Citizen's Summary

Legal Proposals on Information to Patients by pharmaceutical companies

1. WHAT IS THE ISSUE?

Patients are increasingly interested in decisions about their health and want to take part in them. In addition, the optimal outcome of medical treatment can only reached, if the patients have full information about their medicines.

However, the current situation on patients' access to information about medicines in the EU is unsatisfactory. The amount and the quality of available information depend on whether people can use the Internet and which languages they speak.

2. WHAT IS THE BACKGROUND TO THE PROBLEM? WHY SHOULD THE EU BE INVOLVED?

In 2007, the Commission services[1] published a report considering the current practises with regard to information provision in the EU[2]. Evidence showed that while advertising of prescription-only medicines to the general public is forbidden, a lack of detail on information provision has led to the situation in which different Member States interpret the EU regulatory framework in very different ways. This has created significant inequalities in the information provision and in the possibility for citizens to access information on medicinal products. The responses to the public consultation[3] confirmed that the legislative framework on information to the patients should be improved.

The Community approach on information provision can contribute to the promotion of public health across the EU. This is of major importance in particular in the era of Internet where citizens are able to reach information from all over the world.

3. WHAT ARE THE PROPOSED ACTIONS?

The Commission has prepared a legal proposal on information to patients. Specifically, it proposes the possibility for pharmaceutical companies to disseminate information about their prescription-only medicines to the general public. The key elements of the proposals are:

- Only certain information about prescription-only medicines may be published such as the patient leaflet or a different presentation of its contents.

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1 http://ec.europa.eu/enterprise/index_en.htm

2 Article 88a of Directive 2001/83/EC, introduced by Directive 2004/27/EC, called upon the Commission to present a report to the European Parliament and the Council in 2007 on "current practice with regard to information provision – particularly on the internet – and its risks and benefits for patients".

3 http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new_en.htm

- Only certain communication channels for the dissemination of information shall be allowed, including Internet and health-related publications as defined by the Member State of publication. TV and radio are excluded.

- Strict quality criteria must be fulfilled.

- Adequate and effective monitoring and control must be ensured.

4. WHY ARE THESE ACTIONS USEFUL FOR EUROPEAN CITIZENS?

Citizens will benefit from these actions in many ways. First and foremost, the information provision will be improved and harmonised across the Community and more possibilities to receive high quality, non-promotional information will be provided. Secondly, European citizens shall be able to receive information which is in line with the Community legislation which diminishes the risk for misleading and bad quality information.

5. WHAT ARE THE NEXT STEPS?

The legal proposals will now be debated in the European Parliament[4], representing citizens, and in the Council, representing Member States[5].

4 http://www.europarl.europa.eu/
5 http://www.consilium.europa.eu/