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Information to patients on prescription-only medicinal products

EU citizens have become more empowered and proactive consumers of healthcare, increasingly seeking information about medicines and treatments. EU citizens want to be able to access information on existing medicines and treatments and at the same time to be more actively involved in making decisions regarding their health. With the increased Internet use, ensuring the reliability and quality of information, particularly on websites, has become fundamental. Action at EU level will benefit EU citizens in many ways. First and foremost, the information provision will be improved and harmonized across the EU. There will be more possibilities to receive high quality objective and non-promotional information. Secondly, European citizens shall be able to receive information that is in line with EU legislation. This reduces the risk of receiving misleading and bad quality information.

EU citizens have **unequal access to information** across the EU. Although advertising of prescription-only medicines to the general public is forbidden, a lack of detail on information provision has led to a situation in which Member States interpret EU legislation in very different ways and have developed divergent practices on the provision of information on medicinal products. Harmonization at EU level can contribute to changing the current situation and promoting public health across the EU. This is of major importance in particular in the era of the Internet where citizens can access information from all over the world.

There are a **range of sources from which patients receive information** on medicinal products, most notably through consultations with healthcare professionals. However, bearing in mind that patients have become more independent and empowered as regards their own health, they also actively seek information by themselves. Consequently, other sources of information are needed.

What are the key measures proposed?

The European Commission has prepared a legal proposal on information to patients. Specifically, it proposes

- that companies can make **information on their prescription-only medicines available to the general public,**
- while **maintaining the existing advertisement ban**

The **key elements** of the legal proposal are:

Only certain information about prescription-only medicines is allowed:

- **summaries of products characteristics**, labelling and package leaflets, as approved by the competent authorities;

- information which does **not go beyond the elements of the summary of product characteristics**, labelling and patient information leaflet of the medicinal product, but presents them in a different way;
- information on the **environmental impact** of the medicine, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;
- **medicinal product-related information** about non-interventional scientific studies, or accompanying measures to prevention and medical treatment or information which presents the medicinal product in the context of the condition to be prevented or treated shall be allowed.

Only **certain communication channels** for the dissemination of information shall be allowed:

- health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public;)
- **internet websites** on medicinal products, to the exclusion of unsolicited material actively distributed to the general public;
- **written answers** to request for information of a member of the general public.

All the information provided shall fulfil **harmonized quality criteria**:

- **objective and unbiased**; in this regard, if the information refers to the benefits of a medicinal product, its risks shall also be stated;
- take into account the **general needs and expectations of patients**;
- **based on evidence** and be verifiable and include a statement on the level of evidence;
- **up-to-date** and include the date of publication or last revision of the information;
- **reliable**, factually correct and not misleading;
- **understandable** for the general public or members thereof;
- clearly **state the source of the information** indicating the author and giving references to any documentation that the information is based on;
- **not contradict the summary of product characteristics**, labelling and patient information leaflet of the product, as approved by the competent authorities.

The information made available will be monitored by Member States. In general, the information shall be subject to monitoring after it has been disseminated. Internet sites containing information on prescription-only medicinal products shall be registered and monitored by the Member States.

When will this become law?

The proposal will now be transmitted to the European Parliament and the Council where it will be discussed and voted in the “co-decision procedure”.

More information on information to patients on prescription-only medicinal products
http://ec.europa.eu/enterprise/pharmaceuticals/patients/patients_en.htm

More information on the complete pharmaceutical package
http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm

Ton van Lierop: 29.665.65
Catherine Bunyan: 29.965.12