

The Informed Patient What the European Union has to do

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European Life Science Circle

European Parliament

Brussels, Room 3G3

Thursday 6 December 2007

9.00–13.00

- First of all, I would like to thank the MEP Chatzimarkakis for organising this debate in such a timely period. Also, to MEP Grossetête and Roth-Behrendt, we are grateful for your continuous personal involvement on that issue.
- Information on diseases and on pharmaceuticals is becoming a key element in the society. Indeed patients are playing an increasingly active role in the healthcare environment. Being more involved in the decision-making regarding their health, patients require a better and easier access to high quality information. Enhanced information on pharmaceuticals also contributes to increasing patient safety with effects on medication errors for instance. At the same time, we have all experienced how information currently varies considerably amongst Member States and media. Internet for instance may not always provide reliable or understandable data.
- Recognising the primarily role of national authorities in ensuring the provision of information to their citizen, the Commission has been fully engaged in favour of promoting access to high quality information. Two separate initiatives are of particular interest for today's meeting:

Pharmaceutical Forum

- The Pharmaceutical Forum, a high-level political platform , was created by Vice-President Günter Verheugen and Commissioner Markos Kyprianou in 2005, as follow-up to the G10 Medicines process. Its objective was to take forward 3 remaining themes out of the 14 wide-ranging recommendations of the G10 Group including Information to patients on disease and treatment options.
- Today, after two years of discussions, Member States and stakeholders have reached a large degree of common understanding on needs and challenges in terms of access and quality of information for patients.
- In addition, the working group has been engaged in a constructive approach to deliver practical elements to support Member States in enhancing access to high quality information:
 - The recognition of the role of health professionals in the delivery of information to patients and the identification of good examples(in pharmacies, GPs or hospitals) which could contribute to reduce the existing barriers
 - A set of core quality principles for information and a methodology for their use is being produced
 - Finally, the recognition of the value of involving all the stakeholders, including industry, in collaborative approaches such as partnerships to develop and generate information to patients.
- Those outcomes have been possible thanks to the involvement of members of the working group. Nevertheless, the Pharmaceutical Forum is a discussion platform where all the members are invited to be part of the exercise on a voluntary basis. We managed to create a certain level of

trust among the members. Our challenge is now to facilitate implementation of the results. Some changes are already visible at the national level, but the final year, 2008, will be key to see volunteering moves towards better and easier access to information on diseases and treatment options.

Report on the Current Practice with Regard to Provision of Information to Patients on Medicinal Products and the possible changes to the legal framework

- In April 2007, DG ENTR launched a public consultation of a Draft Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products concerning the provision of medicines information in Member States. During the consultation, DG ENTR received 73 contributions, from all stakeholders.

- There was an emerging consensus that:
 - information provision to patients should be improved
 - the ban on direct-to-consumer advertising should be retained
 - the internet is a good but not the only channel for providing information to patients
 - there is a clear need to adopt common standards and quality criteria for information provision.

- There were mixed views on the distinction between informing and advertising and on the possible best mechanism to ensure quality of information and enforcement of rules.

- The summary of the responses has been published in DG ENTR website.

- The final report has been finalised within the Commission and is awaiting final adoption by the College for transmission to the European Parliament and the Council by the end of the year. Its adoption should occur over the next two weeks.

- For ensuring the provision of valid and high-quality information to patients, the Commission has announced its intention to adopt a legislative proposal to the European Parliament and the Council by the end of 2008 on information to patients. The general policy objectives of this legal proposal should be
 - to establish a framework for providing citizens of EU Member States with high-quality and non-promotional information about the benefits and the risks of their medicines
 - to maintain the ban on direct-to-consumer advertising of prescription medicines
 - to maintain the confidence of citizens, regulators and healthcare professionals, while putting the interests of patients first
 - to avoid unnecessary bureaucracy, in line with the principles of Better Regulation

- The main purpose of the Commission proposal is to ensure further harmonisation in the rules concerning the provision of information on medicinal products authorised in the EU, taking into consideration evolution in society.

[Recently the ECJ has concluded that the legislation provides for a complete harmonisation of the rules applying to advertising of medicines. This shows the

need for introduction of clear rules for activities related to the provision of information]

- As a next step, DG ENTR is preparing an assessment about the possible impacts of the forthcoming legal proposal. This Impact assessment started in May 2007. The aim of the assessment is to identify the main options for achieving the objectives mentioned above, to analyse their likely impacts and to outline advantages and disadvantages of each option and examine possible synergies and trade-offs, also in relation to different types of information.
- A great challenge in the forthcoming legal proposal and in the impact assessment is to make a differentiation between informing and advertising. This indicates clear orientations to the framework to establish clear rules on what type of information can be provided, who can provide it, how it can be provided and on enforcement mechanisms.
- All the information provided to patients should fulfil certain quality criteria. The high-quality information should be objective and unbiased, patient oriented, evidence-based, up-to-date, reliable, understandable, accessible, transparent, relevant and consistent with statutory information. These quality criteria have been agreed by Pharmaceutical Forum and they show general consensus amongst all parties; therefore they should be respected.

In conclusion, the Pharmaceutical Forum process is the opportunity to engage the dialogue on information to patients, to build trust among the national authorities and stakeholders but also to propose concrete actions that can be

implemented within the current legal framework. In relation to the possible changes of the legal framework, the next step will be the transmission of the report on the provision of information on medicines to the European Parliament and to the Council.