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Empowering the patient: European Commission wants clearer rules for information on prescription medicines

Brussels, 11 October 2011 – Today, the European Commission adopted revised proposals clarifying the information that industry can supply to the public on prescription-only medicines.

Patients are increasingly interested in learning more about the medicines they take and want more of a say in how they are treated. At the same time, patients are confronted with a growing volume of information from various sources and often find it difficult to identify reliable information about medicines. The increased use of the internet over recent years makes the need for clarity even more important. Online information on medicines must be accurate and reliable.

In its revised proposals, the Commission amends its original proposals of 2008 and responds to requests from the European Parliament. The proposals maintain the current advertising ban on the prescription-only medicines and foresee that:

- **Only certain information** on prescription-only medicines would be allowed. For example, information on the label and on the packaging leaflets; information on prices; on clinical trials; or on instructions for use.
- Information on prescription-only medicines would only be allowed through **limited channels of communication**. For example, information on officially registered internet websites; or printed information made available when specifically requested by members of the public. A publication in general print media will not be permitted.
- The information must fulfil recognised **quality criteria**. For example, it must be unbiased; it must meet the needs and expectations of patients; it must be evidence-based, factually correct and not misleading; and it must be understandable.
- As a general principle, information which has not been approved before needs to be **verified by competent authorities prior** to its dessimination.

Revising these proposals has also been an opportune moment to further strengthen the current system for **monitoring the safety of medicines** (known as the *pharmacovigilance* system) in the European Union.

John Dalli, European Commissioner for Health and Consumer Policy , said: *"The revised proposals put rights, interests and safety of patients first. They oblige industry to provide certain key information to patients and set clear rules for additional, voluntary information on prescription medicines. In addition, they further strengthen the control of authorised medicines."*

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Next steps

The revised proposals will now be debated by both the European Parliament and the Council of Ministers.

Further information:

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

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