A prescription for Clarity

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By Dr. Laura J Sahm and Dr. Karel van der Waarde

This article explores the efficiency and effectiveness of the visual information that patients receive when they need to take medicines. We examined a number of examples that might present problems for healthcare professionals and for patients. We then looked at these from both a pharmacists' and a designers' point of view. As an initial step, we give some of the reasons for these problems and suggest some opportunities.

What are the problems?

Several steps influence the development of patient information, and they reduce the efficiency and effectiveness of the information patients receive about medicines.

1. THREE DIFFERENT FRAMEWORKS WORK IN PARALLEL

Information about medicines can be viewed from a regulatory/legal perspective, an economic/financial perspective, and a healthcare/medical perspective, all of which have different aims.

The Regulator needs to be sure that the information conforms to the required legislation and guidelines. The manufacturer needs to comply with the Regulator but also has to balance costs and profits. The third perspective takes the health of an individual patient as the main criterion.

Unfortunately, these three perspectives run almost parallel and do not share as much common ground as would be hoped. More significantly, the actual end user –the patient – is to a large extent ignored in the development process. There is little need to pay attention to the requirements of patients as long as information conforms to the legislation and can be produced for reasonable costs. For regulators and manufacturers, there are no direct benefits to make sure that information enables patients to act appropriately.

2. A LINEAR PROCESS SEPARATES WRITING, DESIGNING, AND TESTING

The current regulatory framework in Europe separates the writing, designing and testing of information about medicines. The EMA-QRD template must be used to write the texts on packaging and package leaflets. Some parts of the obligatory texts in the template are not really suitable in all situations. On the other hand, the visual design of packaging and leaflets is largely determined by marketing and production requirements.

This separation leads to lot of text in a very small space. It does not lead to a visual design that supports patients taking their medicines appropriately.

In addition, only the package leaflet needs to be tested on a limited number (about 25) of healthy volunteers. The outer packaging is not tested, nor are combinations of three, four, or more medicine packs tested.

We argue that "best practice" should start with the patient. This would ask patients and/or those looking after the patient about their needs. Second, examples would be made in which texts and design are considered together. User testing would be done to check if understanding is reached. An iterative process would help to ensure that patients are able to act appropriately. This process would not only involve regulators and industry, but also doctors, pharmacists, patients and their caregivers.

3. PATIENTS HAVE DIFFERENT CHARACTERISTICS

The lack of individualized information also makes information about medicines hard to understand and apply. The European legislation for medicines standardizes information through a template. This approach ignores the differences between:

- patients (old/young, health literate/less health literate)
- medicines (chronic/short term, life threatening/benign)
- languages and cultures.

4. INFORMATION STRATEGY IS NOT COORDINATED

Another source of the difficulties patients have is that the information comes from many sources. A prescribing doctor provides verbal instructions; a pharmacist adds verbal/written advice and one or more labels; the industry adds the obligatory information on the outer packaging and information in the package leaflet.

In addition, patients may have to take more than one medicine, which multiplies the information from all sources. Motivated patients ask others, search on the internet, join discussion groups, and join patient associations. It is likely, however, that some patients may not ask or be able to access this information, leading to higher risks.

What are some examples?

The following examples show the potential issues from the perspective of the reader.

EXAMPLE 1: CONFUSING PACKAGING: METRONIDAZOLE & METFORMIN / ZITHROMAX / LEXAPRO.

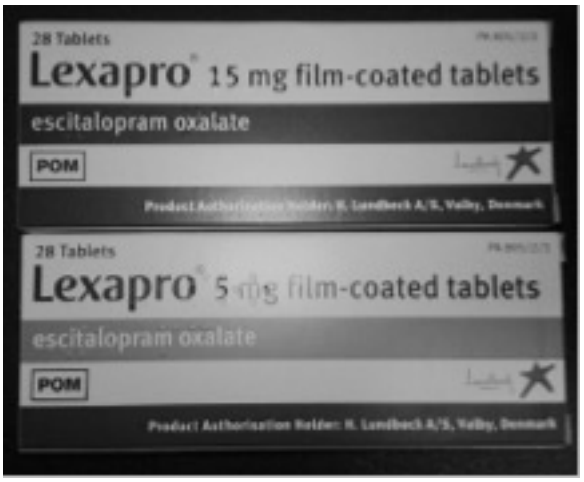
Pharmacists today are being confronted with new yet similar packaging every week. In Ireland, this is due to the introduction of interchangeable and generic medications. The increased availability of drugs with similar packaging containing different drugs and/or different strengths of the same drug increases the cognitive burden on the pharmacist. This in turn may increase the risk that a patient receives the wrong medicine.

The visual similarity of some outer packaging does not help this, as figures 1, 2, and 3 show. Whilst every pharmacist is aware of this risk and will make an extra effort during dispensing, it nonetheless introduces a risk that could be avoided if packaging was required to be noticeably different.

Figure 1 Metronidazole and Metformin.

Figure 2: Zitromax

Figure 3: Lexapro



EXAMPLE 2: POOR READABILITY OF OUTER PACKAGING FOR POM MEDICINES: PERINDOPRIL

Even if different medicines can be clearly distinguished, reading some of the vital texts on the outer packaging is made more difficult by small type, low contrast, and distorted letterforms. The visual design of the package, especially the combination of the colours, typefaces, and braille code requires extra effort to decipher the detailed information (Figure 4).

The 200mg Ibuprofen over the counter (OTC) package in Figure 5 was bought in the United Kingdom. The first instruction on the back of the box suggests the outer packaging does not have all the information, and a consumer can open the box to check the package leaflet. In practice, this is unlikely to happen. The rest of the text is very difficult to read because:

- it uses a light version of a typeface
- the type is condensed
- there is very little space between the lines
- the contrast between the black type and the grey background is low
- the background is highly reflective
- there are braille dots pushed through the text.

There is evidence that each of these factors individually does reduce readability. A combination of such factors has not yet been investigated.

Figure 4: Perindopril (POM)

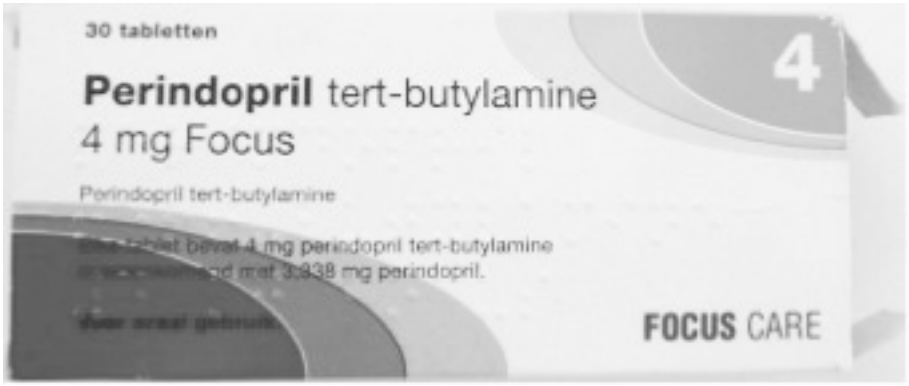
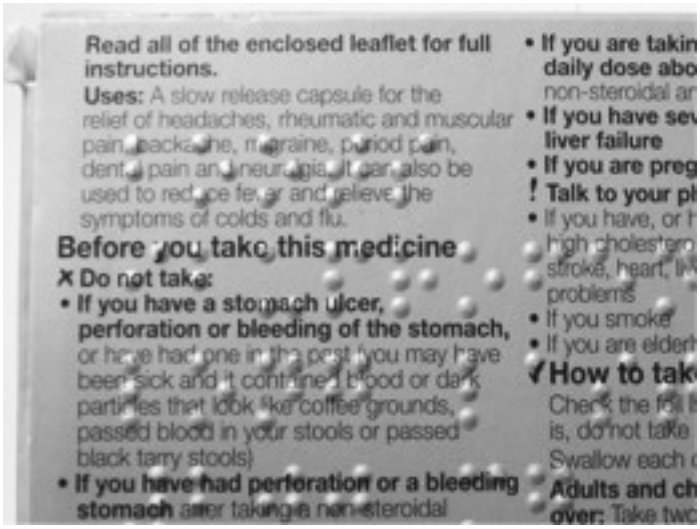


Figure 5: Ibuprofen (OTC)



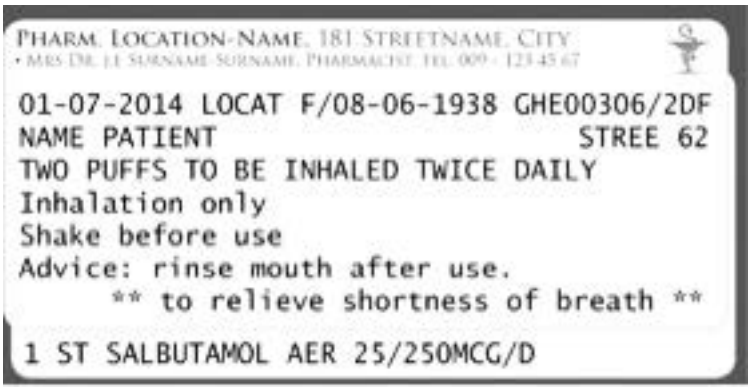
EXAMPLE 3: UNSTRUCTURED PHARMACISTS' LABELS

Pharmacists print labels with specific instructions, which are added to the medication before the patient receives it. However, as the visual design in Figure 6 shows, this information does not have either a:

- hierarchy (what is the most important?)
- sequence (in which order should I read this information?).

This problem may increase as the pill burden also increases – when patients need to take several medicines at the same time, and they must compare the different labels and work out a daily regimen.

Figure 6: Pharmacy generated labels



These examples show that some of the information patients receive is easy to confuse, difficult to read, unstructured, and hard to apply in a real life situation. Of course, not all outer packaging, inner packaging, package leaflets, and pharmacy labels suffer from all four of these issues to the same extent. It is, however, difficult to find examples that are "absolutely excellent" on all four criteria.

What would a solution look like?

It is clear that some of the regulations and guidelines need to be changed. The European Commission is aware of these shortcomings and published two reports in 2015. Unfortunately, the recommendations have not lead to any change in regulations or guidelines. The uncertainty about the future location of the European Medicines Agency – it has to leave London after Brexit – is likely to mean the provision of usable information about medicines will receive little attention in the coming years.

However, at least four actions can be taken to improve the current situation within the current regulatory framework.

1. MAKE SURE THAT THERE IS ENOUGH HIGH-LEVEL SUPPORT

To change situations, it is essential to have support from people at the top of organisations.

2. DEVELOP PROTOTYPES AND ALTERNATIVES

Prototypes can be tested to show which performance levels can be reached. We can visually enhance current information in both digital and paper media so that it can be understood by those with limited literacy and numeracy skills.

3. GET THE RIGHT DATA

To change legislation and situations, it is vital to know the current state of affairs, with measures such as the:

- number of confusing packs
- frequency of incorrect dispensing
- numbers of patients interpreting instructions incorrectly.

It is likely this kind of research will show a complete range from "best practice" to "harmful practice". But without data, it is not possible to distinguish these.

4. GET THE RIGHT PEOPLE

The solution must involve doctors, pharmacists, healthcare professionals, industry, regulators, and patients. A coordinated approach can only be based on cooperation between all stakeholders.