Package leaflets today: a betrayal of Europe's patients

Anders Blanck and *Kenneth Nyblom* call for a completely new approach to providing information on the risks of drugs to patients in the EU.

"Do you really need to know all of this? It almost makes you ill just reading it. If there are so many risks with the medicine, then why are they selling it?"

This quote is from an individual who participated in a study commissioned by the pharmaceutical industry in Sweden into how people assess patient leaflets (PL).

The questions the man asked are highly relevant and highlight something that all stakeholders in the sector – industry, regulatory authorities, patient organisations and healthcare providers – have known for too long: that the PL that is legally required to be included in each pack of medicine does not meet the needs of the patient for information about the medicine. The consequences of this have equally long been known. Unjustified worries on the part of the patient affect compliance in a negative way. This can result on the one hand in patients failing to take the medicines they need; on the other, it can lead to unnecessary side effects in patients as a result of their misunderstanding the risk factors that can be associated with the medicines in question.

The study was commissioned by two Swedish industry groups – LIF, which represents research-based companies, and the FGL, representing generics companies – as a pilot project on how PLs can be improved and developed to be more user-friendly and contribute to better adherence through greater clarity and simplicity.

The study was conducted in light of the fact that the system is officially up for review. Under Directive 2010/84/EC, the European Commission is required to produce by 1 January 2013 an assessment report on current shortcomings in both the PL and in the summary of product characteristics (SmPC) and on how the documents could be improved in order to better meet the needs of patients and healthcare professionals. On the basis of the report, the commission may decide to present proposals to improve the readability, layout and content of the SmPC and the PL.

The results of the Swedish pilot show that it is time for both the pharmaceutical industry and the regulatory authorities to act on the knowledge that the current PLs – variously known as package leaflets, patient leaflets and patient information leaflets – do not meet patients' needs. There have been initiatives at European Medicines Agency level and also in various member states to address the shortcomings of the current system[1]. These are, however, not enough. And while the fact that there is a central initiative underway to address the problem is a positive development, stakeholders have to accept that it is not enough to rewrite existing PLs – we need to start from scratch.

Vehicle for information

The SmPC forms the base document from which the PL is derived. It sets out the agreed position on a medicinal product as distilled during the course of the assessment process and its content cannot be changed except with the approval of the originating competent authority.

The Swedish pilot project showed that it is possible to create PLs in such a way as to ensure that patients can understand and absorb the information

The PL itself is a vehicle for information and thus provides a channel of communication. Its purpose is to convey important information from the manufacturer and the regulatory authorities to the patient to ensure that the medicine is taken correctly and used as intended. The golden rule that applies to all communication is that compliance occurs when the recipient has absorbed and understood the information. This means that the starting point for anyone wanting to communicate is the viewpoint of the recipient, which is the patient. If the patient cannot understand the information, then it is irrelevant whether or not the PL is written to comply with current regulations and with an updated list of every conceivable interaction and side effect.

New rules requiring readability tests have not made PLs any shorter or simpler. In fact, the trend has been towards an increasingly longer and increasingly more complicated document in which side effects, precautions and warnings make up an increasingly greater proportion of the content. For the patient, these complicated documents appear to be designed to prevent any future complaints against drug companies.

One can compare the PLs for prescription-only medicines to the legal terms and conditions of sale or use that one is required to accept when, for example, downloading a programme from the internet. How many internet users carefully read through these conditions before clicking the accept button? The fact that important information about medicines is likely to be viewed as something that the patient does not expect to understand and therefore avoids reading constitutes a health risk.

Let us pose the following rhetorical question: would PLs look the way they do today if we were to start from scratch, with the main intention being that the patient should really understand the effects and benefits of the medicine, how it should be used and stored correctly, what risks and risk factors there may be and where further information can be found? The answer, clearly, is no. We would not have produced a long, hard-to-grasp and linguistically complicated document containing medical terms that the patient does not understand. On top of that, the information is presented in a font size that requires almost perfect vision on the patient's part. It is also by no means a trivial matter that the PL is folded up in such a complicated way that the patient never manages to fold it back up again and reinsert it in the pack, but often discards the PL after trying to consult the contents.

If we were to seek the best possible patient safety without any preconceptions, we would have asked whether the information should contain a better balance between benefit and safety of the medicine. Current PLs with their strong bias towards safety in terms of side effects result in far too many people failing to follow their doctor's instructions, leading to decreased patient safety. It is unreasonable to ask the patient to assess the potential risks of the treatment if the risks cannot be compared with the effects and benefits that the medicine is expected to have. What effect is the medicine intended to have on the body and the disease, and what signs and symptoms should the patient expect? These are relevant questions that the PL should address simply and clearly.

If we could start from the beginning, we would ask straight away how PLs could benefit from the possibilities offered by digital technological developments. The possibility of conveying PLs via electronic platforms such as the internet and different types of mobile devices solves many problems. The patient can

have immediate access at all times to up-to-date information by using digital platforms instead of paper PLs. At present, it can take up to a year-and-a-half before an update of a PL reaches patients, depending on printing and the manufacturing process of the medicine. An electronic update, on the other hand, would be available to patients immediately. With digital PLs, it is also possible to meet the needs of functionally impaired patients, who, for example, can access the PL via an audio version or by choosing a larger font size.

There is already the possibility in some member states for everyone to consult PLs and SmPCs via digital platforms, such as FASS.se[2] in Sweden and eMC[3] in the UK, where the patient can view an updated PL directly via the internet. These portals are now launching versions for mobile devices. Access to PLs via digital and mobile media for all patients in the member states is a natural step, even if the information in the medicine packs most likely still needs to be present for a transitional period. At a later stage it may be possible for patients who do not have internet access to get the PL printed when the pack is dispensed in the pharmacy.

The study

In our qualitative study, focus groups involving patients of different ages assessed PLs for three selected medicines: Fosamax (alendronic acid), Ipren (ibuprofen) and Omeprazol Actavis (omeprazole).

The focus groups expressed both positive and negative opinions on the PLs. The underlying positive aspect was the very existence of a PL as a sort of guarantee that the medicine is tested and safe. Overall, the focus groups perceived the PLs as credible and serious and the information was generally considered to be factual and objective. The most common negative viewpoint was that the PLs were too extensive and therefore difficult to grasp. For instance, the patients wondered whether it really was necessary to have long lists of rare and very rare side effects. Another opinion was that long descriptions of the disease itself were something that should come more naturally from the treating doctor.

As part of the project, a major revision of the three PLs was then undertaken in consultation with the Medical Products Agency in Sweden. The revisions involved both content and layout. The central aspect of the revisions was that the PLs should have simpler, more direct language, a clearer, more easily comprehensible structure and a lighter design, while at the same time continuing to provide all the important information. One important aim was that the PLs should also be considerably less comprehensive; the initiative involved reducing the number of words by 40-50%.

When the focus groups expressed their opinions on the revised PLs, the overall feedback was very positive for all three medicines. The respondents considered that important information was easier to understand. The language was more comprehensible and to the point. The print was larger and easier to read. All in all, the Swedish pilot project showed that it is possible to create PLs in such a way as to ensure that communication really occurs – that the patients can understand and absorb the information.

It is time for both the pharmaceutical industry and the regulatory authorities to realise that the current PLs do not meet the needs of patients. Professionals and authorities write them for other professionals and authorities. Due to the current legislation, the package leaflets are designed and delivered in a way which rather makes the patients perceive them as unimportant or even unnecessary. This is completely counter-productive when it comes to ensuring patient safety. It is a betrayal of Europe's patients.

Shared responsibility

The pharmaceutical industry and the regulatory authorities have a shared responsibility to develop a common agenda resulting in PLs that help patients to truly understand. By starting entirely from the patient's point of view, we can develop PLs that make it easier for patients to absorb important information that is shorter, more to the point and available on the internet so they can be kept up to date. To do this, it is not enough to amend existing regulations. We need to start from the beginning.

References

1. *Joos A et al, The future of product information in the EU, Scrip Regulatory Affairs, 12 August 2011*
2. *www.fass.se/LIF/home/index.jsp*
3. *www.medicines.org.uk/emc/help.aspx?view=7&title=eMC%20mobile*

The authors wish to express their thanks to the Swedish Medical Products Agency (Läkemedelsverket) for its support during the preparation of the study.

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Medtech news in brief

Commission writes to EU panel on industry concerns over labelling

The European Commission's Directorate General for Health and Consumer Policy (DG Sanco) has written to the EU medical device Central Management Committee regarding the latter's Decision No 3 on device labelling; the decision, issued in July 2011, requires the full postal address of manufacturers and authorised representatives to be placed on medical devices.

Sweden's updated guide on medical information systems due in October

The Swedish Medical Products Agency is planning to issue in October updated guidance on the regulation of medical information systems; the original version of the document, which was published in 2009, formed the basis for the European Commission's EU-wide guidance on the regulation of standalone software as a medical device, published earlier this year.

UK issues guidance for notified body reviews of self-test diagnostics

The UK Medicines and Healthcare products Regulatory Agency has published guidance for notified bodies on the regulation of IVDs for self-testing that focuses on how notified bodies should assess the manufacturer's design and labelling of diagnostic tests for lay users.

BSI issues UK standards for nanotech products

Standards organisation BSI has published three new standards, and is developing a fourth one, to help support the emerging nanotechnologies market in the UK; the standards are intended to help mitigate the risks involved in the manufacturing and disposal of such products.

UK MHRA places vCJD assays in highest-risk category

The UK has amended its medtech rules to ensure that medical devices that are used to identify variant Creutzfeldt-Jakob Disease (vCJD) in human blood undergo the highest level of scrutiny before they are placed on the market.

US FDA explains study, pre-market rules for CADe detection devices

The US Food and Drug Administration has issued updated versions of two related guidelines on computer-assisted detection (CADe) devices applied to radiology images and radiology device data.

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