence group

The aim of the modifications of the test insert of experiment 1 can be divided into three objectives:
- the first objective is to reduce the difference in the results between the prominence and importance group in the grouping/separating task of graphic components
- the second objective is to increase the agreement between subjects within the importance group and within the prominence group
- the third objective is to make the importance/prominence differences in the ranking of graphic components smaller

The main reason to modify the graphic presentation is to create a test situation in which it is possible to monitor differences. The responses of subjects to the modified graphic presentation can be obtained. The level of agreement of subjects about a feature of the graphic presentation can be compared with the results of the first experiment. As was discussed in section 4·4·3, the variation in responses of subjects can be used as a measure of the suitability of the graphic presentation.

Three points need to be mentioned about this modification. In the first place this modification is based upon an interpretation of the results of the first experiment. These results could be interpreted in several different ways. The modification is therefore not

the only possible alternative graphic presentation. The second point that needs to be mentioned is that this modification of the graphic presentation is made with little reference to the representation of the topic (the information content) of the insert. The modification is mainly aimed to achieve the objectives that were set for this modification, and not to represent the topic of the insert. In other words, it might be the case that the modification of the graphic presentation reduces the concordance of the graphic presentation. A third point that needs to be mentioned is that the modifications will have to be kept to a minimum. If the graphic presentation were changed substantially, it would not be possible to compare the experimental results. These three points make the proposed modifications a compromise between the changes suggested by the results of the first experiment, and some practical restrictions.

The main part of this section describes the modifications of the graphic presentation of the insert that was used in experiment 1. The result is reproduced in **figure 5·11**. In order to make a comparison easier, I have reproduced both figures 5·3 and 5·11 on the next page.

In the first experiment, components 1, 2, 3, and 4 were combined by 34 out of 40 subjects; 23 separated these four components as a unit (figure 5·4). In order to try to increase the number of subjects that combined these four components into a unit, the distance between the group of components 1, 2, 3, and 4 and the other component in the insert was enlarged. This is an adjustment of the proximity relation. The type weight, the type size and the line space of verbal component 1 were reduced, in order to reduce the emphasis on component 1. The position of components 2, 3 and 4 were altered to be in the same proximity relations with component 1 as in the first insert. The specifications of graphic components 2, 3 and 4 were not modified.

Graphic component 5, the illustration (mean I=5.5 [rank 2], mean P=4.2 [rank 1]) was reduced in size in an attempt to reduce the emphasis on the illustration.

The configuration (spatial relations) of graphic components 5, 6, 7, 8, and 9 was modified. Three results of the first experiment formed the basis for this change. In the first place, graphic component 8 has the largest difference between the mean of the importance ranking and the mean of the prominence ranking (mean I=5, mean P=10.9). The difference in the mean of the importance ranking and the mean of the prominence ranking for component 9 was second largest (I=6.2, P=11). Secondly, the rank order of the importance indicated that component 8 was more important than component 5, followed by component 9 and the combination of components 6 and 7 (figure 5·9). And thirdly, component 9 and component 6 have a similar importance ranking (I=6.2 and I=6.3), but their prominence ranking is very different (P=8 and P=11 respectively). In order to modify the graphic presentation of these five components, the following alternative was suggested. The sequence of the graphic components in insert 2 follows the sequence of the importance ranking in insert 1. Graphic component 8 was the most important and was therefore placed above components 5, 6, 7 and 9. Component 9 was placed before component 6. Although the means of the importance ranking of these components are nearly equal, the difference between the means of the prominence rankings warrants a more prominent place for component 9.

In the first experiment graphic component 6 was always combined with component 7. Graphic component 7 was noticed by 22 subjects in the first experiment. Most of these subjects underlined this graphic component (I=9, P=9). The underlining task indicated that patients found the words: 'one or two drops' important as well. In order to see whether patients would rank the importance of this component according to its emphasis, or to its grouping, a modification was made. Component 7 in test insert 1 was replaced by another component 7 in test insert 2. Component 7 in insert 2 was specified by the same set of graphic variables as component 7 in insert 1.

Graphic components 10 and 11 were ranked higher in importance than prominence, but were not modified. This was necessary in order to keep the specification of graphic components 6, 8, 9, 10, and 11 similar to each other. An alteration of the specification of graphic components 10 and 11 would have modified the graphic presentation too much. Only the distance between component 10 and 11 was enlarged, in order to group component 10 with components 5, 6, 7, 8, and 9 and separate component 11 more clearly.

Graphic components 12, 13, 14, 15 and 16 were more clearly grouped by adding more space between component 11 and 12. The prominence of components 12 and 15 in the first insert was ranked higher than their importance. In order to relate the prominence of these components closer to their importance rankings, the specification of the variables was modified. The similarity of components 7, 12 and 15 has been mentioned in section 5·1·3. In order to make the difference between component 7 (which was underlined

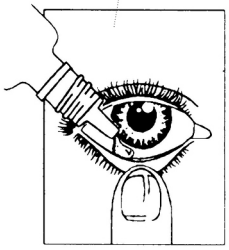
1 2 3 4

330-1-69

How to use Farnilon® Aqueous eye drops

8 To use, place one or two drops into each eye, four times a day or as directed by your doctor.

9 Sit down in front of a mirror, so that you can see what you are doing. Pull the lower eyelid gently, and then carefully place **one or two drops** in the gap between the eye and lower eyelid. 7



5

It is vital to use Farnilon Aqueous eye drops regularly, every day. This is to prevent further symptoms from occurring when your eye condition is controlled. 6

10 Now release the lower eyelid, and blink a few times to make sure the whole of the eye is covered by the liquid.

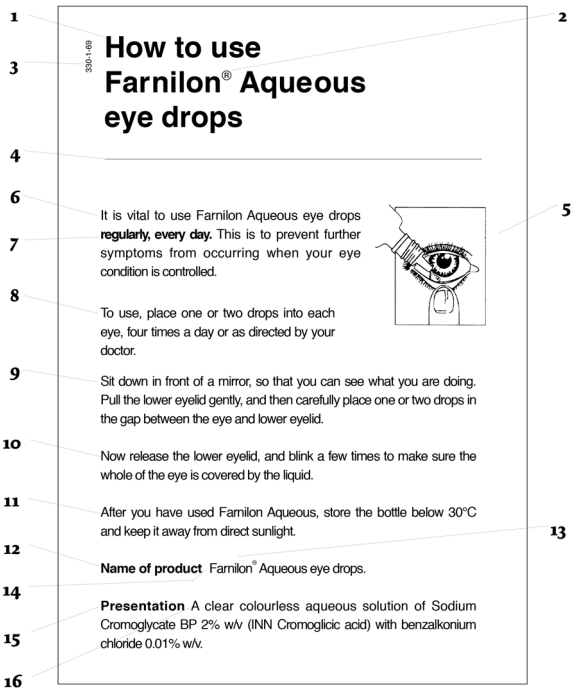
11 After you have used Farnilon Aqueous, store the bottle below 30°C and keep it away from direct sunlight.

13

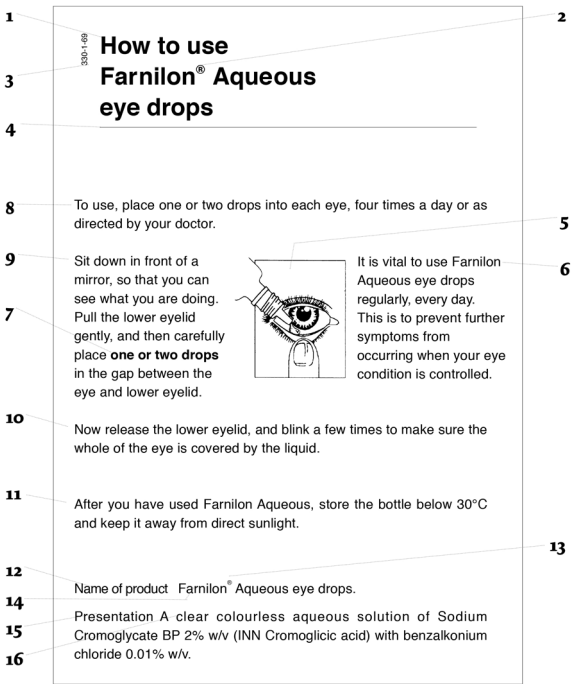
12 Name of product Farnilon® Aqueous eye drops.

14 15 16 Presentation A clear colourless aqueous solution of Sodium Cromoglycate BP 2% w/v (INN Cromoglicic acid) with benzalkonium chloride 0.01% w/v.

Figure 5·11. Test insert 2 with graphic component numbers.



Copy of Figure 5·3. 45 per cent reduced.



Copy of Figure 5·11. 45 per cent reduced.

by 18 subjects [I=9, P=9]), and component 12 and 15 clear (underlined by respectively 7 and 6 subjects in the prominence group), component 12 and 15 were made different from component 7.

All the modifications to the first test insert that are mentioned above can be described with the use of the framework of figure 4·4. The alterations were on level 1 for components 1, 6, 7, 8, 9, 12 and 15. The specification of the set of graphic variables was modified for these components. The relations between graphic components could be described with the four types of relations as they were given in section 4·3. These modifications can be summarized in these four types of relations.

- similarity: the similarity of graphic components 7, 12 and 15 was modified
- proximity: the distance between graphic components 1, 2, 3, and 4 and the other components was enlarged. The distance between graphic components 5, 6, 7, 8, and 9 were modified. The distance between component 10, and component 11 was enlarged. The distance between component 11 and components 12, 13, 14, 15, and 16 was enlarged. These increases in distance were made to separate these components more clearly
- prominence: the emphasis of graphic component 7 was reduced. A new component 7 was introduced by emphasizing part of component 9. The emphasis on component 12 and 15 was reduced. The emphasis of component 1 was reduced. The emphasis of component 5 was reduced.
- sequence: the sequence of components 5, 6, 7, 8, and 9 was modified

However, it must be stated again that these four relations are interrelated: modifying one relation will modify others as well. The third level of the framework was not deliberately modified.

This experiment set out to find if these modifications are identified by patients and if these modifications cause a different reaction of patients when the results are compared with the results of the first experiment.

5·2·3 Results.

In this section, the results of the second experiment are shown and these results are compared with the results of the first experiment. The similarities and differences between these results are discussed in section 5·2·4.

Separating/grouping of graphic components.
The subjects in the importance group separated 62 units in total (mean 5.63, SD=1.57), the subjects in the prominence group separated 69 units in total (mean 6.27, SD=1.42). This difference is not statistically significant (t=1.00, d*f*=20, 0.1<p<0.5). These results are different from the first experiment, in which the number of units separated in the importance group and the number of units in the prominence group, was significantly different (p<0.01; section 5·1·3). There is a significant difference between the number of importance units in the first experiment and the number of importance units in the second experiment (t=2.62, d*f*=29, 0.01<p<0.02). The number of importance units in the second experiment was significantly smaller. There is no significant difference in the number of prominence units in the first and second experiment (t=0.78, d*f*=29, 0.1<p<0.5). These results indicate that the differences in the results, in terms of the number of units, between the importance group and the prominence group, have been reduced.

Separated/grouped (graphic component number)	**i.**	**p.**
1+2+3	0	3
1+2+3+4	4	5
1+2+3+4+8	7	3
4+6+8	-	1
4+6+8+9+10+11	-	1
4+6+8+9+11+15+16	-	1
5	2	7
5+6+7+9	1	-
5+6+7+9+10	1	1
5+7+9	5	3
5+7+9+10	2	-
6	8	7
6+10	1	-
7	-	3
7+9	2	4
8	4	5
9	-	1
10	5	7
10+11	-	1
10+11+12+13+14+15+16	2	1
11	8	5
11+12+13+14+15+16	1	2
12+13+14	1	1
12+13+14+15+16	7	7
15+16	1	-

Figure 5·12. Number of subjects that separated and grouped graphic components.
i = importance, **p** = prominence.

The above result does not mean a great deal if the user units consist of different combinations of graphic components. This was not the case, as a comparison of the results in figures 5.4 and 5.12 shows. The subjects in the importance group separated 18 different units. The subjects in the prominence group separated 21 different units. This result is not significantly different from the results of the first experiment (χ^2=0.18, d*f*=1, 0.5<p<0.7). Several groups of graphic components are identical between the experiments (1-2-3-4, 12-13-14, 12-13-14-15-16, and 15-16).

The purpose of the modification of the graphic presentation was to achieve a higher agreement between subjects in the grouping of components 1, 2, 3, and 4. Nine subjects grouped graphic components 1, 2, 3, and 4 in the importance group in experiment 1, while 4 subjects grouped these components in experiment 2 (χ^2=0.22, d*f*=1, 0.5<p<0.7). The grouping of components 1, 2, 3, and 4 did therefore not improve in the importance groups, nor in the prominence groups. In the prominence group, 8 subjects grouped in the first experiment and 5 subjects grouped components 1, 2, 3, and 4 in the second experiment (χ^2=0.087, d*f*=1, 0.7<p<0.8). It can therefore be concluded that this modification failed to achieve its objective. The modification tried to separate graphic component 11 more clearly. This proved not to be successful either. Neither in the importance groups (χ^2=1.56, d*f*=1, 0.2<p<0.3), nor in the prominence groups (χ^2=2.24, d*f*=1, 0.1<p<0.2) were increases in the separation of component 11 significant.

The subjects in the importance group in experiment 2 did not group graphic components 12, 13, 14, 15, and 16 more than the importance subjects in experiment 1 did (χ^2=0.22, d*f*=1, 0.5<p<0.7), although this was attempted by the modification. The influence of an increased distance between this group of graphic components, which was added to separate this group of graphic components more clearly, does not seem to be reflected in the importance groupings. Only for the grouping of these graphic components in the prominence groups could a statistically significant difference be detected between experiment 1 and 2 (χ^2=7.67, d*f*=1, 0.001<p<0.01). This seems to indicate that adding additional space does influence the prominence

of this group of graphic components.

There is one main difference between the grouping of graphic components in the first and the second experiment: the separation of component 8. In the first experiment, this component was clearly separated by the subjects in the importance group (I=17). In experiment 2, component 8 was frequently combined with components 1, 2, 3, and 4 (I=7). This was not the intention of the modification, which tried to separate components 1, 2, 3, and 4 more clearly by increasing the distance. This result might be caused by a disregard for the 'heading' (components 1, 2, 3, and 4). Components 1-2-3-4 were combined with component 5 (I=4, P=0) or 5-6-7 (I=3, P=1) in experiment 1, and with component 8 (I=7, P=3) in experiment 2.

The problem with the confusion about the prominence of component 7 compared with component 12 and 15, as it was the case in the first insert, disappeared. Component 7 was more prominent (I=0, P=3), while component 12 and 15 were not individually separated in the second experiment.

A summary of the comparison of the results of the

Importance ranking:

	component number:															
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
subject number:																
1	3	3	3	3	7.5	7.5	7.5	3	7.5	13	13	13	13	13	13	13
3	3	3	3	3	7	10.5	7	3	7	10.5	9	14	14	14	14	14
5	9.5	9.5	9.5	9.5	3	1	3	5	3	6	7	14	14	14	14	14
7	3	3	3	3	7	10	7	3	7	9	11	14	14	14	14	14
9	14.5	14.5	14.5	14.5	1	4	2.5	5	2.5	9	9	9	9	9	9	9
11	2.5	2.5	2.5	2.5	6	9	6	10	6	8	13.5	13.5	13.5	13.5	13.5	13.5
13	3	3	3	3	8	8	8	3	8	8	11	14	14	14	14	14
15	12.5	12.5	12.5	12.5	3	4	1.5	6	1.5	5	10	8	8	8	15.5	15.5
17	3	3	3	3	8.5	6	8.5	3	8.5	8.5	11	14	14	14	14	14
19	3	3	3	3	7.5	11	7.5	3	7.5	7.5	10	14	14	14	14	14
21	3	3	3	3	7	10	7	3	7	9	11	14	14	14	14	14
Total:	**60**	**60**	**60**	**60**	**65.5**	**81**	**65.5**	**47**	**65.5**	**93.5**	**115.5**	**141.5**	**141.5**	**141.5**	**149**	**149**
Mean:	**5.4**	**5.4**	**5.4**	**5.4**	**6.0**	**7.4**	**6.0**	**4.3**	**6.0**	**8.5**	**10.5**	**12.9**	**12.9**	**12.9**	**13.5**	**13.5**
Rank:	**3.5**	**3.5**	**3.5**	**3.5**	**7**	**9**	**7**	**1**	**7**	**10**	**11**	**13**	**13**	**13**	**15.5**	**15.5**

Prominence ranking:

	component number:															
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
subject number:																
2	7	7	7	7	2	4	2	7	2	10	11	14	14	14	14	14
4	6.5	6.5	6.5	6.5	2	9	2	4	2	13	13	13	13	13	13	13
6	3	3	3	13.5	1	13.5	5	13.5	13.5	13.5	13.5	8	8	8	8	8
8	8	8	8	8	2	5	2	8	2	4	13.5	13.5	13.5	13.5	13.5	13.5
10	3.5	3.5	3.5	3.5	1	12	13.5	11	13.5	15	16	8	8	8	8	8
12	9	9	9	9	3	6	1.5	9	1.5	4	5	14	14	14	14	14
14	2.5	2.5	2.5	2.5	7	7	7	10	7	7	13.5	13.5	13.5	13.5	13.5	13.5
16	2.5	2.5	2.5	2.5	5	8	6.5	15	6.5	15	15	11	11	11	11	11
18	3	3	3	10	1	10	5.5	10	5.5	7	8	14	14	14	14	14
20	4	4	4	13	1	13	2	13	13	9	13	7	7	7	13	13
22	3.5	3.5	3.5	3.5	1	14	6	16	15	12.5	12.5	9	9	9	9	9
Total:	**52.5**	**52.5**	**52.5**	**79**	**26**	**101.5**	**53**	**116.5**	**81.5**	**110**	**134**	**125**	**125**	**125**	**131**	**131**
Mean:	**4.8**	**4.8**	**4.8**	**7.2**	**2.4**	**9.2**	**4.8**	**10.6**	**7.4**	**10**	**12.2**	**11.4**	**11.4**	**11.4**	**11.9**	**11.9**
Rank:	**3.5**	**3.5**	**3.5**	**6**	**1**	**8**	**3.5**	**10**	**7**	**9**	**16**	**12**	**12**	**12**	**14.5**	**14.5**

Figure 5·13. The above numbers present the rank order of the graphic components for 22 subjects.

first and second experiment contains four points.

- the user units that are separated in experiment 2 are similar to the user units that were separated in experiment 1
- subjects in the prominence groups separated more different user units than subjects in the importance groups in both experiments 1 and 2
- the number of user units separated in the importance group in experiment 2 was significantly smaller than the number of user units separated by the importance group in experiment 1. The total number of user units that was separated by the subjects in the prominence groups in experiment 1 and 2 is not significantly different. This indicates that the first objective of the modification, which is to increase the agreement between the importance group and the prominence group about the grouping of graphic components, is achieved
- the increase of the distance between groups of graphic components, in order to separate these components more clearly, did not improve the separation of these components. This might be an indication that the grouping of graphic components in the first insert was clear already

Ranking of graphic components.

The ranks of the units separated by subjects in the importance group and of the ranks of the units from the subjects in the prominence group are presented in **figure 5·13**. These results of the second experiment are ranked, as before, according to a method suggested by Wilcoxon for the analysis of tied ranks. The Kendall Rank Correlation Coefficient, corrected for tied ranks, for each of the 22 subjects in the importance and the prominence group with the mean is shown in **figure 5·14.** The number of subjects who had significantly different ranks was reduced in the second experiment. None of the subjects in the second experiment had a negative rank correlation coefficient. There is a significant difference in rank correlation coefficients between both groups (n=11; mean 0.697; SD=0,338 in the importance group, n=11, mean 0.563; SD=0.156 in the prominence group). Both groups show a significant improvement in the level of agreement. Kendall's concordance coefficient for the importance group in experiment 2 is W=0.59 (p<0.001). This figure indicates that the subjects in the importance group agreed to a significant extent in the importance ranking of the graphic components. Kendall's concordance coefficient for the prominence group in experiment 2 is W=0.52

Importance		**Prominence**	
subject	t	subject	t
1	.88	2	.61
3	.91	4	.64
5	.37˙	6	.48
7	.93	8	.60
9	.04˙	10	.27˙
11	.75	12	.39˙
13	.92	14	.80
15	.16˙	16	.65
17	.88	18	.76
19	.90	20	.49
21	.93	22	.50

Figure 5·14. Rank correlation coefficient (τ) of each subject when compared with the mean of the importance and prominence group. (˙ denotes not statistically significant. p>0.01)

(p<0.001). Both concordance coefficients are higher than in the first experiment. The ranks of graphic components of both groups are presented in **figure 5·15**.

The rank correlation coefficient of the importance ranking of graphic components in the first experiment and the importance ranking of graphic components in the second experiment is significant (τ =0.66, p<0.001). Most components (8, 10, 11, 12, 13, 14, 15, and 16) were in the same order in the second experiment as they were in the first experiment. The components 1, 2, 3, and 4 were ranked even higher in the second experiment. The increased distance between these components and the other graphic components did not improve their separation, which was the aim of the modification, but made this group even more important. The prominence ranking is similar to the first experiment. The rank correlation coefficient for the prominence ranking in the first experiment and in the second experiment is significant (τ =0.66, p<0.001). The prominence of components 8, 9, and 10 was ranked higher in the second experiment. The change for component 9 is particularly interesting. The sequence of the graphic components seems to influence the prominence ranking of these three components.

A summary of the comparison of the results of the first and second experiment in the ranking task consists of two points.

- The ranking of the importance of the graphic components has not changed significantly between

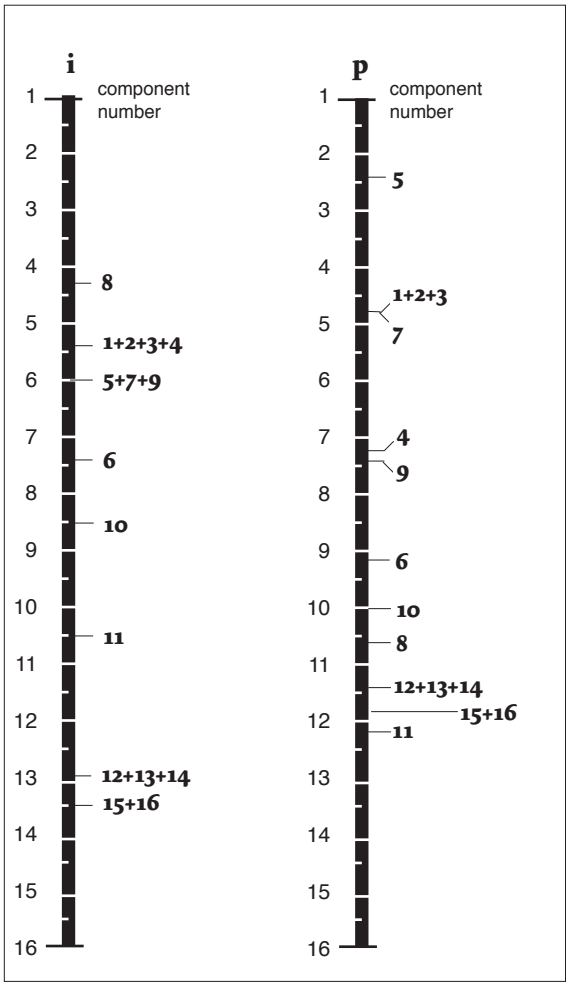


Figure 5·15 Comparison of the means of the ranking per graphic component in the importance and prominence group.

experiment 1 and experiment 2. This indicates that for the importance group, the modifications did not change the perception of the importance of graphic components. This can be seen as positive, because the modifications attempted not to alter the importance relations between graphic components. The ranking of the prominence of the graphic components has not changed significantly between experiment 1 and experiment 2. For the prominence group, this similarity between the rankings of the first and second experiment indicates that the modifications were on a minor scale. However, some graphic components changed ranks, in the importance group as well as in the prominence group, between the first and the second experiment. This is an indication that the graphic presentation does have an influence on the ranking of specific graphic components, but not on the overall ranking.

- In the importance group, the concordance coefficient is higher in experiment 2. This indicates that there was a higher agreement between subjects about the importance of graphic components in the second experiment. The same is the case for the prominence groups. The concordance coefficient increased from experiment 1 to experiment 2. This indicates that there is a higher agreement between subjects about the prominence of graphic components in the second experiment.

Relation between importance and prominence.
The relation between the ranking in the importance group and the ranking in the prominence group was calculated. The Kendall rank correlation coefficient adjusted for tied ranks was $\tau = 0.68$ ($p<0.001$). This figure indicates that the ranking of the importance group and the ranking of the prominence group are similar. This coefficient was $\tau = 0.26$ and insignificant in the first experiment. This fulfils the third objective of the modification.

Figure 5·16 shows the difference in the mean of the importance ranking and the mean of the prominence ranking in experiment 2 of single graphic components. The differences between the means is smaller for most graphic components. This was the second objective of the modification of the graphic presentation. The largest shift was for graphic component 9 (from a difference in mean of 4.8 to a difference of 1.4). This is mainly due to a shift in the prominence rank. The specification of the graphic component 9 changed the line length and included component 7, but these modifications do not seem to explain why this shift is so large.

The exceptions are graphic components 4, 5, 6, 7, 8. The difference between the means of the ranks increased for these components. This result is contrary to the objectives of the modification of the graphic presentation. A closer look at these five components is necessary in order to determine reasons for these results. For component 4, this difference is caused by the results of the ranking tasks of three subjects in the prominence group. These three subjects grouped component 4 with other components, which caused this difference in ranking. The reduction in size of component 5 did not reduce its prominence ranking, but the repositioning seems to have increased the prominence. The difference between the mean from the importance rank is therefore increased. The difference between the means of the importance rank and the means of the prominence rank for component 6 did not

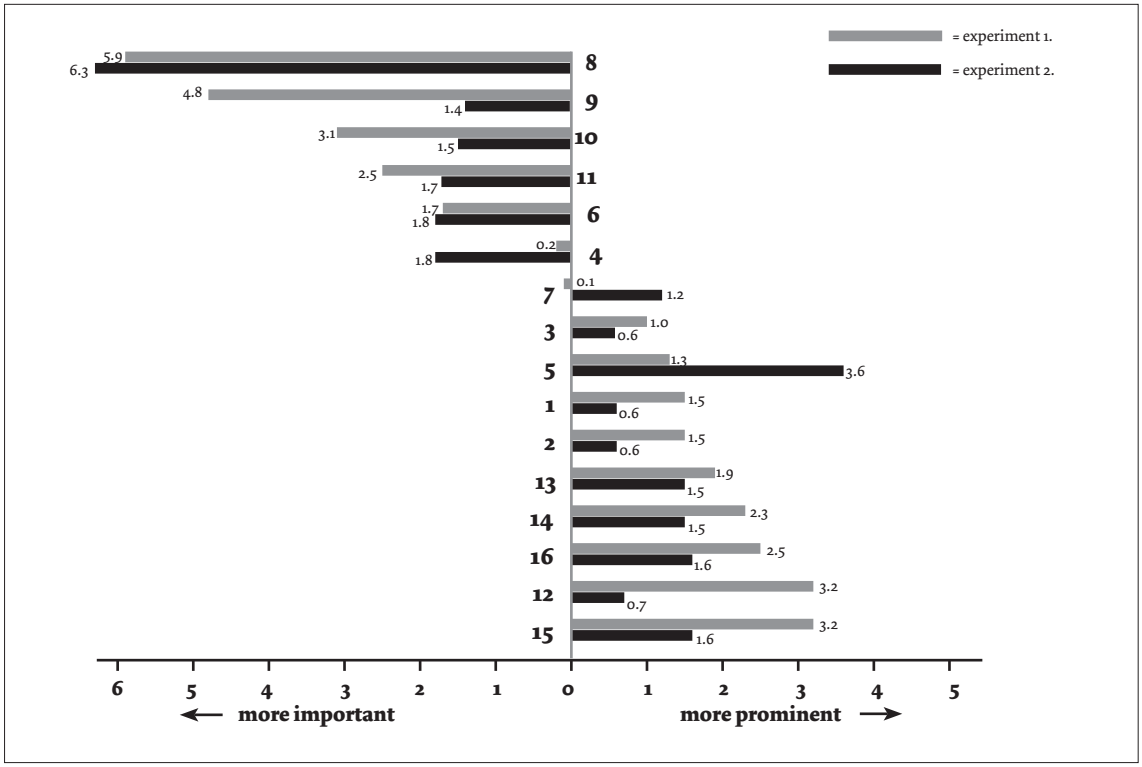
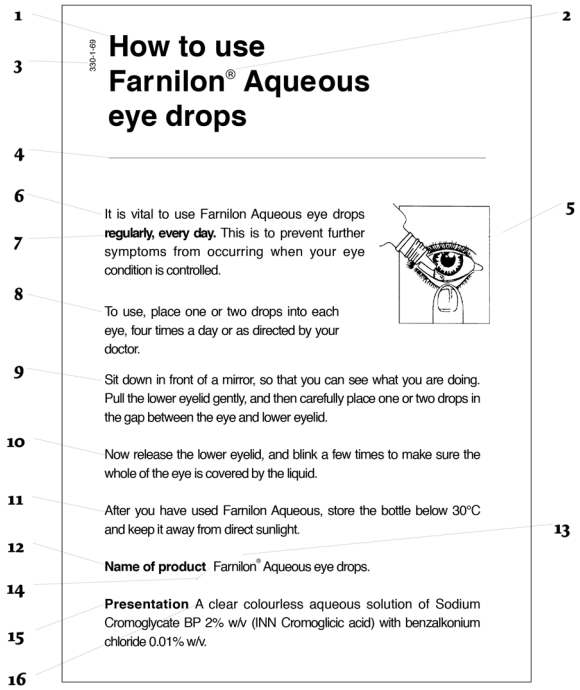
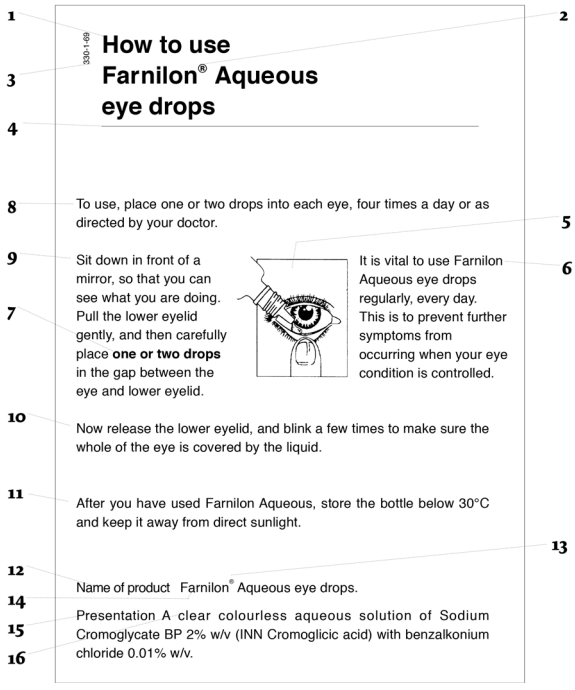


Figure 5·16. Difference of the mean of the importance and prominence per component. Component numbers are in bold.



Copy of Figure 5·3. 45 per cent reduced.



Copy of Figure 5·11. 45 per cent reduced.

change, despite the repositioning. For component 7, the increase in the difference between the mean of the importance rank and the mean of the prominence rank might be explained by the fact that a different component was used in the second experiment. They are therefore not directly comparable. For component 8, the mean of the importance rank was again larger than the mean of the prominence rank. Despite being placed first, the prominence rank remains low. The similarity of component 8 with other components, like 6, 9, and 10 might have caused this result. However, it has to be mentioned again that these differences between the means should not be seen as absolute measures, but as a comparative indication.

A conclusion about the relation between the importance and the prominence of graphic components can state two points.

- The importance/prominence relation of individual graphic components can be influenced by a modification of the graphic presentation. However, it is also clear that there is not a direct relation between the prominence rank and the importance rank of graphic components. Other factors, such as proximity, similarity, emphasis, and sequence may play a role.
- The correlation between the importance ranking and the prominence ranking has significantly improved.

5·2·4 Discussion of the results of experiment 1 and experiment 2.

This section discusses the results of the first and the second experiment. Three objectives were set for the execution of the second experiment. In the first place, the experiment was set up to investigate whether the differences in the graphic presentation would cause different responses from patients. The main purpose of the modification of the test insert of experiment 1 was to alter the graphic presentation in such a way that the importance of graphic components would be more closely related to the prominence of these graphic components. In order to discuss the influence of the modification on the results, I have divided the results again into the separation/grouping of graphic components, the ranking of components, and the relation between importance and prominence.

Separating/grouping of graphic components.
One of the reasons for undertaking the second experiment was to investigate whether graphic presentation does influence the grouping of graphic components. Four points were mentioned in section 5·2·3. The number of user units separated in the second experiment by subjects in the importance group was significantly smaller than the number of user units separated by subjects in the importance group in the first experiment. The number of user units separated by the prominence groups was not significantly different in both experiments. This indicates that graphic presentation does have an influence on the grouping of graphic components according to their importance. This is in agreement with the objectives of the modification. What the effect of this grouping of graphic components according to their perceived importance is on other aspects of document use remains to be investigated.

Ranking of graphic components.
The comparison of the ranks indicates that there is no significant change in rank order of graphic components between experiment 1 and 2 within the importance group or within the prominence group. The overall ranking of graphic components is therefore not influenced by the modification of the graphic presentation. However, Kendall's Concordance Coefficients are higher for both groups in the second experiment. This indicates that there is a higher agreement within the importance group, and within the prominence group about the ranks of graphic components. This higher agreement between subjects seems a positive result. This point was mentioned in section 4·4·3.

Relation between importance and prominence.
The results show that graphic presentation does have an influence on the responses of subjects about the importance and prominence of graphic components. Kendall's rank correlation coefficient suggests that the importance and the prominence ranking in the second experiment are significantly correlated. There was no rank correlation between the importance ranking and the prominence ranking in the first experiment. This indicates that the importance and the prominence of the graphic components in the second experiment are matched closer than in the first experiment. This higher correlation has been achieved by the modification of the graphic presentation. This conforms to the results of the separation task (smaller difference between importance and prominence group in the number of components), and the ranking task (higher agreement within groups).

A look at the relation between importance and prominence of individual graphic components reveals that the modification of the graphic presentation does influence this relation. For most graphic components in the test

inserts, the difference between the mean of the importance ranks and the mean of the prominence ranks was smaller. However, this was not true for all components. It can therefore be concluded, that the modification was successful to a certain extent, but that the modification can still be further improved.

It can be concluded that the prominence and the importance of the graphic components of the second test insert are more closely related. The number of user units, the combination of graphic components within a user unit, and the ranking of the graphic components all indicate that the importance and prominence of graphic components in the second insert are more related. What the effect of this relation is on other aspects of document use remains to be seen.

A summary of the conclusions of the second experiment can be condensed to four points:

- graphic presentation influences the number of units that are separated by subjects
- graphic presentation influences the grouping and separation of units
- graphic presentation influences the level of agreement between subjects about the ranks of graphic components
- the rank correlation coefficient of the ranking of graphic components, according to their perceived importance and their perceived prominence, is greater than in experiment 1

1. I would like to know your overall impression of this insert.
Do you find this insert: very good ☐
good ☐
neutral ☐
poor ☐
very poor ☐

2. Which aspects are good?

3. Which aspects are poor?

4. Do you find this insert: very well organized ☐
well organized ☐
neutral ☐
poorly organized ☐
very poorly organized ☐

5. Do you find the size of the letters:
very good ☐
good ☐
neutral ☐
poor ☐
very poor ☐

6. Do you find the length of the insert: too long ☐
alright ☐
too short ☐

7. We have made four different designs with the same text.
Can you please rank these four according to your preference?

- Why did you choose this order?

8. How useful are the pictogrammes? very useful ☐
useful ☐
neutral ☐
not useful ☐
useless ☐

- Why?

9. How useful do you find the colour? very useful ☐
useful ☐
neutral ☐
not useful ☐
useless ☐

- Why?

10. I am male ☐ female ☐

11. My age is under 40 ☐
between 40 and 59 ☐
bove 59 ☐

12. Last attended school level: primary ☐
secondary ☐
further education ☐
higher education ☐

January 1993

Figure 5·17 Questionnaire for the third experiment. 60 per cent reduced

5·3 Experiment 3.

This section describes a third experiment. The experiment used an insert which was developed according to the European regulations (Directive 92/27/EEC, 1992). This experiment is not related to the previous two experiments. This small experiment is described here because it demonstrates some other facets of the influence of graphic presentation on the use of inserts. The results report opinions of patients about the graphic presentation of information in inserts.

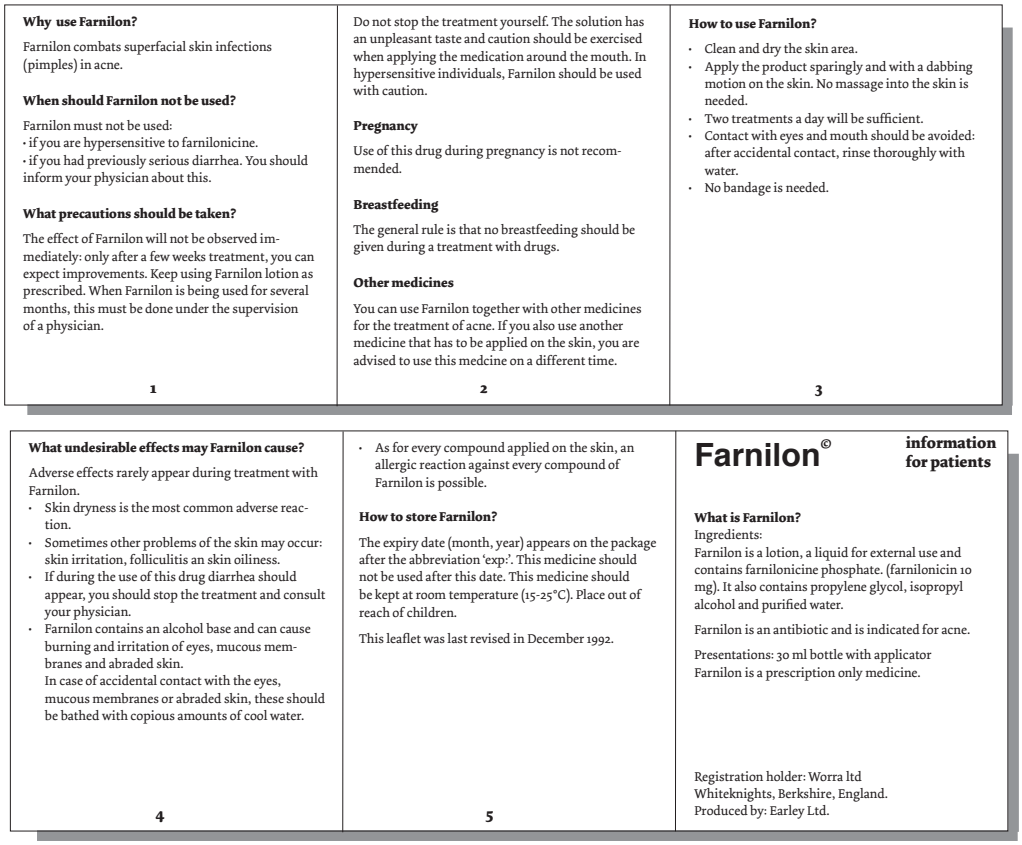
5·3·1 Method.

The main objective of this experiment was to investigate opinions of patients about the graphic presentation, and to see whether patients agree in their preferences. Only a small number of questions was asked in order to obtain reactions of patients about the graphic presentation of information in an insert. A questionnaire and several test inserts were developed to investigate the above objective.

Questionnaire.
A questionnaire was developed consisting of 12 questions. Nine questions were about the inserts, three questions asked for personal information. This questionnaire is reproduced in **figure 5·17**. The questionnaire was also produced in Dutch.

Materials.
A set of four inserts for a non-existing product, called *Farnilon* was developed. The structure of the graphic presentation accurately follows the European regulations, and incorporated the anticipated guidelines for the graphic presentation (Joossens, 1993b). The differences between the inserts was in the treatment of the headings, the pictograms and the use of colour. These four inserts are reproduced in **figure 5·18**.

The content of the insert was generated from several inserts that accompanied medicines for the treatment of skin infections. The graphic presentation of insert a was the most plain. The text is set in Lucida (x-height= 1.5 mm, line space= 4.2 mm). The insert contains several lists. The first line of each item of the list is indicated by a bullet, subsequent lines are indented. When text within a section needed to be separated, additional line space was added (+ 2.2 mm).



Why use Farnilon?

Farnilon combats superfacial skin infections (pimples) in acne.

When should Farnilon not be used?

Farnilon must not be used:
· if you are hypersensitive to farnilonicine.
· if you had previously serious diarrhea. You should inform your physician about this.

What precautions should be taken?

The effect of Farnilon will not be observed immediately: only after a few weeks treatment, you can expect improvements. Keep using Farnilon lotion as prescribed. When Farnilon is being used for several months, this must be done under the supervision of a physician.

1

Do not stop the treatment yourself. The solution has an unpleasant taste and caution should be exercised when applying the medication around the mouth. In hypersensitive individuals, Farnilon should be used with caution.

Pregnancy

Use of this drug during pregnancy is not recommended.

Breastfeeding

The general rule is that no breastfeeding should be given during a treatment with drugs.

Other medicines

You can use Farnilon together with other medicines for the treatment of acne. If you also use another medicine that has to be applied on the skin, you are advised to use this medcine on a different time.

2

How to use Farnilon?

- Clean and dry the skin area.
- Apply the product sparingly and with a dabbing motion on the skin. No massage into the skin is needed.
- Two treatments a day will be sufficient.
- Contact with eyes and mouth should be avoided: after accidental contact, rinse thoroughly with water.
- No bandage is needed.

3

What undesirable effects may Farnilon cause?

Adverse effects rarely appear during treatment with Farnilon.

- Skin dryness is the most common adverse reaction.
- Sometimes other problems of the skin may occur: skin irritation, folliculitis an skin oiliness.
- If during the use of this drug diarrhea should appear, you should stop the treatment and consult your physician.
- Farnilon contains an alcohol base and can cause burning and irritation of eyes, mucous membranes and abraded skin.
  In case of accidental contact with the eyes, mucous membranes or abraded skin, these should be bathed with copious amounts of cool water.

4

- As for every compound applied on the skin, an allergic reaction against every compound of Farnilon is possible.

How to store Farnilon?

The expiry date (month, year) appears on the package after the abbreviation 'exp:'. This medicine should not be used after this date. This medicine should be kept at room temperature (15-25°C). Place out of reach of children.

This leaflet was last revised in December 1992.

5

Farnilon© **information for patients**

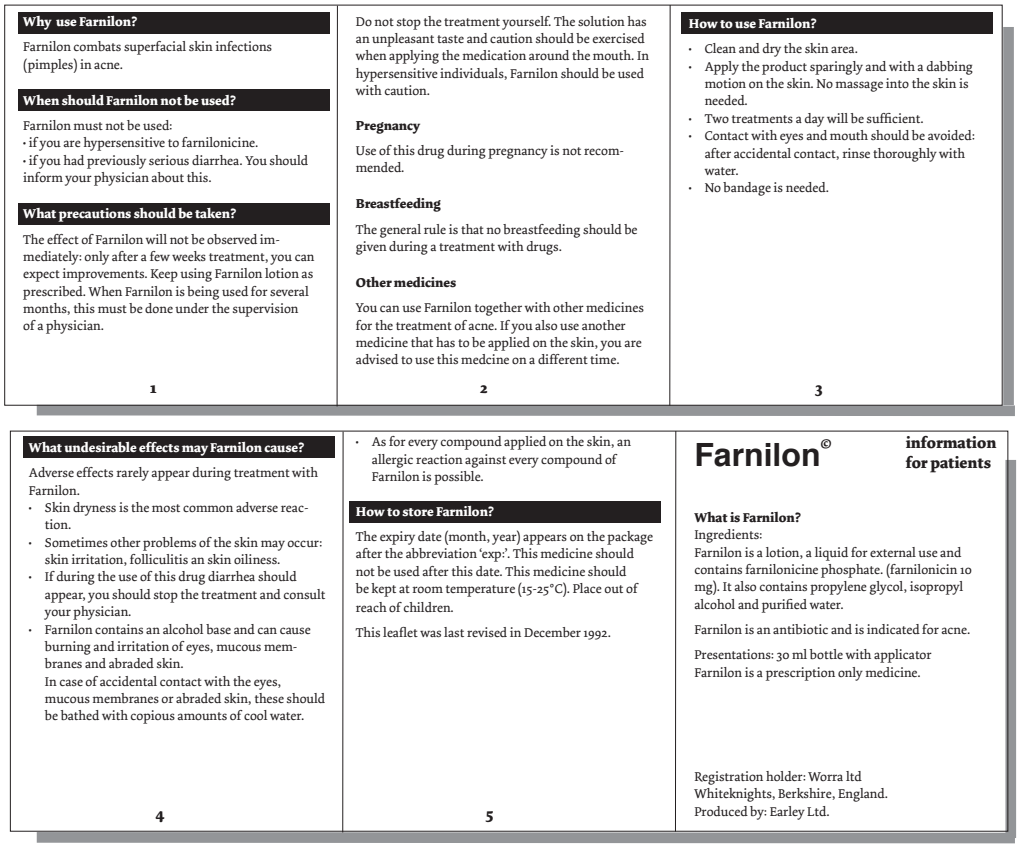
What is Farnilon?
Ingredients:
Farnilon is a lotion, a liquid for external use and contains farnilonicine phosphate. (farnilonicin 10 mg). It also contains propylene glycol, isopropyl alcohol and purified water.

Farnilon is an antibiotic and is indicated for acne.

Presentations: 30 ml bottle with applicator
Farnilon is a prescription only medicine.

Registration holder: Worra ltd
Whiteknights, Berkshire, England.
Produced by: Earley Ltd.

Figure 5·18a. Farnilon insert a. Original size: 240 by 95 mm, Reduced to 55 per cent.



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What precautions should be taken?

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1

Do not stop the treatment yourself. The solution has an unpleasant taste and caution should be exercised when applying the medication around the mouth. In hypersensitive individuals, Farnilon should be used with caution.

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Use of this drug during pregnancy is not recommended.

Breastfeeding

The general rule is that no breastfeeding should be given during a treatment with drugs.

Other medicines

You can use Farnilon together with other medicines for the treatment of acne. If you also use another medicine that has to be applied on the skin, you are advised to use this medcine on a different time.

2

How to use Farnilon?

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- Apply the product sparingly and with a dabbing motion on the skin. No massage into the skin is needed.
- Two treatments a day will be sufficient.
- Contact with eyes and mouth should be avoided: after accidental contact, rinse thoroughly with water.
- No bandage is needed.

3

What undesirable effects may Farnilon cause?

Adverse effects rarely appear during treatment with Farnilon.

- Skin dryness is the most common adverse reaction.
- Sometimes other problems of the skin may occur: skin irritation, folliculitis an skin oiliness.
- If during the use of this drug diarrhea should appear, you should stop the treatment and consult your physician.
- Farnilon contains an alcohol base and can cause burning and irritation of eyes, mucous membranes and abraded skin.
  In case of accidental contact with the eyes, mucous membranes or abraded skin, these should be bathed with copious amounts of cool water.

4

- As for every compound applied on the skin, an allergic reaction against every compound of Farnilon is possible.

How to store Farnilon?

The expiry date (month, year) appears on the package after the abbreviation 'exp:'. This medicine should not be used after this date. This medicine should be kept at room temperature (15-25°C). Place out of reach of children.

This leaflet was last revised in December 1992.

5

Farnilon© **information for patients**

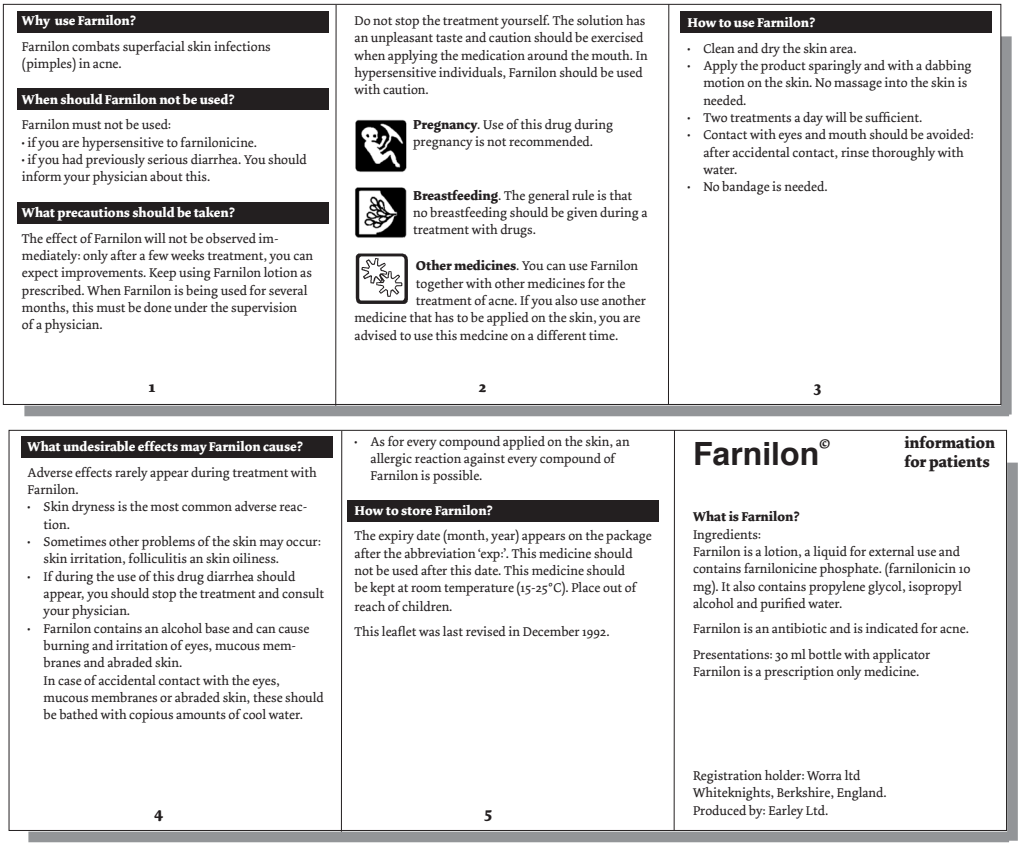
What is Farnilon?
Ingredients:
Farnilon is a lotion, a liquid for external use and contains farnilonicine phosphate. (farnilonicin 10 mg). It also contains propylene glycol, isopropyl alcohol and purified water.

Farnilon is an antibiotic and is indicated for acne.

Presentations: 30 ml bottle with applicator
Farnilon is a prescription only medicine.

Registration holder: Worra ltd
Whiteknights, Berkshire, England.
Produced by: Earley Ltd.

Figure 5·18b. Farnilon insert b. Original size: 240 by 95 mm, Reduced to 55 per cent.



Why use Farnilon?

Farnilon combats superfacial skin infections (pimples) in acne.

When should Farnilon not be used?

Farnilon must not be used:
- if you are hypersensitive to farnilonicine.
- if you had previously serious diarrhea. You should inform your physician about this.

What precautions should be taken?

The effect of Farnilon will not be observed immediately: only after a few weeks treatment, you can expect improvements. Keep using Farnilon lotion as prescribed. When Farnilon is being used for several months, this must be done under the supervision of a physician.

1

Do not stop the treatment yourself. The solution has an unpleasant taste and caution should be exercised when applying the medication around the mouth. In hypersensitive individuals, Farnilon should be used with caution.

Pregnancy. Use of this drug during pregnancy is not recommended.

Breastfeeding. The general rule is that no breastfeeding should be given during a treatment with drugs.

Other medicines. You can use Farnilon together with other medicines for the treatment of acne. If you also use another medicine that has to be applied on the skin, you are advised to use this medcine on a different time.

2

How to use Farnilon?

- Clean and dry the skin area.
- Apply the product sparingly and with a dabbing motion on the skin. No massage into the skin is needed.
- Two treatments a day will be sufficient.
- Contact with eyes and mouth should be avoided: after accidental contact, rinse thoroughly with water.
- No bandage is needed.

3

What undesirable effects may Farnilon cause?

Adverse effects rarely appear during treatment with Farnilon.
- Skin dryness is the most common adverse reaction.
- Sometimes other problems of the skin may occur: skin irritation, folliculitis an skin oiliness.
- If during the use of this drug diarrhea should appear, you should stop the treatment and consult your physician.
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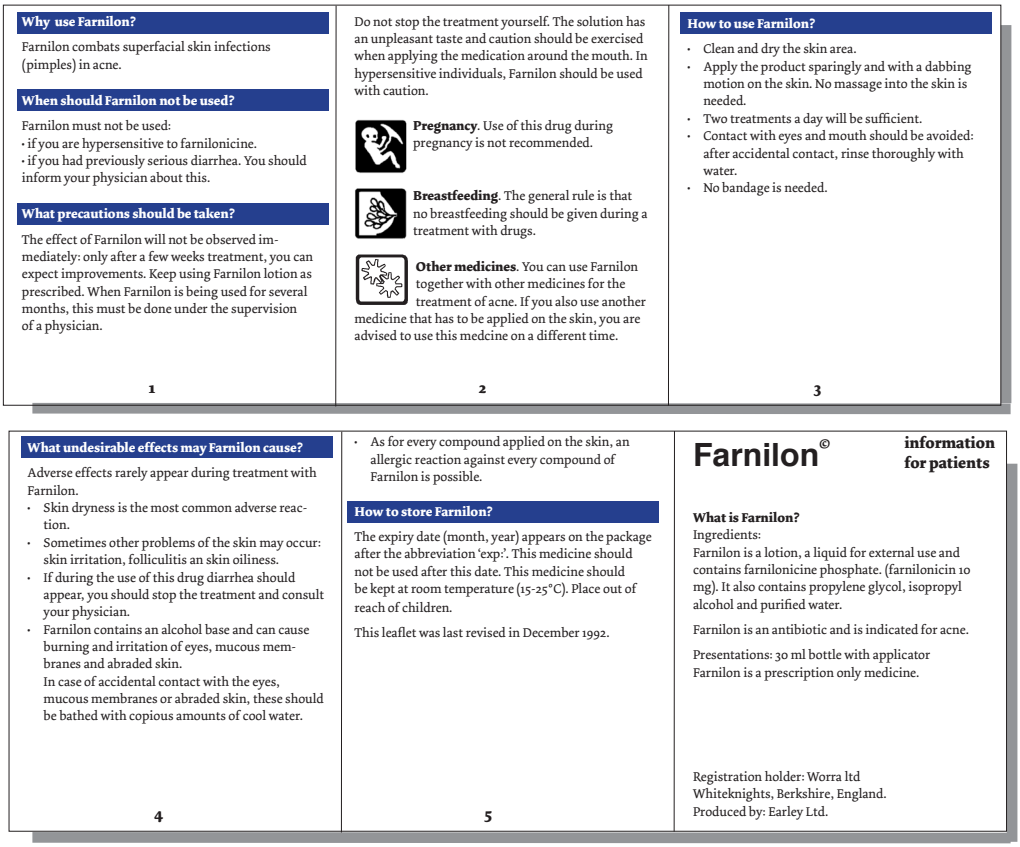
Produced by: Earley Ltd.

Figure 5·18c. Farnilon insert c. Original size: 240 by 95 mm, Reduced to 55 per cent.



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- if you had previously serious diarrhea. You should inform your physician about this.

What precautions should be taken?

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Pregnancy. Use of this drug during pregnancy is not recommended.

Breastfeeding. The general rule is that no breastfeeding should be given during a treatment with drugs.

Other medicines. You can use Farnilon together with other medicines for the treatment of acne. If you also use another medicine that has to be applied on the skin, you are advised to use this medcine on a different time.

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Figure 5·18d. Farnilon insert d. Original size: 240 by 95 mm, Reduced to 55 per cent.
Original in colour

The headings were set in Helvetica black (x-height= 1.5 mm, distance baseline heading to baseline subsequent line= 5.8 mm, distance baseline heading to baseline previous line= 8.7 mm), subheadings were set in Lucida bold (x-height= 1.5 mm, distance baseline heading to baseline subsequent line= 4.2 mm, distance baseline heading to baseline previous line= 6.5 mm). The line length is 71 mm (maximum 50 characters). Only the specification of graphic components 'Farnilon', 'information for patients', and the address of the registration holder do not fit into this description, and were specified in a different way.

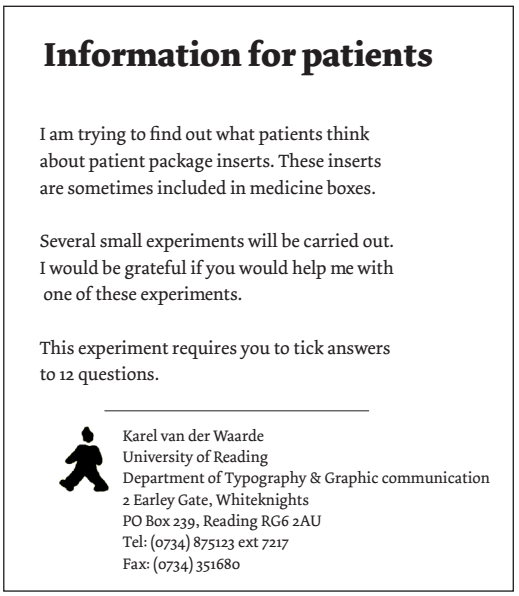
Insert b is identical to insert a, except for the headings. The text of these headings is reversed (white on black), in a rectangle of 75 mm by 5.5 mm. The distance between the baseline of the text in the heading and the previous and subsequent line was kept identical. Insert c is identical to insert b, except for the addition of three pictograms. These pictograms were placed adjacent to their descriptive subheadings. However, for this reason it became necessary to place the subheadings on the same baseline as the text, reduce the line length to 60 mm, and adjust the space between the baseline of the subheadings and the previous lines. Insert d is identical to insert c except for the use of colour. The six main headings were printed in blue. The same four variations of the insert were produced in Dutch.

Procedure.

Patients were approached in a waiting room of a hospital and asked if they would like to participate in a small experiment. An information sheet was handed over with the request to read it (figure 5·19). The second insert (b) was given to a subject to look at first. The questionnaire was handed over and the patient filled in questions 1 to 6. Then, in sequence, insert a, than c, and than d were handed over, and subjects were asked to rank the four variations. Question 8 and 9 were asked to extract opinions about the use of colour and the use of pictograms.

Subjects.

Thirty patients were interviewed in a waiting room of the Royal Berkshire Hospital and in a waiting room of the Battle Hospital in Reading (English subject group). A similar experiment was undertaken on 33 subjects in the Dutch speaking part of Belgium (Belgian subject group). A profile of the subject groups is presented in **figure 5·20**. The experiments in England were undertaken on January 27th, 28th and February 2nd and 4th 1993.



Information for patients

I am trying to find out what patients think about patient package inserts. These inserts are sometimes included in medicine boxes.

Several small experiments will be carried out. I would be grateful if you would help me with one of these experiments.

This experiment requires you to tick answers to 12 questions.

Karel van der Waarde
University of Reading
Department of Typography & Graphic communication
2 Earley Gate, Whiteknights
PO Box 239, Reading RG6 2AU
Tel: (0734) 875123 ext 7217
Fax: (0734) 351680

Figure 5·19. Consent form/ information sheet. 60 per cent reduced

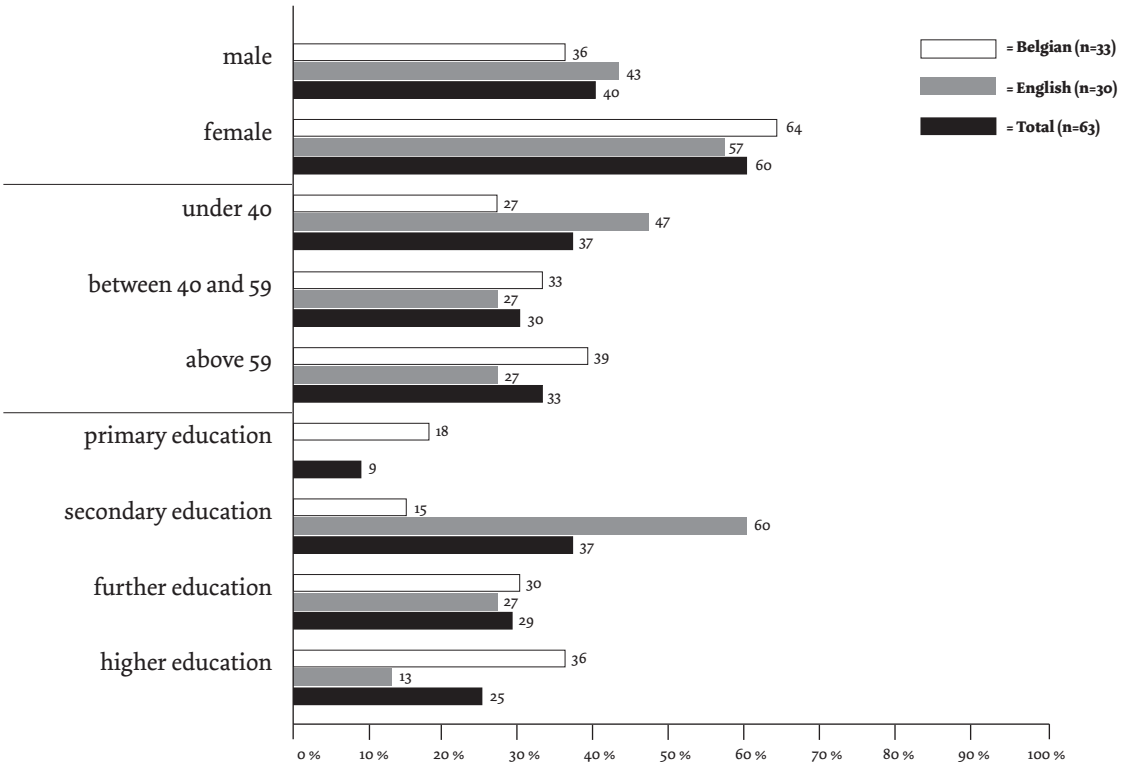


Figure 5·20. Subject profile. The figures refer to the percentage of subjects according to sex, age and educational level.

5·3·2 Results.

The profile of the English subject group was similar to the Belgian subject group. There was no significant difference between the age of the subjects in both groups (χ^2=2.56, df=2, 0.3<p<0.2). There was no significant difference between the number of female and male subjects in the samples (χ^2=0.32, df=1, 0.7<p<0.5). However, there was a significant difference in the educational level (χ^2=14.61, df=3, 0.01<p<0.001). This might have been caused by a difficulty in the comparison of the different educational systems between the two countries. The English and Belgian results are combined in the graphs that are reproduced in **figures 5·21 to 5·27**. Some of the patients' reactions in English were noted verbatim. The following section only describes the results of the experiment in Reading. It would be difficult to provide accurate translations of the reactions of the Flemish subjects. However, some results from the Belgian experiment will be mentioned.

The responses to the first six questions are related to insert b (**figure 5·18b**). The responses to questions 1, 2, and 3 were positive (**figure 5·21**). Twenty two subjects found the overall impression good, 4 very good, 3 neutral, and 1 poor. The subject who found the insert poor, and that is probably more interesting, stated that she thought that for a skin product for younger patients, all the information should be on one side, and should be presented in a more attractive way (female, 40-59, secondary education). Most subjects reacted with statements like: 'good idea, everything you need to know' (male, >59, secondary education), 'quite useful, seems fairly clear' (female, <40, secondary education), 'not too waffly, all medicines should have inserts like these' (female, <40, further education).

The answers to question 4 seem to indicate that the insert was well organized (**figure 5·22**). Twenty five subjects found the insert well organized. Three found it very well organized, 1 subject ticked neutral, and the same subject as is mentioned above found the insert poorly organized. Comments were like: 'stands out' (male, 40-59, further education), 'very comprehensive' (female, 40-59, secondary education), 'set out in language understood by laymen' (male, >59, secondary education), and 'explains everything' (female, >59, secondary education).

The type size in the insert was good according to 21 subjects, very good according to 4 subjects, and 5 subjects answered by ticking the neutral box (**figure**

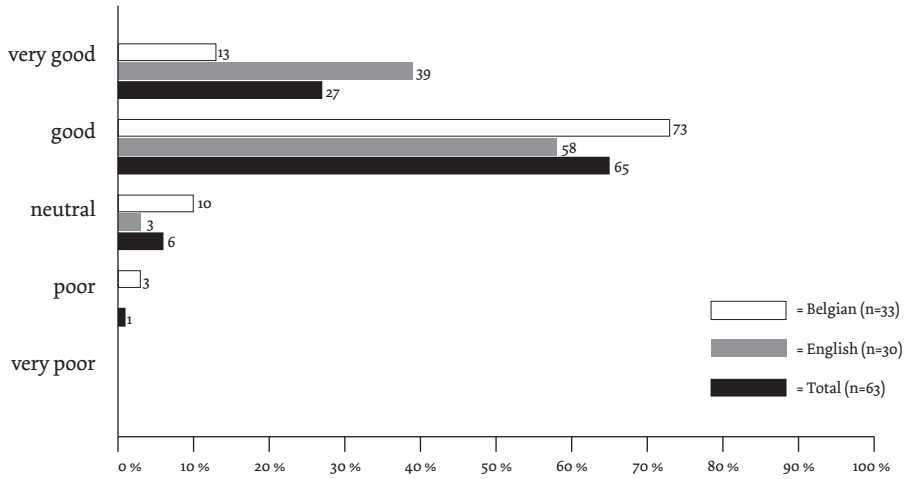


Figure 5·21. Overall impression of insert b.

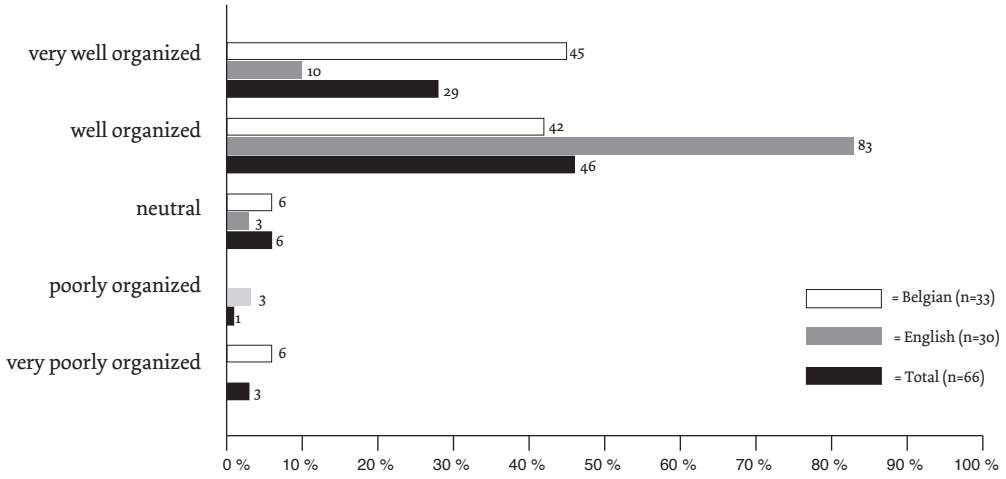


Figure 5·22. Organization of insert b.

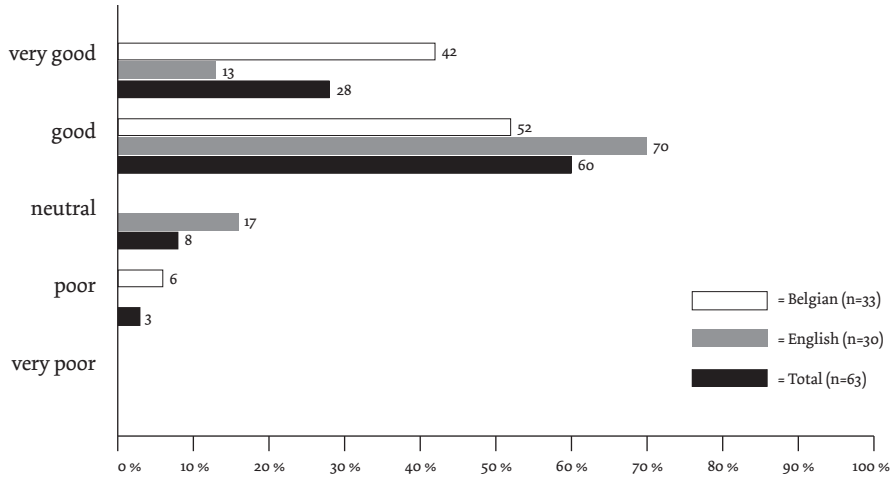


Figure 5·23. Type size.

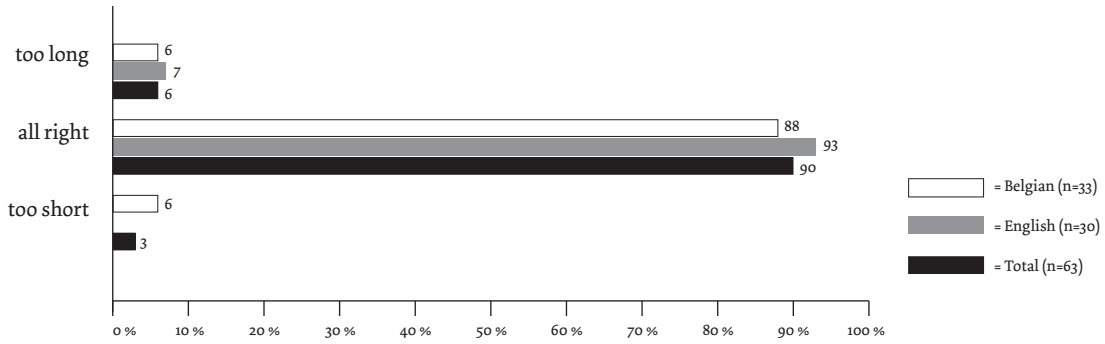


Figure 5·24. Length of the insert.

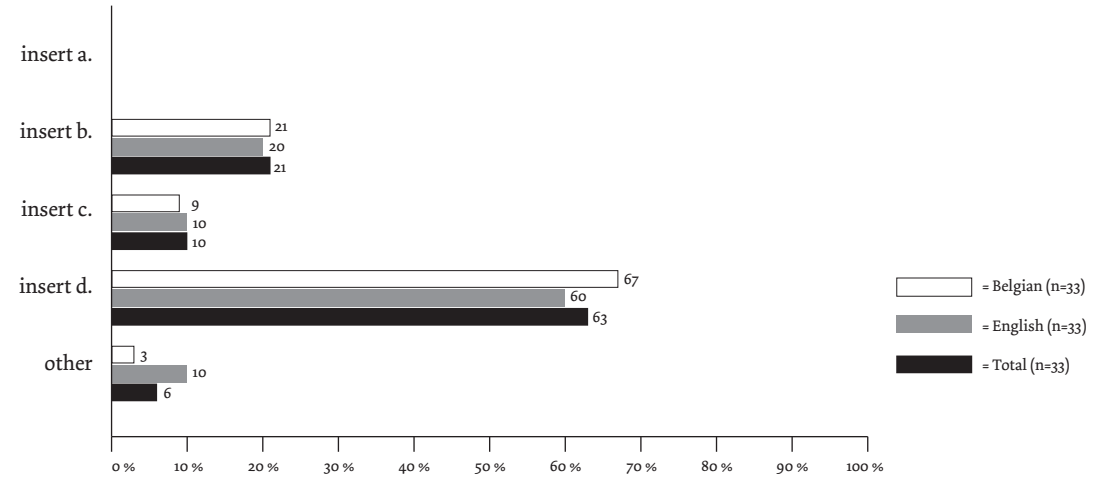


Figure 5·25. Preferences for insert. The inserts are reproduced in figures 5·18a-d.

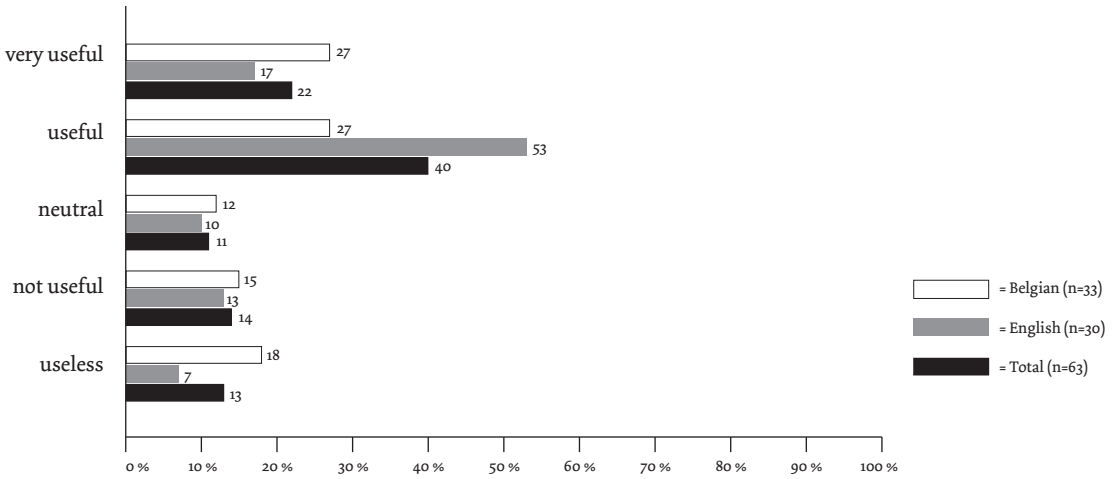


Figure 5·26. Usefulness of pictograms.

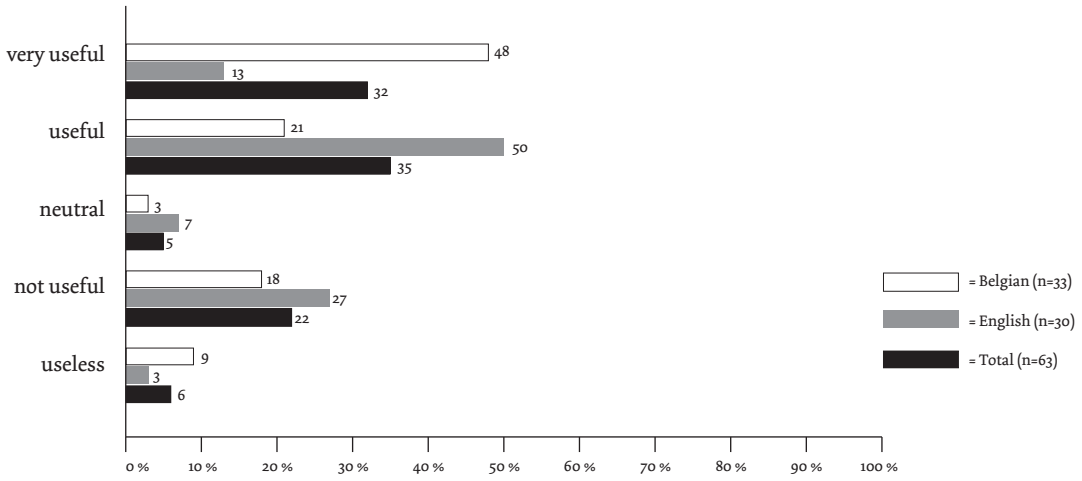


Figure 5·27. Usefulness of colour.

5·23). These responses gave a different opinion from the spoken reactions. Subjects stated that they did not have any problems with the reading of this type themselves, but that they assumed that other people would have problems. The reactions were: 'could do with a bit bigger' (female, >59, higher education), 'should be bigger' (female, <40, further education), 'no problem' (female, >59, secondary education), 'it's ok without glasses' (female, 40-59, secondary education). There were no significant relations between age and type size, or male/female and type size.

The length of the insert was all right for 28 subjects in Reading (**figure 5·24**). Two subjects found the insert too long. The comments were: 'about right' (female, >59, secondary education), 'certainly would read it all' (female, 40-59, secondary education), 'information is there, just pick out what is relevant' (male, 40-59, secondary education).

At this point, the subjects were given three other inserts. First, insert a (**figure 5·18a**) was handed over. Than insert c (**figure 5·18c**), and insert d was handed over last (**figure 5·18d**). There is some variation in the responses and there is a difference in the responses and the comments of subjects (**figure 5·25**). Eighteen subjects preferred insert d, 6 subjects preferred insert b, 3 subjects preferred insert c. One subject wanted to see insert d without the pictograms. This was also the opinion of the Belgian subject who is classified in **figure 5·24** preferring another insert. One subject would have liked insert a with the pictograms, and one subject stated that there was no difference between the inserts. The similarity in the responses between the subject groups in Belgium and England seems remarkable. The main reasons to choose insert d were: 'catches your eyes' (female, 40-59, secondary education), 'draws peoples attention to it' (female, >59, secondary), 'stands out' (female, 40-59, secondary education), 'visually easier to read and interpret' (female, <40, further education). The reasons to choose insert b were: 'takes everything into account, it is enough' (female, >59, secondary education), 'not too fussy, is perfectly adequate' (female, <40, further education), 'you can turn to it easily' (male, 40-59, secondary education).

The responses to question 8 showed a variation as to the usefulness of the pictograms (figure 5·26). Sixteen subjects found the pictograms useful, 5 found them very useful, 4 responded with not useful, 3 neutral and 2 found them useless. One of the more frequent reactions was that pictograms might help people who have problems with reading. Comments like: 'for people who can't read so easily' (female, <40, secondary education) and 'some people can't take it all in, don't know what you are on about, they might just add something' (male, >59, secondary education), 'for people who can't read, will help' (male, 40-59, secondary education). Others subjects saw the pictograms more to attract attention. 'stands out and you read it' (female, 40-59, secondary education), 'makes you read them' (male, <40, secondary education), 'draws it out' (female, 40-59, secondary education), 'jump out more' (male, <40, secondary education), 'drawn to them, attracts attention, for me it makes no difference' (female, 40-59, secondary education), 'pictograms are without glasses

necessary' (male, 40-59, further education). Several subjects were very positive about the use of pictograms in this insert. Their comments: 'pictures gives thing in mind what it actually is' (female, 40-59, secondary education), 'very useful to a lot of people, quick look and recognize' (female, >59, secondary education).

On the other side, several patients criticized the use of pictograms. Their responses ranged from: 'doesn't matter' (female, >59, secondary education), 'do no like pictograms' (female, >59, secondary education), 'not really necessary, depends how intelligent you are, probably instead of reading, rather ignore them' (female, >59, higher education), 'do not see the point of pictures' (male, <40, secondary education), 'what is that symbol, don't mean anything' (male, 40-59, secondary education). A pattern in these reactions was that several subjects seem to answer by taking other people into account. Pictograms would be useful 'for people who can't read' was mentioned 6 times. Subjects expected that pictograms would be useful for older patients. This was mentioned 4 times. However, when the results of the older group (>59 years) were analysed, pictograms were not favoured more by this group than in other age groups.

The responses to question 9 showed that 15 subjects found the colour in insert d useful, 8 subjects found the colour not useful, 4 subjects found the colour very useful, 2 ticked the neutral box and 1 subject found the colour in insert d useless. These results are represented in figure 5·27. The comments fall into two groups: the group of subjects who favour the use of colour in this insert, and the group of subjects who dislike the colour. The comments in the last group are mainly along the lines of: 'not necessary' (female, >59, secondary education), 'doesn't matter' (female, <40, further education), 'no point' (male, <40, secondary), 'breaks it up, same colour is easier to read' (female, 40-59, further education), 'not useful, only makes it attractive' (female, <40, higher education).

The subjects who found the colour useful commented along the lines of: 'highlighting the questions more' (female, <40, secondary education), 'stands out, look at it and read it' (male, <40, further education), 'helpful, look again, look quickly, it makes you read it' (female, >59, secondary education), 'like it, stands out' (female, 40-59, secondary education), 'brings it to the person more readily' (female, >59, higher education), and 'draws attention to relevant paragraphs for you' (male, <40, secondary education). Several comments indicated that the difference between the inserts was not so much that the colour would make a difference. The colour was 'not necessary' (male, 40-59, secondary education), 'doesn't matter' (female, <40, further education), 'it is all in it anyway' (female, <40, further education).

5·3·3 Discussion.

This section makes some concluding remarks about the third experiment. Some of the results of this experiment seem to indicate that a majority of the patients liked insert d. However, the results need to be carefully interpreted because the sample size is small. Some of the results might therefore not be reliable, although the results of the experiments in England and in Belgium were similar.

Four issues need to be mentioned before a more general conclusion can be formulated. These four issues are the relation of the graphic presentation with the descriptive framework of figure 4·4, the questionnaire, the subjects and the results. All four are briefly described below. These issues are described in more detail in section 5·4.

The differences between the graphic presentation of the information in the four test inserts was small, but could easily be seen by subjects. The content of this insert was not investigated, although some topic elements could have been formulated more appropriately. None of the subjects in the English experiment commented on the content of the insert. Again, as in the first two experiments, there was a mismatch between the medicine (an anti acne lotion) and the subject group. Only one subject in the English group mentioned that 'she would be a bit too old for acne' (female, >59, secondary education).

Questions in the questionnaire asked subjects to respond at two levels of the descriptive framework. On the first level, subjects were asked to comment on the type size and the pictograms. On the third level, the overall organisation, the overall impression and the length of the insert were questioned and a choice between alternative graphic presentations was asked for. This will be discussed further in section 5·4. There were several problems with the questionnaire. The first one is the translation of the questions. The choice of words in the questionnaire in Dutch and English probably influences the comparability of the results. An accurate translation of the questions does seem to be difficult and a compromise had to be made. A second, and minor, problem with the questionnaire are the

differences between the educational systems in England and Belgium. Despite pilot tests, the education level of subjects is not satisfactorily established, and is therefore not comparable between the countries.

A possible difference between the subjects in Belgium and the subjects in England was, that most of the Belgian subjects will have seen inserts before, while the English subjects reacted without this previous knowledge.

The results of this third experiment are only interpreted in order to get an indication of opinions of patients. There is a high degree of agreement within subject groups in Belgium and England about the overall impression, the organisation, the type size, and the length of the insert. The subject groups were divided about the use of pictograms and the use of colour in inserts. It is my impression that subjects made assumptions about the graphic presentation on behalf of other patients. This became clear when subjects were asked about the type size and pictograms. During the experiment, all subjects seemed to be able to read the insert, so it might be assumed that the type size was large enough. However, several subjects wanted to increase the type size. Not because they could not read the type themselves, but because they thought that other people would have problems with the reading. The criticisms on the pictograms seem to reflect the same impression. Subjects like or dislike pictograms, but assume that they will be appropriate for other patients. Some subjects did not find them useful for themselves, but assumed that they would be good for other people.

Two conclusions can be drawn from this experiment. In the first place, there is agreement between the 63 subjects about the organization, the overall impression, the type size, and the length of the insert. Responses about the usefulness of colour and pictograms were more varied. In the second place, this experiment indicates that a group of subjects can be interviewed about the graphic presentation on level 1 and on level 3 of the descriptive framework. Subjects can make judgements about the graphic presentation and notice differences between graphic presentations. Although opinions and preferences are not measures that monitor the effectiveness of graphic presentation, the results of this experiment indicate that graphic presentation influences responses of subjects.

5·4 Review of experiments.

This section describes the scope and some of the limitations of the results of the experiments. The section ends with a description of some preliminary conclusions. The purpose of this section is to review some specific issues related to the conditions of the three experiments.

The three experiments were executed in order to provide some evidence of how graphic presentation influences the responses of patients. The main question was whether a modification of the graphic presentation causes a difference in the responses of patients. Two approaches were used. The first approach was an analysis and comparison of experimental results obtained from two different subject groups who saw the same graphic presentation. This approach was applied in the first and second experiment. One group of subjects was asked to separate and rank user units according to their perceived importance, and the other group of subjects was asked to rank user units according to their perceived prominence. This approach assumes that the composition of both subject groups is similar. The second approach is a direct comparison of alternative graphic presentations by subjects. Three issues need to be mentioned: the graphic presentation of the test inserts, the subjects and the experimental techniques. The experimental conditions make it necessary to make these three issues clear, in order to be able to apply the results to other inserts.

The first issue is related to the graphic presentation of the test inserts. An analysis of the graphic presentation of the inserts used in the three experiments shows that features on the first, second, and third level of the descriptive framework were investigated. Four points need to be mentioned with regard to this graphic presentation. In the first place, only a very small number of components, relations between components and overall graphic presentations were experimentally investigated. Secondly, it is evident that the graphic presentation of an insert must be treated as one entity. Although the descriptive framework is divided into three levels, it is clear that a modification of a single graphic component on level 1 will alter the relations between graphic components on level 2 and the overall presentation on level 3. Thirdly, the result of the development of the modification of the insert of experiment 1, and the development of the four variations of the inserts of the third experiment could

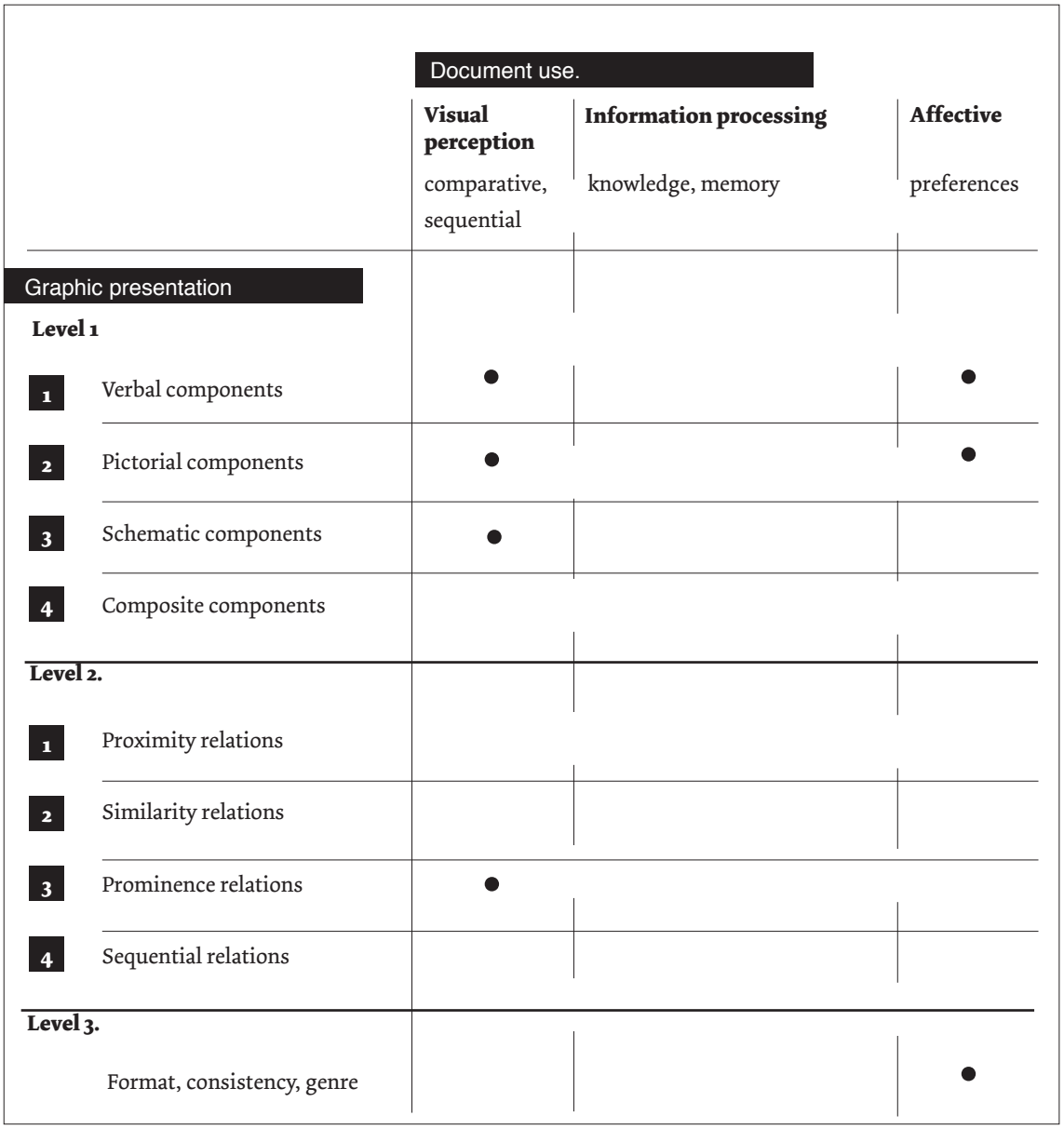


Figure 5·28. The document-use matrix.
A • indicates that some features of this cell have been investigated.

have been different. Other developers of graphic presentation could have interpreted the experimental results in a different way, and could have applied these results in a different way to the graphic presentation. After the second experiment, it became clear that the modifications made could have been more daring. The fourth point that needs to be made is that the inserts used in the three experiments are all about relatively minor ailments. An allergic inflammation of the eye, or acne, cannot be seen as representative of other ailments. This might reduce the possible application of some of the conclusions to inserts for medicines for long term use, or for major illnesses. However, the choice of inserts of relatively minor ailments was essential in order to be able to approach patients in waiting rooms.

The second issue is related to the subjects in the experiments. In total, 125 subjects were interviewed in

three experiments. The majority of these subjects can be classified as patients. Although these numbers can certainly not be seen as representative of the population of users of the inserts about eye drops or acne lotion, they have provided some results that seem to be generalizable. The choice of the waiting room of a hospital pharmacy, as well as the time of interviewing, might have influenced the composition of the subject groups. However, these influences on the experimental results seem unavoidable.

The third issue is related to the experimental techniques. The purpose of the techniques was to investigate the use of inserts by patients. Several techniques have been used in the three experiments: cutting, underlining, ranking of importance and ranking of prominence, and asking opinions. These techniques do not represent ordinary use of inserts and the validity of the results can therefore be debated. However, the techniques showed that modifications of graphic presentation do lead to different results.

Some aspects of these experiments can be placed in the matrix of figure 4·5 (**figure 5·28**). A bullet in a cell in this matrix indicates that the experiments provided some results in these cells. The three bullets in the perceptual column on level 1 of the graphic presentation refer to the separation of these graphic component by patients in experiments 1 and 2. The two bullets in the affective column on level 1 refer to the questions about the type size and the pictograms in the questionnaire in experiment 3. On level 2, the prominence relations between graphic components were investigated in experiments 1 and 2. However, the results of the experiments gave some indications of responses of patients about the other three relations (the similarity relation, the proximity relation, and the sequential relation) as well. The preferences of patients about the overall graphic presentation were investigated in experiment 3. It seems therefore clear, that only a few measures in a few cells were taken. The matrix also shows that several other cells could have been applied to investigate the influence of the graphic presentation on the use of inserts. Examples of other possible investigations are experiments into the understanding of pictograms, the recall of information, the recognition of the illustration (component 5 in insert 1) to mention but a few.

Experimental conclusions.

A summary of the main results of the three experiments can be reduced to four points. These four points are directly related to the cells in the matrix. However, the limitations and conditions of the experiments, as they are described above should be taken into account.

- separation/grouping of graphic components. Patients identify graphic components, and group graphic components. This identification and grouping is essential in order to be able to understand the topic, or to make this understanding easier to achieve
- comparing prominence of graphic components. Patients can compare and rank the perceived prominence of graphic components. This comparison is important, because it influences the perception of the importance of a graphic component
- patients have clear preferences for specific graphic components
- patients have clear preferences for particular forms of overall graphic presentation in an insert

Three more conclusions can be drawn in relation to the experimental method.

- the graphic presentation of information in inserts can be usefully modified according to the results of experiments. Such modification can be re-tested to establish whether it can be seen as an improvement
- measures have been developed that are able to demonstrate that features of graphic presentation can influence the use of inserts. The first measure is the level of agreement between patients' responses. This measure indicates how much a feature influences an aspect of the use of an insert. The second measure, which is probably more important, is the variation in the responses of patients to a particular feature of the graphic presentation of an insert. This measure indicates whether the graphic presentation is effective in achieving this influence
- the descriptive framework proved useful in describing and analyzing of the experimental results

These points all seem to lead to the conclusion that some specific features of graphic presentation do influence some specific aspects of the use of inserts by patients, and that modification of graphic presentation does alter the responses of subjects. This is the experimental proof of the main hypothesis of this investigation.

6 Discussion.

This study set out to investigate the influence of graphic presentation of information in inserts on the use of these inserts by patients. Section 6·1 provides a summary of the conclusions of the whole investigation. This section summarizes the conclusions in the three points that are mentioned in the introduction: patient package inserts, graphic presentation, and document use. The fourth point re-evaluates the experimental method and the final point in section 6·1 mentions three main conclusions of this thesis related to the influence of graphic presentation on the use of patient package inserts by patients. Section 6·2 discusses some possible developments that could be pursued as a result of this investigation.

6·1 Summary of the conclusions.

This section presents a summary of the conclusions of this investigation and is divided into five sections. The first three sections describe graphic presentation of information, patient package inserts, and use of inserts by patients. The last two sections describe the investigation method, and summarize the conclusions of this thesis. The sequence of the description of these points follows the sequence of the chapters in this thesis.

6·1·1 Patient package inserts.

Current medical and pharmaceutical practice is not specifically equipped to supply information about medicines to patients. An adequate information supply is essential in order to stimulate and increase the appropriate use of pharmaceutical products. This is discussed in chapter 1. Four aims in supplying printed information to patients were distinguished: to increase knowledge, to change attitudes, to improve compliance and to increase appropriate reactions of patients. These aims are described in section 2·2. The patient would like to receive more information about medicines in order to know more about medicines, to react correctly, and to reduce anxiety. These issues are described in section 2·4. Patient package inserts could provide this information.

A number of medicines are already accompanied by an insert, and investigations have shown that a high proportion of patients read inserts (figure 2·2). Although the supply of inserts appears to be a good idea, evidence for this idea is still dispersed and inconclusive. The appearance of several types of inserts make the study of the usefulness of inserts diffuse. An overall assessment of the value of the supply of patient package inserts is therefore difficult to give at this moment.

6·1·2 Graphic presentation.

This study set out to investigate one facet of the patient package insert: graphic presentation. Two main approaches were used in this study. The first approach is the distinction of the graphic presentation into a producers' domain and into a patients' domain. The relation between information content and graphic presentation (concordance) falls in the producers' domain. The relation between graphic presentation and use (suitability) falls in the patients' domain. This division made it possible to concentrate on the influence of graphic presentation of information in inserts on the use of these inserts by patients.

The second approach is the division of the graphic presentation into several features. Several frameworks are discussed in section 4·2, and a modified framework is proposed in section 4·3. The modified descriptive framework proved useful in the analysis and description of graphic presentation. It also proved useful in reviewing experimental studies, and during the analysis of the experimental results.

6·1·3 Use of patient package inserts.

The third point of this summary that was investigated in this thesis is the use of inserts by patients, or the more general area of document use. There are two conclusions in this section. The first conclusion is that a crude division of aspects of document use that can be influenced by graphic presentation can be made. These aspects are described in section 3·2. This categorization proved, despite its coarseness, useful during this investigation. The second conclusion is that two measures can be used for an investigation into the suitability of graphic presentation. The first measure is the level of agreement between the responses of patients about a feature of the graphic presentation. This level of agreement can be determined by monitoring the responses of patients. The second measure is the variation in these responses.

Some aspects of the perceptive (grouping, separating, identifying) and affective (preferences) fields were investigated, and it was shown that aspects in these fields are influenced by graphic presentation. What the effects of these influences are on comprehension, attitudes, and behaviour of patients is not further pursued in this investigation.

6·1·4 Investigations.

The combination of graphic presentation and patient package insert use was visualized by a matrix (figure 4·5). This matrix illustrated the combination of some aspects of insert use with some features of graphic presentation. Two conclusions can be drawn in this section.

In the first place, this study shows that it is necessary to incorporate the context into a suitability investigation. The combination of the features of

graphic presentation and aspects of insert use that are investigated need to be carefully chosen, in order to be a reliable indication of the intended use of inserts. The intended use of inserts is discussed in sections 2·5·1. Although one of the aims of the supply of inserts is to increase the knowledge of patients, comprehension was not investigated. The main reason for this omission is that there is no indication that graphic presentation has an influence on any comprehension measure. It was therefore more rewarding to focus, in the first instance, on measures in the field of visual perception and on preference measures.

The second conclusion of this section is that this form of investigation provides two kinds of results. The first kind of result is verifiable and is generalizable. The second kind of result is only applicable to the test insert. This study has shown that some generalizable results, as well as more specific results can be generated by the same investigation.

6·1·5 The influence of graphic presentation on insert use by patients.

There are three main conclusions of this investigation into the influence of graphic presentation of information in inserts on the use of those inserts by patients. The conditions and limitations that are mentioned above need to be taken into account.

- graphic presentation of information in inserts does influence the use of these inserts by patients. The experimental results showed that some aspects of the use are influenced by some features of graphic presentation
- the level of agreement between patients, about the influence of a feature of a graphic presentation on an aspect of the use, is an indication of the suitability of graphic presentation. The experimental results showed that the level of agreement can be ascertained, and that a modification of the graphic presentation can improve this level of agreement
- the suitability of a graphic presentation can be seen as an indication of effectiveness of graphic presentation. A suitable graphic presentation is an essential condition for a usable insert

6·2 Further developments.

This second section of the final chapter describes some areas that could be further investigated. These areas seem to be expansions of most of the issues that are raised during this investigation. The areas can be divided into three main groups. The first group are developments which are directly connected to suitability investigations. These areas are described with the aid of the matrix of figure 4·5. The second group looks at expansions of the use process and of the development process. And the third group looks at the application of the approach of this investigation to other types of documents.

6·2·1 Suitability.

There are at least four questions related to suitability that could be explored. A first area is the categories of the division of the use process. These categories were used to separate different aspects of the use of inserts. It is recognized that this division is coarse, and that a more detailed categorization could be beneficial. Other column headings, for example by substituting aspects of insert use by experimental measures could be helpful as well. A second area is the choice of the aspect of the use that is used as an indicator of the 'real' use of an insert. This area would find out which cells of the matrix are beneficial and appropriate to investigate for a specific document. The aspects of the use process that could be further investigated are mainly related to the connection between graphic presentation and the interpretation of graphic presentation. Several studies have been reported in section 4·4, but it seems useful to conduct more studies into all three levels of the descriptive framework. Examples of this type of investigation could find out whether patients interpret graphic components that are placed close together (proximity relation) as belonging together, or whether graphic components that look similar are interpreted as having the same status in the topic structure. Although it seems clear that graphic presentation does not directly influence comprehension, it is an area that need to be investigated. The effect of preferences about graphic features on the use of documents needs to be explored. This choice of cell of the matrix is also important when the validity of the simulated use of an insert needs to be discussed. The third area is the exploration of evaluation techniques. It might be the case that each cell in the matrix needs a specific

evaluation technique. The different kinds of evaluation techniques need to be described, compared, and validated.

In the fourth place is the discussion about the application of the results of a suitability investigation. This is the relation between the results of a scientific enquiry and a specific document-use investigation, as it is recently discussed by Sims-Knight (1992). It seems useful to investigate this relation between scientific inquiry, and the evaluation of graphic presentation. The conditions under which scientific results can be applied to specific graphic presentations, and the effect on the user of a document if graphic presentation contravenes these results need to be made clear.

The combination and application of these four points could lead to more experiments. These experiments are essential to acquire more information about the relation between insert use and graphic presentation. Initially, it seems therefore beneficial to conduct several small scale experiments. These experiments could provide indications which can be verified in larger scale investigations.

6·2·2 The development and use of inserts.

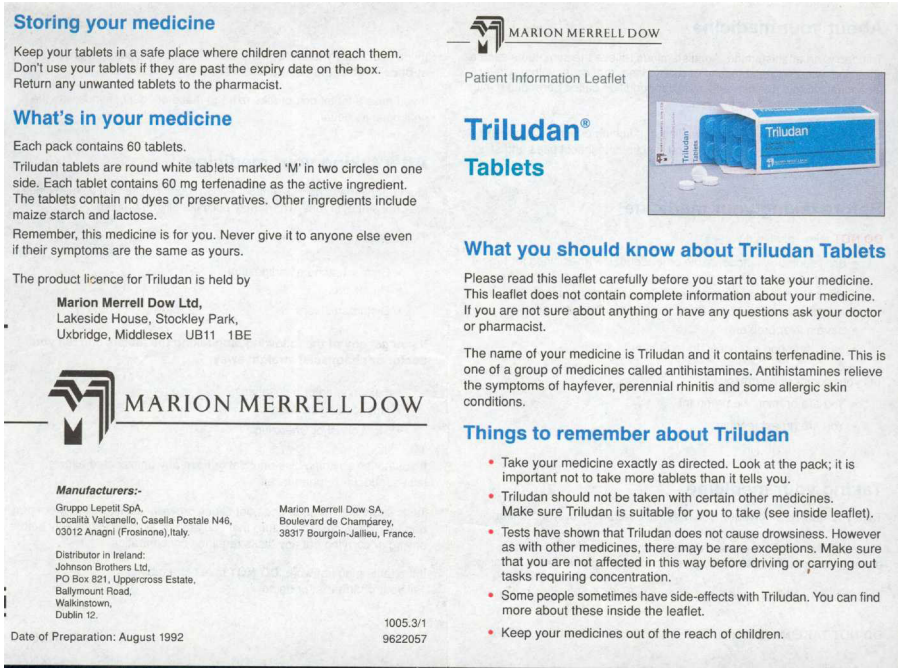
The division between the development process and the use process is applied again in this section. Investigations into the development process could study the relation between the topic and graphic presentation. The investigation into the concordance of graphic presentation with the information content need to find out if it is possible to determine a level of concordance, or if different graphic presentations of the same topic can be seen as equally concordant. This investigation assumed that the development of graphic presentation in inserts is always a compromise between the concordance and the suitability. Two diverging strands can be followed. The practical strand suggests that in order to develop effective inserts, it is essential to conduct experiments, and integrate results into the graphic presentation. However, although it is certainly beneficial to undertake some sort of evaluation, the invested time and effort need to be balanced with the improved effectiveness. A secondary issue is that the results of experiments related to graphic presentation should be published. The publication of findings might however conflict with the commercial interests of developers of inserts. A collection of inserts, as for example in a compendium, could be very helpful, as long as the original graphic presentation is reproduced. **Figure 6·1** provides a current example of an insert, and could be compared with figure 1·0. From a theoretical point of view, it seems interesting to investigate the compromise between suitability and concordance.

A second area that needs to be investigated could also take the ethical aspects of information provision to patients, and the influence of the graphic presentation on this provision into account. It is clear that graphic presentation can deceive patients. These ethical aspects are a worthwhile area to explore, especially with regard to information about side effects, indications, and precautions. Other areas that seem interesting to develop further in the development process domain are the aesthetical, financial, legal and production areas.

A last point that certainly deserves some attention from researchers is the development of regulations for the graphic presentation of information in inserts. The regulations are not meant as a specification for the production, but as a method to legally enforce and control graphic presentation. The benefits and disadvantages, possibilities and scope of this type of regulations needs to be investigated.

6·2·3 The application of the approach to other documents.

It seems clear that the approach of this investigation is not applicable to all types of documents. One of the issues that needs to be investigated is the relation between different types of information. A single printed document frequently contains more than one type of information. Inserts are a case in point, but most manuals, time tables, food labelling, and textbooks contain several different types of information. It might be necessary to identify those kinds of information that are essential to provide in printed form. Two basic requirements seem to be essential for this type of information. The user must use the information: not using it will have negative consequences. The other requirement is from the developers side. The information must be supplied in a printed form: not supplying this information could have negative consequences. It could therefore be more beneficial for further investigations to focus on different types of information.



Storing your medicine

Keep your tablets in a safe place where children cannot reach them.
Don't use your tablets if they are past the expiry date on the box.
Return any unwanted tablets to the pharmacist.

What's in your medicine

Each pack contains 60 tablets.

Triludan tablets are round white tablets marked 'M' in two circles on one side. Each tablet contains 60 mg terfenadine as the active ingredient. The tablets contain no dyes or preservatives. Other ingredients include maize starch and lactose.

Remember, this medicine is for you. Never give it to anyone else even if their symptoms are the same as yours.

The product licence for Triludan is held by

Marion Merrell Dow Ltd,
Lakeside House, Stockley Park,
Uxbridge, Middlesex UB11 1BE

MARION MERRELL DOW

Manufacturers:-

Gruppo Lepetit SpA,
Località Valcanello, Casella Postale N46,
03012 Anagni (Frosinone), Italy.

Marion Merrell Dow SA,
Boulevard de Champarey,
38317 Bourgoin-Jallieu, France.

Distributor in Ireland:
Johnson Brothers Ltd,
PO Box 821, Uppercross Estate,
Ballymount Road,
Walkinstown,
Dublin 12.

Date of Preparation: August 1992

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MARION MERRELL DOW

Patient Information Leaflet

Triludan®
Tablets

What you should know about Triludan Tablets

Please read this leaflet carefully before you start to take your medicine. This leaflet does not contain complete information about your medicine. If you are not sure about anything or have any questions ask your doctor or pharmacist.

The name of your medicine is Triludan and it contains terfenadine. This is one of a group of medicines called antihistamines. Antihistamines relieve the symptoms of hayfever, perennial rhinitis and some allergic skin conditions.

Things to remember about Triludan

- Take your medicine exactly as directed. Look at the pack; it is important not to take more tablets than it tells you.
- Triludan should not be taken with certain other medicines. Make sure Triludan is suitable for you to take (see inside leaflet).
- Tests have shown that Triludan does not cause drowsiness. However as with other medicines, there may be rare exceptions. Make sure that you are not affected in this way before driving or carrying out tasks requiring concentration.
- Some people sometimes have side-effects with Triludan. You can find more about these inside the leaflet.
- Keep your medicines out of the reach of children.

Front

About your medicine

Triludan is an antihistamine. Antihistamines relieve the symptoms such as sneezing, watery eyes, blocked or runny nose, that occur with hayfever (seasonal allergic rhinitis), and a similar condition called perennial rhinitis, that continues throughout the year.

They also relieve the redness, swelling and itching of some allergic skin conditions including nettle rashes and reactions to insect bites and stings.

Before taking your medicine

DO NOT take Triludan if you

- are taking oral ketoconazole or itraconazole (medicines for fungal infections) or erythromycin (an antibiotic). These will have been prescribed for you by a doctor. Tell your doctor or pharmacist if you are taking any other medicines prescribed by a doctor.
- have a liver problem
- have ever had a reaction to terfenadine

Tell your doctor or pharmacist if:

- You are or might be pregnant
- You are breast feeding.

Taking your medicine

Take your tablets with water. You may take them with or without food.

The adult dose is two tablets daily:
either take one tablet twice a day or two tablets together in the morning.

The dose for children aged 6 to 12 years is half a tablet twice a day.

DO NOT TAKE MORE THAN THE DOSE RECOMMENDED ABOVE.

If you accidentally take too many tablets, ask your doctor for advice **at once** or go to the nearest hospital casualty department.

If you miss a tablet do not take extra to make up, but continue with the next dose as usual.

After taking your medicine

Most people have no side-effects with Triludan but as with all medicines it may not suit everyone. There may occasionally be problems.

These may include:

- Stomach ache or indigestion
- Headache
- Disturbed sleep

If you get any of the following stop taking the tablets and tell your doctor or pharmacist straight away:

- Fainting and/or palpitations
- Unexpected swelling
- Tight chest or wheezing

If you notice anything else unusual or have any unexpected effects, tell your doctor or pharmacist.

Tests show that Triludan does not cause drowsiness. However, there may be rare exceptions. Make sure that you are not affected in this way before driving or carrying out any tasks requiring concentration.

If the tablets do not work, **DO NOT** take extra tablets.
Tell your pharmacist or doctor.

1005.3/2

Back

Figure 6·1. Patient package leaflet for an Antihistamine.
(Triludan Tablets, Marion Merrrel Dow, Uxbridge, England (1992).
60% reduced (original size: 200 by 148 mm). Original in four colours

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