Comments to the Public Consultation on the European Commission

Legal Proposal on Information to Patients

PORTUGAL, INFARMED – National Authority of Medicines and Health Products, IP

Highlights

- Infarmed recognizes the need to harmonise the way information on medicinal products is made available in the EU in order to ensure that all patients have equal and better access to information on medicinal products.

- The European Commission report on current practices with regard to the provision of information to patients on medicinal products concluded that there are significant differences regarding the access to and the quality of information across Europe.

- A clear distinction between information and promotion and mantaining the prohibition on advertising of prescription medicines are two of the pre-requisites of the proposal. We are aware of the dificculties in achieving such a distinction but we cannot support that any "Comunication not covered by the definition of advertisement should be regarded as information". We support the idea that only information that complies with the quality criteria can be provided as such. We also endorse mantaining the ban on direct-to – consumer advertising of prescription medicines.

- Infarmed considers than any strategy aimed at improving the quality and access to information should have as a basic principle that health professionals are the primary source of information to patients, not only because of their education but also because specific information needs can only be met within the context of the healthcare settings or the course of a direct interaction between the patients and his/hers provider (doctor, nurse, pharmacist, …).

- Moreover this strategy should focus on finding a solution to overcome the existing barriers to access information by patients, namely those that could more easily be addressed at a EU level, as the abundance of opposite recommendations for the same health problems, lack of patient friendly information materials/systems and the need to improve healthcare professionals communication skills.

- In our view European Commission proposal under consultation does not provide the proper mechanisms to improve quality and access of the information on medicinal products in Europe. Significantly increasing the amount and diversity of information available, namely on the Internet, without proper regulation and control (Commission´s proposal excludes ex-ante validation/approval), will only increase these asymmetries and may contribute for patients miscommunication/confusion.

- Whatever the proposed mechanisms to regulate and control are, either ex-post or ex-ante, the task-load on the Member-States will increase enormously without evidence of the correspondent benefit for patients.

- We disagree that only repeated and severe cases are subject to sanctionatory actions; it is known that the first message is the one that remains and such a sanctionatory scheme is not sufficiently discouraging.

- Nevertheless we consider that the pharmaceutical industry can be an important partner in promoting a better access to and quality of information on medicinal products. However it is essential that any future framework on information to patients promotes the development of partnerships between other relevant stakeholders, namely regulators, healthcare institutions and professionals, academic centres, IT providers and communication professionals.

- Finally we look forward that this initiative on a legal proposal on Information to Patients can be an oportunity to improve the access and the quality of information even if it takes an additional effort for all involved stakeholders to reach a common understanding.

Infarmed, April the 7th 2008