



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 30 May 2008**

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**NOTE**

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from : General Secretariat of the Council

to : COREPER/COUNCIL

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Subject : Communication from the Commission to the European Parliament and the Council concerning the report on current practice with regard to provision of information to patients on medicinal products in accordance with Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use

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Delegations will find in the Annex to this note draft Council Conclusions to be adopted by the Council (EPSCO) at its session on 10 June 2008.

**DRAFT COUNCIL CONCLUSIONS**

**on the**

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT**

**AND THE COUNCIL**

**concerning the**

**REPORT ON CURRENT PRACTICE WITH REGARD TO PROVISION OF  
INFORMATION TO PATIENTS ON MEDICINAL PRODUCTS**

**in accordance with Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC  
on the Community code relating to medicinal products for human use**

THE COUNCIL OF THE EUROPEAN UNION:

1. **WELCOMES** the Commission Communication concerning the Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products presented in accordance with Article 88a of Directive 2001/83/EC on the Community code relating to medicinal products for human use.

2. **NOTES** that, in its Report of March 2002, the G10 High Level Group on Innovation and the Provision of Medicines adopted recommendations that call *inter alia* for better information to patients. As a follow-up to these recommendations, the Commission created the Pharmaceutical Forum in 2005 in order to take the process forward focusing on three key issues, one of them being Information to Patients.
3. **Further NOTES** that the Commission Communication contains an analysis of existing information mechanisms and technologies used at EU and Member State level and takes into account a number of comments in order to obtain a comprehensive overview of the situation as regards information on medicinal products to patients.
4. **RECOGNISES** the need for an adequate response at European level to developments in society and to the increasingly active role of patients as well as the need to reduce differences in access to information for patients in different Member States. This response must take into account particular national circumstances, including population health status and needs, the existing information mechanisms and technologies used at EU and Member State level, the needs of patients and the role of different stakeholders in particular including Member States' authorities and health professionals.
5. **UNDERLINES** the importance of ensuring that patients have access to good quality, objective, unbiased, reliable, complete, comprehensible, relevant, appropriate, patient-oriented, non-promotional information on medicinal products and other treatments in conformity with the statutory requirements as well as access to information that promotes rational and appropriate use of medicines. It also **DRAWS ATTENTION** to the need to identify appropriate communication channels and ways to use them for the dissemination of such information to those who seek it, and to the need for developing methods for updating such information in a way that fulfils the same quality criteria, and for addressing the question of the information source's liability.

6. **NOTES** that in Member States there are different rules, practices as well as sources and methods for dissemination of information on medicinal products to patients.
7. **NOTES** the Commission's intention to present a legislative proposal as stated in its Communication:
  - “- 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 healthcare professionals;
  - Maintaining the ban on direct consumer advertising on 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”.
8. **ENDORSES** the need to maintain the ban on advertising of prescription-only medicines to the general public, and **STRESSES** the need for a harmonised definition and understanding of information that clearly distinguishes it from advertising as well as the need for better control of existing indirect advertising of prescription-only medicines to the general public.
9. **Further POINTS TO** the need for a set of different mechanisms for providing information to the people who actively seek it, bearing in mind that healthcare professionals and competent authorities remain primary sources of information on medicinal products. **NOTING** the role of the Internet as a world-wide information tool, it also **UNDERLINES** the need to find proper ways of ensuring that the Internet and other media are used as channels for communication of reliable information, and the need for ways of ensuring the liability of information sources.

10. **NOTES** that a new proactive role of patients that could contribute to better treatment and quality of life is closely linked to the accessibility of accurate and relevant information on diseases, medicinal products and other treatments. However, this proactive role requires *inter alia* that quality standards for such information be identified and agreed.
11. **EMPHASISES** that wrong, misleading or unclear information can increase the risk of uninformed choices, late diagnosis, unnecessary or inappropriate use of medicines or contribute to a lifestyle based on low risk awareness. Therefore, any active measures to increase access to information should be preceded by an in-depth analysis of the risks and benefits and should include monitoring of information provided to the public on medicinal products and other treatments.
12. **EMPHASISES** that models for providing quality-verified information on medicinal products should be further developed and, in accordance with national practices, could involve public-private partnership or other forms of cooperation involving for example the public sector, patients and health care professionals and marketing authorisation holders, whereas a central role for competent authorities is a prerequisite in the process of organizing the national monitoring and control of information.
13. **NOTES** the Commission's intention to prepare a legal proposal on information on medicinal products to patients and **CALLS ON THE COMMISSION** to further develop means of distinction between advertising and information *inter alia* through providing a clear definition of non-promotional information and at the same time **STRESSES** the need for in-depth reflection on the issue with a view to a more rational use of medicines and to avoiding unnecessary administrative burdens for stakeholders, particularly competent authorities and marketing authorization holders in line with the principles of Better Regulation.

14. **STRESSES** that if the measures or provisions envisaged by the Commission are adopted, a thorough report from the Commission to the Council on the impact of the envisaged measures or provisions in the context of all the other measures or provisions in the field of patient information should be prepared; this report should consider the impact on both patients and the different stakeholders and should be submitted not later than five years after the entry into force of the envisaged measures or provisions.
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