About the MRFG/CMD(h) concept paper

Some comments on the 'MRFG/CMD (h) concept paper - Achieving harmonised patient information.'

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Summary

The concept paper mentions two aims related to package leaflets and labelling: harmonisation and quality improvement. Several positive developments are mentioned, such as the suggested co-operation between manufacturers (point 9), the PIM-project (point 10), increased user involvement (point 11-16), and provisions for the visually impaired (point 20). The concept paper further states that the templates, guidelines and procedures need to be updated and developed to achieve these aims (point 2-8 and 17-19).

Overarching principles and current guidelines: a conflict?

The main guidance documents for the development of package leaflets are the QRD-templates (provided by the EMEA) and the Readability guideline (European Commission, DG III). Both these documents are strongly 'text-centred'. Their main purpose is to provide guidance on how to develop documents. This approach is in conflict with Directive 2004/27/EC, which is 'user-centred'. The aim of the Directive is to provide people with information to enable correct use of medicines.

This conflict between text-centred guidance and user-centred information comes to light in every diagnostic test of a package leaflet. Diagnostic tests of the practical value of the EMEA-template and the Readability guideline would have indicated this conflict. Unfortunately, these tests have not been conducted.

Improving the quality of patient information and labelling with the aid of templates and untested guidance is difficult, because this guidance stifles the developments of alternatives. If the quality of information about medicines needs to be improved, then it would be beneficial to develop *user-centred guidelines*.

Testing information

The emphasis of user testing in the draft paper, and the obligation to test package leaflets in the Directive are positive developments. However, diagnostic tests are only part of a performance based document development process. Without embedding user testing into a larger process, its value remains suboptimal. Structurally involving people - patients, pharmacists, doctors, nurses - in the development of information about medicines will be more beneficial.

Concluding

'Enabling users to act appropriately' must be used as the main criterion for package leaflets, while all information must make it possible to use medicines correctly. A user-centred approach, such as is required by Directive 2004/27/EC is preferable above the text-centred approach provided in the current guidance.

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People and criteria

In the Directive, different descriptions of people are given: consumers, patients, users, and health professionals. These descriptors are not clearly defined. For example article 59(c) of Directive 2001/83/EC provides examples of *users* as 'children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions', while in article 67 of the same Directive the word *user* means *health professional*. The MRFG/CMD(h) concept paper uses both 'patients' and 'users'. Phrases like 'consultation with target patient groups' and 'user consultation methodology' indicate that these terms are synonymous. For many medicinal products that might be the case, but for medicines administered by a health professional, these two words have a clearly different meaning. In order to develop and evaluate information about medicines, it is essential to make very clear for whom the information is intended.

Criteria

The Directives, guidelines and templates provide a plethora of criteria to describe the quality of information. Descriptors like 'full', 'clear', 'understandable', 'legible', 'easy to use', 'readable' and 'comprehensible' are all used. The MRFG/CMD(h) concept paper adds two more criteria in point 7. Documents must be 'interesting' and 'accessible'. The problem with all these criteria is that they are hard to quantify. Questions like 'how clear is it?', or 'is it understandable?' can only be answered in a specific situation in which a person handles a specific medicinal product. The above-mentioned criteria are therefore not very suitable in practice. Adding more unquantifyable criteria does not resolve this issue.

Fortunately, the EU-directives do mention unambiguous criteria. Directive 2001/83/EC states in point 40: '*The provisions governing 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.*' This phrase provides criteria for all information about medicines. For package leaflets, the criterion is even more specific. Directive 2004/27/EC, article 63(b)2 states *'The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals.* Directive 2004/27/EC therefore fundamentally changes the motivation to provide patients with information. Information must not only be comprehensible, but it must enable users to act appropriately.

Both 'information needs to be provided in order that medicinal products may be used correctly' and 'enabling users to act appropriately' can be accurately investigated. These phrases necessitate the involvement of people who handle medicines in practice in the document development process.

Concluding

The Directives provide criteria to establish the quality of information about medicines. These criteria provide a unequivocal basis. Careful consideration must however be given to determine which 'people' need to be taken into account, which 'actions' should be evaluated, and what 'appropriate use' exactly entails.

Principles and guidance

Conflicting principles

The fundamental conflict between the Directive and the guidance documents is that the Directive is 'user-centred, while the advice is 'text-centred'. The Directive puts the actions of users in the center, while the guidance focuses on the development of texts. If the quality of information needs to be improved, the user-centred approach is preferred (Schriver, 1999).

The EMEA/QRD-templates

Most of the issues related to the application of the EMEA/QRD-template in practice stem from the text-focused approach. The main considerations are:

- It is unlikely that a single template can optimally present information that will be used by different users in different contexts in different languages for different medicines to support different actions.
- The template does not consider the combination of information sources that are used in practice
- The template cannot detect problematic practice.
- It is unlikely that standardized information will be read in the longer term.
- The template does not help applicants because it cannot guarantee legal compliance.
- The templates gives the incorrect impression that a package leaflet can be written without the involvement of people who use the information.
- The template has not been tested. Not in English, nor in any of the other EU-languages.
- The use of a single template hampers the development of effective alternatives.
- Rigid templates are also unlikely to relate to longer term issues, such as a reduction of medication errors, improvements in medicine taking behaviour, and better balanced information about the cost-benefit ratio.

Some notes on the value of templates were written as a response to the call for comments on Version 7.0 of the EMEA/QRD-template in May 2005. Click here to download this file (WaardeEnablingTemplates.pdf, 750 kb).

The Readability guideline

The Readability guideline focuses on one side of document development: the writing and designing of text of the label and package leaflet. Strictly following the Readability guideline does not lead to full and comprehensible information, nor is it likely to enhance the correct use of medicinal products.

The testing of package leaflets is mentioned in appendix 2 of this guideline, but this activity is not integrated into a document development process.

The guidance in the Readability guideline (sections A, B, C, and annex 1B) nor the example of a model leaflet (annex 1a) has been tested in practice. Such a test would have highlighted the conflicting approaches.

Concluding

The underlying assumptions of the EMEA-templates and the Readability guideline seem to be in conflict with the European Directive. The guidance documents are text-centred, while the Directive is user-centred. If information about medicines needs to be improved, than it would be beneficial to develop *user-centred guidance*.

Testing information

Guidance
A substantial number of publications provides advice about user testing. David Sless and Rob Wiseman's 'Writing about medicines for people' (1997) forms the basis. The EFPIA guidelines provide a step by step approach in March 2003, and most recently, the MRHA has issued 'Always read the leaflet - getting the best information with every medicine' (MHRA, July 2005). With these publications, and some practical exercise, it is fairly easy to establish whether people can read, understand and apply the information in a package leaflet.

Test method: criteria, validity and reliability?
Sless and Wiseman suggest that a satisfactory result is achieved when 90% of literate adults are able to find the information requested within a package leaflet, of whom 90% can show that they understand it. This level has been copied by the most recent guidance of the MHRA.

Although it is certainly a very good practical level, it has not been investigated thoroughly yet. The validity of the test has not been established either. It is not known if the verbal response of a test-participant is directly related to the actual behaviour of a patient. The reliability of the test-method needs to be investigated too. Are the same test results achieved with different interviewers, in different test-situations, in different languages?

Integrating diagnostic tests in a document development process
The above-mentioned objections related to the criteria, validity and reliability are avoided if 'user involvement' becomes an integral part of document development processes. Diagnostic testing cannot be seen as a single activity that needs to be undertaken in the final stages before an application. User involvement in the development of documents is necessary throughout the development.

A combination of different information sources
Observing current practice will reveal that people rely on a mix of sources to find information about medicines. Focusing on the testing of package leaflets as a singular source will not be sufficient. It is necessary to look at approaches that are based on information searching behaviour of people as well. This implies that packaging needs to be shown to people too. Depending on the type of medicinal product, packaging needs to be tested by dispensing pharmacists, hospital pharmacists, nurses and/or patients.

Concluding
The involvement of patients in the development of package inserts is a positive development. However, both the embedding of user testing within a larger document development process, and the testing of several information sources need further attention. It also seems necessary to undertake some fundamental research to establish the validity and reliability of the diagnostic test method.

Terminology

The MRFG/CMD(h) concept paper mentions several terms that might confuse. The different descriptions of 'people' and 'criteria' are mentioned on page 2. Below are some of the other terms.

'Patient information leaflets' or 'package leaflets'?
'Package leaflets' is the term used in the Directive and is defined as (2001/83/EC, point 26): 'A leaflet containing information for the user which accompanies the medicinal product.' 'Patient information leaflets' might be taken to mean more general leaflets about preventive health behaviour, illnesses or even general information about hospitals that can be picked up in waiting rooms and pharmacies. It might be necessary to define 'patient information leaflet'.

'Mock-up'?
Directive 2004/27/EC states 'One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet'. In point 3, the concept paper mentions that 'applicants should ensure that mock-ups of all packaging components accompany the applicaton ...' and that 'member states will agree on a harmonized leaflet and label involving the agreement of the content, but not the lay-out'. These phrases seem to be contradictory. In a mock-up, the lay-out cannot be separated from its contents. It is not clear what exactly the difference is between 'a draft', 'a mock-up', 'content' and 'lay-out'.

If the lay-out of the information in the package leaflet is not harmonized, and it is recognized that the lay-out is important (point 7 of the concept paper), what is the value of user testing? It is likely that a well-designed, well presented leaflet is tested in one language, and that all other languages are presented without paying sufficient attention to the lay-out.

Furthermore, article 63(b)2 of Directive 2004/27/EC states specifically that '*the package leaflet must be written and designed to be clear and understandable ...*'. Excluding the design from harmonization is in conflict with this article.

It should therefore be obligatory to submit a mock-up of the package leaflet as well, as is suggested in the most recent guidance by the MHRA in the appendix to annex 5, page 96 (MHRA, July 2005).

'Diagnostic user test', 'consultation', 'assessments'?
Although the differences between these terms might seem small, it is necessary to be absolutely clear what is expected. In general, the term 'usability' seems applicable to describe a 'user centred approach' in which a variety of testing techniques are applied to evaluate whether a document enables people to achieve their aims.

Especially the plural form of 'target patient groups' and 'assessments' in articles 59(3) and 61(1) of Directive 2004/27/EC seem to imply that it is obligatory to consult more than one patient group, and undertake more than one type of assessment.

Concluding

In order to avoid confusion, it is necessary to define terms and use these in a consistent way.

Alternative approach

The main reasons to provide information about medicines - according to the Directives - are to use medicinal product correctly, to protect consumers and to enable users to act appropriately. The longer term objectives are not mentioned. These longer term aims are related to a reduction in errors, increasing therapy effectiveness (compliance/concordance), and better decisions related to risk-benefits and cost-benefits of medicine use. Information about medicines is one of the factors related to these longer term objectives.

Patients appreciate package leaflets as a reliable source of information (Vander Stichele, 2004). However, leaflets are not the only information source: people consult all available information sources. It is likely that in the not too distant future, there will be digital alternatives available *in addition to* the paper package leaflet and labelling. Especially this combination of information sources might be beneficial for patients, pharmacists, doctors and nurses. The starting point remains: information needs to enable people to act appropriately.

Alternative approach?

The combination of the longer term objectives and a user-centred approach requires a more rigorous information design process. This process is used in areas like software development, and has been applied in Australia in the development for information about medicines (Sless, 1995 a&b). Details vary, but the process can be described in 7 steps:

1. Start from best practice. Ask patients, pharmacists, nurses, doctors, what they think are the best, and the worst, examples of information about medicines. Package leaflets can be used as a start, but websites, patient information leaflets and packaging are just as important. Describe the current state of affairs through contextual enquiries and benchmarking. Collect and investigate errors. Make best practice available so that it can be used as a starting point.
2. Test best practice to standardize methods, measurements and benchmarks.
3. Test information in different contexts.
4. Involve all stakeholders. Define clear and achievable aims: which information needs to be developed to achieve what?
5. Develop prototypes in a heuristic process: write, design, test, write, design, test.
6. Implement in practice.
7. Monitoring practice, to see which changes occur and deciding if these changes warrant a new development.

Concluding

Starting from current best practice, it is possible to develop information that not only enables people to act appropriately, but also reduces potential errors and increases the effective use of medicines. It's necessary to broaden the scope of 'user centred development' from a readability test at the end of a process to a structural involvement of people in information design developments.

Conclusions

1. Define recipients and criteria accurately

The Directives and guidance use different terms to describe the recipients of information: users, patients, consumers, health professionals. They also describe many different criteria for the evaluation of the quality of a document. It is necessary to make very clear for whom information is intended, the aim that needs to be achieved, and the criteria that need to be applied to check if this can be seen as 'appropriate'.

2. Provide user centred guidance

The current guidance is mainly 'text centred'. The Directives indicate that a 'user centred' approach should be used. If the aim is to 'enable users to act appropriately', than it is necessary to focus the guidance on user centred information development. It is questionable if rigid and untested templates are helpful in this.

3. Integrate user testing in document development processes

Testing cannot be seen as a final step of a document development process. User involvement is an essential ingredient throughout the development of performance based information. Examples of user involvements are the observation through contextual enquiries to detect fundamental needs, diagnostic testing to indicate the likelihood of appropriate actions, and benchmark tests to provide accurate indications of the value of information in practice.

4. Investigate the diagnostic test itself

The diagnostic test is an effective method to detect practical problems with the use of visual information. However, the validity and reliability of this method have not been investigated.

5. Clarify terminology

The Directives and guidance do not use some terms in a consistent way. Examples are 'mock-up', 'patient information leaflets', 'user test'. It would be very helpful if some attention is given to this issue.

6. Consider alternative approaches

In order to address the larger scale issues with medicine use, such as compliance/ concordance, error rates and risk decisions, it seems necessary to consider alternative approaches to develop information about medicines. These alternatives are available. Starting from user-centred information design, and through the development of user-centred guidance, the performance of information about medicines is likely to improve.

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