

Designing information about medicine for people

Abstract

1. *Situation:* In Europe, it is obligatory to provide written information with every medicine, usually in the format of a package leaflet. These leaflets are fairly long and are densely printed on very thin paper.
2. *Problem:* Readability testing and contextual inquiries indicate the practical problems of current package leaflets: they do not reach appropriate minimal performance levels. This is likely to be caused by the internal conflicts in the legislation and guidance, and the poor co-operation of involved stakeholders.
3. *Approach:* The experience with the 'writing-designing-testing process' in combination with a critical look at the current guidelines provides clear pointers for further developments. It is necessary to develop alternatives that start from the perspective of patients, are performance driven, and are context related.
4. *Discussion:* Within the current legal framework, it is unlikely that it is possible to develop package leaflets that 'enable people to use medicines appropriately'. Alternative designs will be seen as 'illegal' and will not be allowed to be used in practice. However, these alternatives are vital to stimulate discussions between stakeholders about legislation, guidelines, and appropriate information about medicines for patients.

Outline of this discussion paper

This text situates package leaflets within the larger context of providing patients with information about their medicines. The first part reviews the current benefits and risks, and points to some contentious issues. In the second part the influence of the legal framework on the writing, designing and testing of package leaflets in Europe is discussed. Both parts provide a suitable basis for discussions among stakeholders about possible approaches to improving the practical value of package leaflets. Furthermore, the results of such discussions could be used for the development of alternative designs of package leaflets and as a basis for modifications of guidelines.

1. Introduction: package leaflets

The development of 'information for patients' is only about 45 years old. Uncritically following doctors' orders is – where possible - gradually replaced by negotiating the most suitable treatment options. Where appropriate, doctors and patients start to share the responsibility for a method of treatment.

The development of written information runs parallel to the increasing involvement of patients in their own healthcare. Patient package inserts, or package leaflets are an integral part of this development. Package leaflets are tiny booklets or sheets of paper containing information about a particular medicine. They are in most cases included in the 'outer packaging', which is usually a cardboard box. Otherwise, leaflets can be glued to bottles, tucked inside the plastic cap of a spray can or integrated into the design of the box.

Before 1987, the differences between the EU countries in the provision of information about medicines were substantial. Package leaflets were obligatory in France and Germany, but they were prohibited in Denmark. There were differences in types of inserts (for prescribers, for patients), different regulatory regimes, and different contents. One medicine could be accompanied by very different types of information in different countries. This gradually replaced by negotiating the most suitable treatment options. Where appropriate, doctors and patients start to share the responsibility for a method of treatment.

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In the late 1980s, the European Department of Trade and Industry started to develop ideas to standardize the pharmaceutical market with a dual aim. The first aim was to make sure that there were no trade-barriers for medicines, and the second equally important aim was to protect the European consumer. An overview of this development was provided by Donnelly in 1991.

This led in 1989 and 1992 to Directives 89/341/EEC and 92/27/EC in which package leaflets were made obligatory. Directive 92/27/EC states:

- Every medicine must be accompanied by information. This information must be 'full and comprehensible'.
- The information in the package leaflet must be exactly the same as the information in the Summary of Product Characteristics (SmPC). [Note: an SmPC contains a succinct overview of all scientific data about one medicine.]
- The information must be presented in a strict sequence.
- The package leaflet must be written 'in clear and understandable terms for the patient and be clearly legible'.

These four points remain the basis for the package leaflet in Europe and are included in the most recent EU Directive 2004/27/EC that was published in 2004.

It seems worthwhile to revisit some of the arguments that were used around 1990 in favour of the inclusion of package leaflets. It has always been clear that package leaflets must be seen as an addition to the information provided by doctors and pharmacists. In this role, supporters of package leaflets expected that they would have the following benefits:

- Package leaflets are a permanent information source for patients. They improve the knowledge of patients, improve satisfaction with a medicine, improve doctor-patient communication, inform patients about appropriate actions (warnings, storage, side effects) and reassure patients about the benefits of appropriate treatment.
- Package leaflets are available to patients when they have to take their medicines.
- The information about a medicine and the medicine itself are always linked. For medicines that can be bought without professional advice, the package leaflet is the only source of information that can be guaranteed to be available.

There were also several arguments against the introduction of package leaflets around 1990. The opposition warned that such leaflets:

- would make patients unnecessarily anxious
- might promote inappropriate self-medication
- could cause patients to experience side effects by suggestion
- might cause patients to be more demanding
- could cause patients to reject a beneficial drug treatment altogether.
- could increase prescription medicine exchange among patients
- could 'de-mystify' medication and reduce the placebo effect.

Critics also noted that package leaflets are produced by the pharmaceutical industry, and

so this information should be treated with caution because it might be biased.

It seems that the factual influence of package leaflets had been overestimated twenty years ago. It is possible to find some evidence to support most of the early assumptions, but none sufficient to argue for specific benefits or specific negative effects. None of the arguments has proven to be absolutely true.

Since the introduction of package leaflets on a European scale, the following argument have been added to the discussion about the value of package leaflets.

'Package leaflets are not very influential.'

One of the main arguments in favour of the inclusion of package leaflets was to increase patients' knowledge about their medicines. Two recent studies indicate that this argument is not supported by practice, nor by empirical studies. Research by Lloydspharmacy (2008) indicates that 'almost one in five people admits that they have taken prescription medicines incorrectly'. The Medicine Use review – a free 20-minute discussion with a pharmacist about personal medicines – led in 55% of the reviews to a recommendation to modify the medicine-taking routine. Raynor (2007) concluded in his review that the printed information did not increase knowledge, or at least that studies did not provide much evidence in that direction. The substantial problems with adherence ('taking medicines appropriately') also point to a low effect of package leaflets on knowledge.

'Package leaflets can never reach all patients.'

There are large groups of functionally illiterate people who simply cannot understand the language of a country. Package leaflets are not suitable for this group and alternatives must be used. This argument links the provision of information in package leaflets to the more general issues of 'health literacy' and 'health education'. Although this is a valid argument, it can only partly be related to package leaflets. Package leaflets are often used as a gauge of illiteracy; but, on their own, they cannot raise the level of literacy. Nor can package leaflets provide information that is suitable for all functionally illiterate people.

The frequency of side effects provides an example. The words 'common', 'uncommon', 'rare' and 'very rare' have very different meanings for patients, doctors and regulators. Patients significantly overestimate risks related to these words. According to the European guideline, 'common' means that between 1% and 10% of patients might experience side effects. Sixty percent of interviewed patients state that 'common' is 'more than 60%' (Berry, Raynor, Knapp, Bersellini, 2004). This discrepancy between the medical/regulatory wording and the interpretations of this wording by patients frequently indicate that these are not 'clear and understandable terms'. This is not only a matter of 'health education' or 'functional illiteracy'.

'Package leaflets do not refer to digital resources.'

The current package leaflets do not refer to websites nor do they make any use of the combination of digital and printed information. Patients increasingly look for medical information on the Internet. They expect, just like for other consumer goods, that there will be relevant information somewhere on the Web. There are websites that present the information from package leaflets, but the reliability and trustworthiness of this information remains questionable.

'Package leaflets are only about one medicine.'

For patients who use several medicines at the same time, the information in package leaflets will be difficult to understand and apply. Comparing different leaflets is an arduous task. For example, if a side effect occurs, it would be very difficult for a patient to figure out which medicine is likely to be the cause. Or, trying to figure out if the combination of three medicines is possible according to the lists of interactions will take some time.

'Package leaflets about the same medicine might differ.'

Package leaflets of generic medicines need to be written, designed and tested too. (A generic medicine is a medicine which is produced and distributed without patent protection. After the patent expires, and if it is economically interesting, a few or many companies will start to produce exactly the same medicine for a lower price.) The information development process unavoidably leads to modifications to the text and design of package leaflets. Although generic medicines themselves are very close to identical, the information in their package leaflets is likely to differ.

'Package leaflets are not used in hospitals.'

Package leaflets are also obligatory for medicines that are only used in hospitals. They are very rarely given to patients, and probably never. It is an unsuitable format for hospital use.

'Package leaflets are only available at the end of the process.'

Package leaflets can be read by patients after a patient has consulted a doctor, received a prescription and made a visit to the pharmacy. Much of the information in the package leaflet comes too late and is not specifically related to the moment of reading. Particularly, the information about the contra-indications and precautions should have been discussed with the doctor during the consultation. If a patient considers these after opening the medicine box, it might only lead to a return visit to the doctor.

'Package leaflets contain too much information.'

A package leaflet must include all information of the Summary of Product Characteristics (SmPC). Especially the lists of contra-indications, precautions, and side effects can be very long. Patients question the necessity of mentioning exceptional situations and the rarest side effects.

The dual role of 'providing patients with complete information' and 'avoiding litigation' reduces the practical value of package leaflets.

Package leaflets should prevent claims against the pharmaceutical industry. The information in a package leaflet needs to mention all warnings, precautions, contra-indications and side effects. Apart from being obligatory, this is seen as necessary by the pharmaceutical company to avoid litigation. Unfortunately, this combination of legal requirements makes some of the leaflets very long and very hard to use for patients.

These nine arguments lead to the conclusion that the current format of package leaflets is not optimally related to its purpose. The tangible benefits seem to be smaller than expected and it is likely that the negative experiences of patients with package leaflets in recent years have reduced their confidence in this particular format.

At the moment, package leaflets seem to have the following characteristics:

- package leaflets are not suitable for all circumstances (for example hospital use, use with multiple medicines, relation with digital contexts)
- package leaflets are not appropriate for all patients (for example functionally illiterate patients)
- package leaflets contain too much information to be helpful (the conflict between legal protection and patient needs)
- package leaflets are an information source, but alternatives are increasingly preferred (for example on websites)
- package leaflets have little effect (there is little – if any – improvement in knowledge, and no effect on medicine taking behaviour).

Walter Modell, the editor of *Clinical Pharmacology and Therapeutics* wrote in 1967 'The stuffers are generally printed in Lilliputian type on Bible paper, are hard to handle and very difficult to read'. Although there have been some improvements, the majority of the package inserts still match Walter Modell's description.

In general, package leaflets can be seen as 'harmless': they don't have clear positive nor negative effects. The question is clear: 'Why doesn't this change?' What are the reasons why, despite major efforts of several stakeholders, the effects of the supply of package leaflets is disappointing?

2. European situation: Current regulations and guidelines

The European legislation provides the legal framework. The following two statements from EU Directive 2004/27/EC make clear that there is a firm basis to work from.

Article 63(2) states: *'The package leaflet must be written and designed to be clear and understandable, enabling the user to act appropriately.'*

Article 59(3) states: *'The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.'* Without a 'user test', it is not possible to get a license to sell a medicine in Europe.

The aim is clearly described in the legislation: a package leaflet must 'enable the user to act appropriately'. This information should be 'written and designed to be clear and understandable' and the package leaflet must be 'tested to show that it is legible, clear and easy to use'. This is an excellent starting point for information designers. Writing, designing and testing are all legally required.

There are at least two reasons why this legal basis has not lead to clearly visible improvements: internal conflicts and a misunderstanding of information design or document design processes.

Internal conflict 1: European Directive

Unfortunately, the European Directive does not only contain the abovementioned articles, but it also includes article 59(1). This article states: *'The package leaflet shall be drawn up in accordance with the summary of product characteristics; it shall include, in the following order,'*. The rest of article 59 provides a substantial list of all the information elements that must be mentioned in a package leaflet. This list starts with 'the name of the product' and ends with 'the date on which the package leaflet was last revised.'

There are some fundamental conflicts between statement 59(1) and 59(3). The statement that *'the package leaflet shall be drawn up in accordance with the SmPC'* means that all information of the SmPC must be included in the package leaflet. It can be phrased in more common language, but everything must be mentioned. And, the package leaflet cannot contain information that is not in the SmPC. This has several practical consequences that are in conflict with 'enabling the user to act appropriately'. For example, the SmPC does not include instructions on how to take a particular medicine. Adding a phrase like 'swallow the tablets with a little bit of water' is considered problematic if 'a little bit of water' is not mentioned in the SmPC. A strict interpretation leads to incomplete instructions, or to a situation in which no instructions are mentioned at all.

For the same reason, even side effects that cannot be noticed by patients must be mentioned in the package leaflet. A patient cannot know if 'their levels of liver enzymes have changed', or if 'a decrease in platelets' has occurred.

A third conflict is caused by the words 'in the following order'. This has as a consequence that the benefits of a medicine – the indications – are mentioned in the beginning, and the risks – the side effects – at the end. This makes it difficult to compare the benefits and risks of a medicine. The strict sequence makes it also impossible to follow the suggestions made by patients on how to improve package leaflets. For some medicines, readability tests indicate that patients would prefer to have the dosage instructions right at the beginning of the leaflet. The required order makes this impossible. It is not clear if article 59(1) prevails above article 59(3): 'In the following order' might not be 'easy to use'.

Internal conflict 2: Guidelines and templates

Focusing only on the European Directives unfortunately tells only part of the story. European Directives must be integrated into national laws, and implemented and controlled by regulatory authorities – of which there are several. The European Medicines Authority (EMA) deals with medicines that are sold across Europe. Each country additionally maintains its own regulatory authority. In the UK, for example, this is the Medicines and Healthcare products Regulatory Agency (MHRA). All national authorities and the EMA provide the industry with guidelines and advice. The MHRA is particularly active in this area and has played a leading role for the last decade or so.

Apart from the guidance from the regulatory authorities, there are also guidelines from the European Commission. The main guideline for package leaflets is the Readability Guideline, in which there is advice on the writing and designing of leaflets, a template and an outline for a testing technique. This testing technique was loosely based on those described in 'Writing about medicines for patients' (Sless, 1996/2007) by the Australian Communication Research Institute (CRIA). The first version of the Readability Guideline appeared in 1998.

A draft for a second version of the Readability Guideline was published in 2006: it copied many parts from the MHRA guidelines and especially from the publication 'Always read the leaflet' (MHRA, 2005). Until now (November 2008), the draft readability guideline has remained a discussion paper and has no legal force. However, the draft cannot be ignored because it is likely to have a substantial influence when it is accepted and approved.

Apart from the EU Directive and the guidelines, there is also a 'template'. An early version of this template was published in the 1998 Readability Guideline. It is now called the QRD-template (QRD, 2008) and has been translated into all 22 EU languages. Although it is not absolutely mandatory to use this template, it is common practice of marketing authorization holders (= the pharmaceutical industry) to adhere to it. This template therefore provides the practical starting point for the development of package leaflets in Europe.

A detailed look at the Directive, guidelines and template reveals that there is a general tendency towards a consensus. At the moment, however, there are several smaller and larger inconsistencies. Some of the conflicts within the regulatory framework are pointed out by Ursula Schickel (2008). In practice, it is necessary to consider all available guidance and choose a strategy that seems to be logical for a particular medicine.

3. The practice of writing, designing and testing package leaflets

A range of guidelines aim to help and support the marketing authorization holder to write, design and test package leaflets. These guidelines provide advice on 'how to make package leaflets suitable for patients' as well as 'how to provide information about package leaflets to regulatory authorities'.

Unfortunately, this combination of guidelines prevents the development of a high standard of well-written and well-designed package leaflets. Writing, designing and testing have all three degenerated to a mediocre level at which these activities become fairly pointless.

3a. Writing

The development of a package leaflet starts with the QRD-template. The activity of medical writing is reduced to modifying the template into a text that reflects the contents of the SmPC accurately. The different information items are copied into the appropriate sections of the template. The pharmaceutical and medical jargon is translated into more patient-friendly terms. This is based on vocabulary lists and a close reading of the approved package leaflets of comparable products. The text-formatting is also strictly regulated. This sounds easy and could be a quick way to write the text of a package leaflet.

One example might indicate some of the practical issues. The template states that the following sentence must appear at the beginning of the leaflet:

- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.>

The following five comments can be made about this sentence.

- a. In every readability test interview, every native English speaker stumbles here. The plural of 'side effects' seems to be in conflict with the singular form of 'gets'. After re-reading the sentence, it is either confirmed to be correct English – 'any' is singular – or a remark is made that it should be 'get' and not 'gets'.
- b. The sentence appears as the 8th line in a package leaflet. A common reaction is: "I've only got to here, and they are already talking about side effects. I don't even know what the medicine is for yet." Line eight is not the correct location to mention side effects because people cannot know what they are at this point in the leaflet.
- c. Within the typical patient's vocabulary, any mention of a 'side effect' is serious. Patients should be encouraged to discuss any worry they have with their doctor. Leaving the interpretation of 'serious' to a patient might not be appropriate in all circumstances. Sometimes, 'less serious' effects might be symptoms of very severe side effects.
- d. If the package leaflet must 'enable the user to tell about side effects', then this should be investigated. 'How many side effects are mentioned by users, and do we find that appropriate'? Otherwise, there is a direct conflict with article 63(2).
- e. 'Please' is nearly always redundant, and dilutes the message.

A writer has the option to modify this particular sentence into a phrase that might be more appropriate. The benefit of modifying a sentence from the template must be balanced against the risk of rejection of the entire text by regulatory authorities. The authorities might reject any text that deviates from the QRD-template. Small changes could be acceptable, but this is discussed on a case-by-case basis. In practice, this means that the sentences of the QRD-template are very rarely challenged.

The guidance available from the Patient Information Quality unit of the MHRA illustrates this dilemma. A guideline from March 2007 – 'Further guidance on designing patient information leaflets' – states: 'Findings from the survey indicate that the wordings of many of the headings and subheadings in the QRD template are not well understood by patients. You should make sure that when preparing your mock-up leaflet for testing you reword your leaflet to ensure that all the information is translated into terms which the patient can understand.'

However, MHRA advice propagated by the same group in April 2008 states: 'The new headings used in the user tested UK PILs will be the standard headings according to the European QRD (Quality Review of Documents) template. These headings should be used.' Both guidelines are downloadable from the MHRA website. A comparison of both guidelines does not make it clear if it is possible to modify the text of the template.

This gets even more complicated if one also reads section 5.4 of the same MHRA 2008 guidance. This states: 'Headings are an important aspect of the written information and, if well used, can help patients navigate the text.' This is the official advice of a regulatory agency to a writer of package leaflets. It implies that the agency finds it likely that there are writers who do not know the value and the function of a heading in a text. Furthermore, it implies that the agency knows exactly how headings help patients to navigate a text. The authorities also imply that they know how to distinguish between 'if used well' and 'if used not so well'. This knowledge is unfortunately not based on any accessible evidence. The quality of this advice is highly doubtful without clear examples of 'well used headings' and the empirical results of valid user tests.

In summary, the author of texts for package leaflets has to decide whether it is worth challenging the text of the QRD-template, and also whether it is worth challenging the assumptions of the available guidance.

3b. Designing

Again, there is ample guidance to help graphic designers to develop leaflets that would pass the quality criteria of the regulatory authorities. In addition, the MHRA provides good examples of package leaflets on their website that could be used for inspiration. However, none of the guidelines seem to take graphic design very serious. The activity of designing has been reduced to 'put the type into columns' by reducing the typesize until it fits. This might also seem the quickest way to achieve results, but it is hardly sufficient if a package leaflet must fit into a 'corporate style' of a particular pharmaceutical industry.

The 2008 MHRA guidance document could be used as an example to show that graphic design 'just needs to follow very simple guidelines to achieve results'. The guidance document states:

- Keep line spaces clear.
- A column format for the text can help the reader navigate the information.

- Do not use italic fonts and underlining as they make it harder for the reader to recognize the word shape.'

This is the official advice of the MHRA to people who develop the visual presentation. It is unclear if this advice is aimed at people who have never had any training in this area, or at experienced graphic designers. It is however fairly difficult to follow the guidance document. Is it really possible to keep line spaces 'unclear'? 'Clear linespace' is not mentioned anywhere in the typographical literature. Is it really possible to set a text without a 'column format'? There are a very few text formats that could be without a column, such as a ticker tape, but these formats would not be suitable for paper artifacts. And where do the authors of this guideline find the evidence that 'italic fonts' make it 'harder for the reader to recognize the word shape'? If that is the case, why have printers and typographers used italics for over five centuries?

The graphic design of a package leaflet is not really helped by the available guidelines. It is hard to prove to regulatory agencies that italic type might be beneficial for patients who read package leaflets.

3c. Testing

The third action that is legally required in the process of developing package leaflets is 'user testing'. This is now known as 'readability testing'. This test has developed over the last years from a 'diagnostic test' into an activity that has very little to do with improving package leaflets.

The test is described in the Readability Guideline (1998) and in Always read the leaflet (MHRA, 2005). The test consists of a series of one-to-one interviews. In each interview, a participant reads the test-leaflet and is asked a structured list of about 15 questions. The interviewer scores the 'correct answers' and notes any comments. Usually there are three steps: one pilot test of five interviews, a first series of 10 interviews and a second series of 10 interviews.

The aim is to reach a score of at least 16 correct answers for each question over two series of ten interviews. The report by Schickel (2008) and an article by Theo Raynor & Peter Knapp (2008) provide some fair comments about the test and the available guidance.

The way in which the readability test is applied in practice at the moment does very little to improve the quality of the text or the design of a package leaflet. The main focus of the guidelines is to achieve the score of 16 out of 20 for each question. This diverts the focus from 'finding problematic areas in a document with the aim to make information easier to find and easier to understand'.

The first reason is that valuable comments or real problems need to be ignored. The major problems will have been indicated by the pilot test. In practice, the marketing authorization holder is unlikely to make any changes after that. Any substantial change that is based on feedback makes another two series of 10 interviews necessary which increases the costs. This also has the effect that any relevant remarks made by the 20 participants will not be incorporated into the text or the design. It is simply cheaper to reach the minimal level and avoid any modifications. In other words, the twenty interviews are not used to find problems that need to be improved, but are only to 'reach the required score'.

A second reason is related to the recruitment of participants. The participants that are most likely to find real problems in a package leaflet are – in general – slightly older and slightly less well educated. An 80-year old lady is more likely to have problems finding or interpreting a text, compared to a 25-year old student. However, the comments of the lady are more likely to be helpful in improving the text of a package leaflet. Unfortunately, it is also more likely that she will make mistakes. In order to reach the required score, it is commercially dictated that the 25-year old will be selected. Reaching the required scores is preferred above improving the package leaflet.

Both reasons are in direct conflict with the aim of Directive 2004/27/EC: 'enabling users to act appropriately'. The test method as it is applied according to the guidelines does not help to achieve the aims of the Directive.

This is not the right place to provide a detailed review of the available guidance related to the writing, designing and testing of package leaflets. It is at least worrying that regulatory authorities provide unsubstantiated guidance. It is very unfortunate that this unverified guidance is also used as a checklist to see if package leaflets follow it accurately.⁴ Discussion.

Since 1992, the European process has resulted in standardized leaflets across Europe. From a regulatory point of view, that might be seen as a success.

From an industry point of view, this has not been an easy process. Writing, designing and testing leaflets has proven to be a substantial task. Uncertainty, caused by unclear and frequently conflicting guidance, has made this task even more difficult.

From the perspective of an individual patient, this argument is irrelevant. Patients are increasingly disgruntled by the poor standard of leaflets, and consult alternative sources for information (Raynor, 2007).

If this process goes on, package leaflets will be standardized across Europe but will be ignored by patients because better alternatives are available. It simply takes too much effort to try to decipher the leaflets and combine this with the information on the label, outer packaging and the advice of doctors and pharmacists.

It is likely that this process will swing the other way at some point. There are four main reasons:

- industry cannot afford to spend so much time and money on a product that has so little effect;

- governments cannot continue to demand an artefact that has so little effect and causes such waste of materials and regulatory efforts;
- patients cannot rely on the current leaflets in practical situations;
- the total costs of incorrectly used medicines, unused medicines, fatal accidents and non-fatal accidents is simply too high to rely on ineffective forms of communication.

This is not suggesting that a package leaflet only can deal with these four main issues. The package leaflet must be seen as part of a fairly complex system that aims to inform patients about their medicines. It is essential to reconsider the whole system.

The list of issues mentioned in section 2 and the discussion about the current guidance in section 3 provide a good starting point for the next generation of package inserts. It is likely that this will require a modification of guidelines and at a later point a modification of the EU Directives. The main reason for this is that the internal conflicts within the regulations and guidelines are too substantial to be ignored.

The following statements could be used as starting points:

- Package leaflets must increase knowledge.
- Package leaflets must be provided in different formats for different educational levels.
- Package leaflets could and should point to alternative digital opportunities for retrieving information about medicines.
- Package leaflets must make it easy to consult several leaflets at the same time.
- Information to be provided in a hospital context should be tackled in other ways.
- Package leaflets should contain only the information that is relevant at the time of reading: at home after a visit to the pharmacist, or after taking a medicine from a medicine cupboard.
- Package leaflets must be short – this is in direct conflict with the ‘full and comprehensible’, but patients want information in different steps, not everything at the same time in one long leaflet. This is similar to the difference between ‘a quick starter guide’ and ‘instructions’ as provided for, e.g., software or consumer electronics.
- The phrasing of difficult concepts (interactions, and frequencies of side effects) needs more effort. Simple solutions do not work.

The main reason for providing patients with information is to ‘enable them to use medicines appropriately’. If that is the starting point, then we must start from the patient’s point of view. Not for all medicines in an identical way, but for specific actions in a specific context. It is necessary to start from observations of current practice to find out how well specific medicines are used at the moment. This will show relevant criteria and indicate current performance levels. Any alternative design can be compared with these current performance levels to establish if the alternative is a real improvement.

This also makes it possible to integrate package leaflets within the doctor-pharmacist-patient triangle. At the moment, the roles of doctors and pharmacists are ignored by leaflet-writers. The package insert is written as if there has never been any contact with a doctor or a pharmacist.

Furthermore, the experience highlights the importance of appropriate guidelines. Poor guidance wastes time and raises anxiety both within the pharmaceutical industry and among personnel of regulatory agencies. It would be very useful if new guidelines themselves could be tested too. It is clear that untested guidance might do more harm than good.

If the available evidence is taken as a basis, it is unlikely that anything similar to current package leaflets would be the result. Most evidence points towards agreement with article 63(2) of the current EU Directive. Unfortunately, this is in direct conflict with article 59 of the same Directive. It is up to the regulatory authorities to decide which of these articles should prevail.

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