

Brussels, 11 October 2011

## Q&A: Information to patients on prescription-only medicines

### What are the challenges of information on medicines in the EU?

Patients are increasingly interested in having access to information on medicines and want to take part in decisions regarding their treatment. At the same time, patients are confronted with a growing volume of information from different sources, finding it difficult to identify reliable non-promotional information about medicines. With the increased use of the internet over recent years, it is becoming equally important to ensure that information available on medicines, particularly on websites, is reliable, clear and up-to-date.

In 2007, a European Commission report showed that while advertising of prescription-only medicines to the general public is banned, a lack of detail on the provision of information has led to a situation where Member States interpret the EU legislation differently. This has led to a big difference in the information available to different people in different Member States. This situation potentially leaves some patients in the EU without access to the information they may need.

The public consultation that followed the report confirmed that the legal framework on information to patients should be improved.

### What does the Commission set out to achieve with these proposals?

With these proposals, the European Commission sets out a clear framework whereby companies with marketing authorisation for a product may – and to some extent must – provide good quality and objective information on their prescription-only medicines to the general public. As a result, the proposals should lead to better empowered patients, more rational use of medicines, whilst, at the same time, maintaining the ban on advertising prescription-only medicines. It also seeks to further strengthen the current system for monitoring the safety of medicines, known as *pharmacovigilance*.

### What 's new in these amended proposals?

The European Commission has amended its **initial proposals of 2008** with a particular emphasis on the rights and interests of patients. The amended proposals incorporate the European Parliament's amendments to the original proposals for legislation on information to patients. The key elements of the amended proposals are:

- 1. Only certain information on prescription-only medicines would be allowed.**  
This information includes, for example:
  - information on the label and package leaflets;
  - information on prices;
  - information on pre-clinical tests and clinical trials of the medicine concerned;
  - information on the instructions for correct use.
- 2. Only certain channels of communication will be allowed for providing information:** For example, via officially registered internet websites or through

printed information, if this had been specifically requested by members of the public.

3. **All information must be of highest quality:** For example, it must be objective and unbiased; it must be evidence-based; up-to-date; reliable; factually correct and not misleading; understandable and clearly understood; and must meet the needs and expectations of patients.
4. As a general principle, information which has not been approved before needs to be **verified by competent authorities prior** to its dissemination.

The amended proposals further strengthen the rights of patients. Companies with marketing authorisation for medicines would, for the first time, not only have the right, but would now be obliged to make available certain information, such as labelling and the package leaflet of the medicine.

Furthermore, the revised proposals will address some remaining weaknesses in the new pharmacovigilance rules in order to strengthen further the pharmacovigilance system in the EU.

### **How do you distinguish between information and advertising?**

It is important to be able to distinguish between advertising and non-promotional information on prescription-only medicines. This is in the interest of providing more and better information to consumers whilst, at the same time, maintaining the ban on advertising prescription-only medicines directly to the public.

Only certain information on prescription-only medicines will be allowed. This information must fulfil strict quality criteria and can only be made available through certain channels of information, such as officially registered internet websites, or printed information if this is specifically requested by members of the public.

### **How would the proposals ensure that information is objective and non-promotional?**

Information which has not been approved as part of the marketing authorisation must be pre-approved by the appropriate national authorities before it can be made available to the public by the company in question. However, those Member States with constitutional issues would be able to impose ex-post controls where the medicines are authorised at national level.

National authorities would generally act as a filter between the companies supplying the information and patients.

### **Would it be possible to give information on medicines via television, radio or via other media?**

To reduce the risk of information being "pushed" to patients, the proposals would, generally speaking, not allow information on prescription-only medicines via the mass media such as television, radio, or the printed press such as magazines.

Some printed material may be useful for some patients. For this reason, some printed material from industry would be accepted, provided that this information is made available if it has been specifically requested by members of the public.

The approach set out in these proposals aims at restricting a "push" approach to information, rather favouring a "pull" approach, where information is only provided to patients who actually ask for it.

### **How about information over the internet? Would this still be allowed?**

Information supplied by companies on their medicines will be allowed on officially registered websites. Such information must conform to strict quality criteria which will be introduced through these revised proposals. The information will be monitored by the appropriate national authorities.

### **Should only industry be allowed to give information on prescription-only medicines?**

The amended proposals only cover the rights and obligations of industry. Third parties, such as the press or patients' organisations, should be able to express their views on prescription-only medicines, provided that they are acting independently from industry. To ensure transparency about their independence, they would have to declare whether they had gained any financial, or other, benefits from the pharmaceutical industry.

### **What are the next steps?**

The amended proposals will now be scrutinised by the European Parliament and the Council of Ministers.

### **For further information:**

[http://ec.europa.eu/health/human-use/information-to-patient/legislative-developments\\_en.htm](http://ec.europa.eu/health/human-use/information-to-patient/legislative-developments_en.htm)

[http://ec.europa.eu/health/human-use/pharmacovigilance/index\\_en.htm](http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm)

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