PUBLIC CONSULTATION

On the Legal Proposal on Information to Patients

5/2/2008 **Commission launches a Public consultation on the key ideas of a legal proposal on information to patients**

The 'Report on current practices with regard to the provision of information to patients on medicinal products', published on our website for public consultation in 2007, revealed the need to harmonise the way in which information on medicinal products is made available in the EU in order to ensure that all patients have equal access to information on medicinal products.

With this in mind, DG Enterprise and Industry invites you to give your opinion on the key ideas of a legal proposal aiming at ensuring that all EU citizens have access to good-quality, objective, reliable and non promotional information on prescription-only medicinal products.

Please click here to access the Consultation paper. EN - FR

All responses to the public consultation should be sent by e-mail to ulla.narhi@ec.europa.eu by 7 April 2008.

Comments and ideas of the State Institute for Drug Control on the "Legal Proposal" on the provision of information on medicinal products to patients

1. SUKL welcomes the fact that the purpose of the Proposal of the European Commission is to ensure good-quality, objective, reliable, and non-promotional information on prescription-only medicinal products to the citizens of the EU.

2. The guarantee that healthcare professionals should remain the primary and most important source of information relevant to health is also much welcome.

3. We identify ourselves with the idea to retain the ban on advertising for prescription-only medicinal products.

4. We consider, however, the Proposal for amending Directive 2001/83/EC (hereinafter referred to as the "Directive") to be premature, as the Communication form 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 (hereinafter referred to as the "Report") has not been discussed in the Council (the working party on pharmaceuticals and medical devices should prepare the Council position in the form of Council Conclusion) nor in the EP. The "Legal Proposal" has been prepared and provided for public consultation without being able to reflect the position of the EP and of the Council on the Report. For this reason we recommend suspending any further discussion on the "Legal Proposal", as the conclusions of the EU Council and of the EP may express different positions of the Member States.

5. There is a doubt as to whether the Proposal in its contents might be diverting from the meaning of the Article 88a which speaks about the development of an "information strategy" to ensure the provision of information to patients, while the Legal Proposal focuses mainly on the regulation of the provision of information by the marketing authorisation holders and refers only to medicinal products and does not mention therapeutic procedures as anticipated by Article 88.

6. The purpose of the harmonisation to establish rules to govern the possible provision of information about prescription-only medicinal products by pharmaceutical companies seems to be somewhat debatable. We wonder whether a legislative background focusing upon the liberalisation of provision of information by the marketing authorisation holders may be considered harmonisation of legal provisions of individual Member States, when this very way to provide information has not been legally stipulated in the Member States as yet and seems to be the most controversial one. We consider the risk that the information provided directly by the pharmaceutical industry may be biased and that it will represent a form of advertising to be too high. We can hardly expect information which would cover the true needs of patients. We wonder whether in such a case the Proposal is based upon the existing practice in the Member States On the contrary, as suggested by the Report, the practice knows and develops also other public or non-profit independent sources and thus objective information for the patients, both with the participation of pharmaceutical industry or without it.

7. The rationale of the purpose of the Legal Proposal in this form seems to be insufficient as yet. We would appreciate better justification in particular, why the proposal does not address a broader strategy and the fulfilment of the need for information to patients. Legal proposal focuses only on the initiative to regulate information provided by the industry. As implied by the Report, this source of information is the most controversial one, particularly for possible conflicts of interests. Risks are, furthermore, incorporated also in the fact that it opens the possibility for pharmaceutical companies to disseminate information on prescription-only medicines via any media and in any form.

8. An effective enforcement system would have to process practically any information disseminated by all media and assess whether they involve advertising. It is hard to imagine that all information disseminated by all media, can be controlled in advance and assessed as to their quality, objectivity, impartiality and clarity.

9. The Communication seems to omit the regulatory impact assessment, in particular the increase of the administrative burden associated with the enforcement mechanism. The legislation allowing for the establishment of a co-regulatory authority with e.g. monitoring powers has not been in place in all Member States (for example, it does not exist in the Czech Republic).

10. We can also hardly agree with the establishment of additional, three-level enforcement structure on the European level. We have some doubts, whether the enforcement model would be efficient. The initiative for the establishment of yet another, three-level enforcement system, does not correspond to the objective in item 3, the need to prevent any unnecessary bureaucracy in compliance with the "Better Regulation“ principles, focused upon the reduction of bureaucracy.

11. We are afraid that the system would imply an excessive administrative burden for the regulatory authority (or the necessity to establish a new body), which is inconsistent with the effort of the Member States to reduce administrative costs, while the benefit of the information provided by the pharmaceutical industry, as suggested by the Proposal, would be debatable.

12. We emphasize that the definition of information should be clearly outlined – we do not agree with the negative definition of the term “information” with regard to the term “advertising”. We insist that a clear, positive wording be established to clearly determine what permissible information of pharmacotherapeutic nature for patients is, incl. the definition of qualitative criteria binding for such information.

13. We believe that the Proposal, differently from the task stipulated by Article 88a of the Directive deals with information on medicinal products only, is lacking essential information on therapeutic procedures, their benefits and risks, whose provision is an integral part of any unbiased information sought for by patients.

14. The Proposal does not take into account that according to Directive 2001/83/EC, marketing authorisation holders in the Member States are obliged to provide an publicly accessible professional information service on medicinal products.

15. The Proposal should pay more attention to the internet which, as suggested by the Report, is becoming a major source of information for patients. We propose to consider a system of "accreditation" of websites providing information on medicinal products, therapeutic procedures and their risks and benefits for the patient.

Conclusions:

Due to the fact that the Proposal of the Commission has been, so far, presented only in the form of key ideas and lacks adequate explanation why a particular solution has been proposed, we consider the Proposal difficult to comment and lacking proper justification.

We are afraid, that the Report cannot be considered as sufficient basis of the proposed amendment of Directive 2001/83 EC. We believe that providing marketing authorisation holders with the possibility to disseminate information does not seem to be the way we prefer to take as the common strategy.

We are afraid, that the Proposal implies inadequately high administrative costs associated with the establishment and increase of the administrative agenda of the bodies which would have to be established for the purposes of monitoring and control of “information”. Instead, we prefer a way where information on treatment options for patients would be provided by entities which are independent of the pharmaceutical industry and have professional background, hence complying with the requirement for objectivity and professional quality of information provided to patients, without the necessity to establish yet another surveillance and enforcement mechanism. This should be the one of the key ideas of the information strategy the establishment of which is anticipated by Article 88a. If Member States implemented as demanding an enforcement system as suggested, it would imply high demand on public resources, both for expert and administrative capacities. The Report itself does not explain what burden for the public health insurance and for public administration would be associated with the new system in the Member States and what would be the impact on patients, as the Proposal has not been preceded by an adequate risk/benefit analysis.

The “unbiased nature” of the information provided by the marketing authorisation holders which might not be quite in line with the business interests of pharmaceutical companies, is debatable as well. In addition to our agency and the Ministry of Health we continue to consider the major sources of information on medicinal products for patients to be healthcare professionals, doctors of medicine, pharmacists, and other healthcare personnel, whose professional education qualifies them for the provision of such information.