Public consultation on the legal proposal on information to patients

Introduction

On 20 December 2007, the European Commission adopted a Communication including a staff working document on the current practices with regard to the provision of information to patients on medicinal products. Both documents describe available sources of information, particularly on treatments and medicinal products. They also note that patients have become 'more empowered and proactive users of health care, increasingly seeking information about their illnesses and treatment options including medicines from an ever growing and diverse range of sources.'

The Communication announces the Commission's intention to propose to the European Parliament and the Council amendments to the current rules on the provision of information to patients by the end of 2008.

The following main policy objectives are laid down in the consultation:

- Establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and health care professionals.
- Maintaining the ban on direct-to-consumer advertising of prescription medicines,
- Making sure that there is a clear distinction between advertising and non-promotional information.
- Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation.

The forthcoming proposal would amend article 88 in the directive 2001/83/EC and should set rules on the provision of unbiased information by marketing authorisation holders. In this document the Netherlands authorities comment on the main issues at stake in this consultation.

In this document we use the terms *medicinal products* and *medical products* several times. By *medicinal products* we mean pharmaceutical (prescription only) products. By *medical products* we mean a broad spectrum of products ranging from pharmaceutical products to medical devices, advanced therapies and combination products.

General comments by the Netherlands

1. Key players regarding the use of medicinal products

Providing patients with high-quality and understandable information is primarily the task of health care professionals. Health care professionals are and should remain the primary source of health information, particularly on treatments and medicinal products. Therefore the interaction between patients and health care professionals must be safeguarded, especially a proactive dialogue between physician and patient is essential. Not only physicians have a role to play when it comes to using medicinal products. Pharmacists have a key role in advising consumers about non-prescription medicinal products, about the availability and proper use of prescription medicines. Nurses can also play an important role, particularly in advising hospitalised patients about the proper use of their prescribed therapies.

Physicians, pharmacists, nurses and other health care professionals have access to information via the SPC (summary of product characteristics) and PARs (public assessment report). In addition to their general knowledge of medicinal products health care professionals should be up to date via training. It's also important that health care professionals get into conversation with their patients about their treatment and the medicinal products they use. In brief, it is necessary in order to establish a genuine partnership between patients and health care professionals. Patients have a right to be informed about the available treatments and the medicinal products that are part of their treatment. By law, medicinal products in the EU have to include a package leaflet containing information intended for and relevant to the patient. Package information leaflets should be written in an understandable way and be subject to consultation with target patient groups to ensure their readability. And package information leaflets should be easy accessible for example via the Internet.

Studies in the Netherlands show that package leaflets, despite readability tests, are still not easy to read for patients. The mentioning of all the possible adverse effects may discourage patients. This has to do with the apparent double function that package leaflets have. On the one hand package leaflets are designed to be an information provider to patients. On the other hand they have to correspond with the templates made up by the Quality Review Documents Group of the EMEA (QRD) and therefore they perform a juridical function. These two functions are difficult to combine in one document. An additional problem is that, following directive 2001/83 the templates lay out fixed sections. Standard formulations are however not always applicable for different groups of patients. A general point is the emphasis in patient leaflets on risks or pharmacovigilance and less on efficacy. An EU wide evaluation on package leaflets is necessary and should be brought in the discussion on information to patients.

2. A clear distinction between advertising of and information provided on prescription medicines
During the review of directive 2001/83/EC the discussion on a clear distinction between information and advertisement was long debated. At that time no solution has been found. In the current consultation the Commission opens up the debate on the definition of the distinction between information and advertisement again. However, the Netherlands authorities are of the opinion that the initiative on taking the lead in bringing forward a more elaborated definition should rest with the European Commission, not with those parties who are being consulted in this procedure. We acknowledge that it will be a difficult task to make a clear distinction between information and advertising. On top of that, when a clear distinction is being developed we ask specific attention for the possible risk of undue bureaucracy. Patients who seek information should get all the information they want. Nevertheless to ensure the objectivity of the information, measures should be taken to ensure verification before presentation. This could mean that all communication has to be checked before presentation. That could lead to a significant increase of workload and bureaucracy. Or it could mean that by means of repeated inspections the quality of information is to be safeguard. This can also lead to an increase of workload and bureaucracy. Who is going to monitor information at a national level (not being advertisement)? Suggestions are made in the Working Group 'Information to Patients' of the Pharmaceutical Forum to implement a permanent network at a European level. The Netherlands is hesitant to support the realisation of another permanent body, considering the linked increase of bureaucracy. However, when the task of safeguarding the quality and objectivity of information provided is laid down at either the European or the national level, it should be clear that adequate instrumentation and financing is essential.

As long as there is no clear solution for the above mentioned issues, the Netherlands authorities will not support any change in the current strict ban on direct to consumer advertising.

3. The quality criteria and the framework

De Working Group 'Information to Patients' is working on quality criteria. Information should be understandable, objective, relevant, of high-quality and non-promotional. Contribution from all stakeholders and interest parties dealing with medicines or with provision of information on medicinal products to citizens are welcome; this covers for example information providers, health care providers, regulatory authorities and pharmaceutical industry. However, a co-authorship of all these contributions does not guarantee per se a more understandable and coherent drug information, since these stakeholders financially and intellectually pursue different interests. The Netherlands foresees, due to the commercial interests, that the supply of information about medicinal products will not be spread evenly over the whole range of medicinal products. This may result in a profusion of information on certain products and a lack of information on others. This is not in the best interests of patients. Information to patients should be professionally organized and need adequate financing. Patients should be provided with a broad spectrum of information on all types of medicines and not just the ones that are commercially interesting.

4. Combination products

The range of medicinal products is growing and varied. Until recent, there seemed to be a clear distinction between medicinal products and medical devices and there was a firm line between those two groups of products. Nowadays there are also tissue engineered products, advanced therapy products, medical devices which contains medicines and so on. The Netherlands sees a host of products that are used in health care and for humans which are to a smaller or greater extent adjacent to pharmaceuticals. The Netherlands feels that it would be most important that the Commission would take that fact sufficiently into account. Transparency and coherence in regulation across product categories are necessary. One of the major developments in science and technology is the so-called convergence of technologies. It is a major challenge to proactively consider which efforts – legislative of otherwise- are needed for coherent regulation of products resulting from convergence of technologies. Several areas of science and technology, such as biological sciences, nanotechnology, cognitive sciences, information technology and materials science have emerged. Products are being developed in which one or more of these technologies are utilised (such as combination products in the area of advanced therapies, medical devices and functional foods, especially those with health claims). This convergence of technologies blurs the traditional boundaries between pharmaceuticals and the adjacent product categories and cannot be solved by comitology only. Cooperation and coordination with other sectors will therefore be unavoidable but challenging at the same time.

When patients use products they are entitled to good quality information. Not only about their medicinal products but also about their medical products. Information about medical products, adjacent to pharmaceuticals, that patients use should be under the same legislation of set of rules as information about medicinal products.

5. Maintaining the ban on direct-to-consumer advertising of prescription drugs

As mentioned before the Dutch Authorities is of the opinion that the maintaining of the ban on direct-to-consumer advertising of prescription drugs is essential. To safeguard this ban clear quality criteria to distinguish information and advertisement should be defined by the European Commission. The methodology and the criteria to make all this possible are still not clear.

6. Current legislation

It is possible to give good quality information about medicinal products to patients within the current legislation. Article 86 of directive 2001/83 points out that pharmaceutical companies can give information to patients who actively seek for information (the so-called pull strategy). The Netherlands is not in favour of providing patients with information they didn't ask for (the push strategy). When patients receive too much information it will be difficult for them to distinguish what they need to know or what is nice to know.
It is not necessary to change the legislation, but changing of legislation can help to achieve the aim to improve the quality and access to information about medicines. Nevertheless there are several other possibilities. The patient information leaflet could be improved and it is recommended to change directive 2001/83 on this point to make sure that the benefits and the efficacy of medicinal products are included. The working group 'Information to Patients' has formulated a set of criteria on good quality information. That also helps to reach the objective: a well informed patient. According to the Netherlands there are several institutes who deliver (or can deliver) independent information on medicinal products. Their activities lead also to better and unbiased information to patients. They may need to be supported more. It is not clear to patients which sources of information are considered reliable and which aren't. Transparency on this issue is also needed.

7. Major topics

In short the opinion of the Netherlands is that:

- Consumers and patients are entitled to good-quality information about health, medicinal products and treatments.
- Health care professionals have the primarly task to provide patients with good and understandable information.
- It is up to the European Commission to bring forward proposals for a clear definition of the distinction between information and advertisement.
- We acknowledge that it will be difficult to make a clear distinction between information and advertising.
- In developing proposals for a new definition the risk of undue bureaucracy should be taken very seriously.
- As long as there are no satisfying solutions for the definition problem maintaining of the strict ban on direct-to-consumer advertising of prescription medicines is essential.
- The current legislation does not have to be changed to guarantee the provision of good quality of information to patients. Patients should only be provided with information when they request information (the so called pull strategy). We are not in favour of providing information that has not been asked for (the so called push strategy).
- A host of products that are used in the health care are to a smaller or greater extent adjacent to medicinal products. Convergence of regulations, cooperation and coordination with other sectors will therefore be unavoidable but challenging at the same time.