ANSWER TO THE PUBLIC CONSULTATION "LEGAL PROPOSAL ON INFORMATION TO PATIENTS", DEADLINE 7/4/2008

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With regard to the Commission document "Public consultation on a legal proposal on information to patients", I would like, as practicing pharmacist in Belgium, to express the following views and concerns.

With regard to point 2.1. The reasons for this proposal.

The Commission document indicates that there is in the Member States unequal access of citizens to information on prescription-only medicinal products. The question however is whether citizens or patients in one of the Member States have expressed to be in a situation of insufficient access to information on these medicines, which anyhow need to be prescribed by a healthcare professional. If the answer to this question is no, why a E.U. measure is necessary ; if yes in a Member State there would be a real lack of access to such information, why not leave it to the Member State concerned to fill up this lack by appropriate measures according to the specific healthcare situation in its territory. Anyhow, as far as I see it in my country, I see no need for a provision authorizing passively received information for this type of medicines (*see further hereunder action 3.3.1*).

Action 3.3.3. Pharmaceutical companies answering questions from citizens. The proposed regime of monitoring of the answers given, based on complaints, seems an appropriate measure to ensure that the good quality of the answers is guaranteed.

Action 3.3.2. Information actively searched by citizens. The proposed regime authorizing such information (e.g. on the internet) with a monitoring system seems an improvement of the current situation, as currently pharmaceutical companies (and other organisations) can place such information on the internet without systematic monitoring.

The terminology in the consultation paper reading "without validating ex-post or ex-ante specific actions" is however not clear at all on what monitoring is aimed for. But I expect this text means that the coregulatory body will be informed systematically and in advance of the information pharmaceutical companies place on the internet, so that an adequate and timely monitoring is possible.

It should also be emphasised that the information given by pharmaceutical companies should be fully coherent with the approved data of the submitted dossier and with the approved information leaflet accompanying the pharmaceutical product on the market (When e.g. the information would mention a use which is not provided for in the approved information leaflet, this information could not be considered as coherent).

Action 3.3.1. Information passively received by citizens, i.e. information which pharmaceutical companies bring to the public through the media (TV, radio, journals, printed leaflets), either directly or via healthcare professionals. This is the key issue and also most controversial part of the proposal.

It is not correct to put on the same line information brought to citizens directly and information brought to patients through the filter of the healthcare professionals, as in the last

case the quality and the appropriateness of the information for a specific patient has been checked by the healthcare professional.

This type of information directly from the interested pharmaceutical company to citizens should not be authorized. There is a too big risk that such information will increase the demand for and use of such products, that it will put pressure from patients on healthcare professionals to prescribe, and that it will disorient patients on the right choice of the most effective medicine.

Prescription-only medicines are special products which should only be used after a thorough examination of the patient by a healthcare professional, taking into account the specific problems and situation of each patient. Medicines are biologically active compounds with always possible undesirable effects. In the interest of patients and of public health their use should be limited to cases where they are indispensable.
The medicines concerned are the response to a specific diagnosis made by the healthcare professional, not by the pharmaceutical company. Information campaigns on a specific medicine to the public in general are therefore not necessary.

Moreover the provided monitoring system seems insufficient : in case of an inappropriate information action, the burden of proof lies with the monitoring body, and the pharmaceutical company can go on until decision has been taken in court.

Action 3.1. The current rules, allowing the advertisement of OTC medicines should not be changed.

I do not agree with this statement in the Commission document. As said before, all medicines – including OTCs - are biologically active compounds with always possible side effects. In the interest of patients and of public health their use should always be limited to cases where they are necessary. As the basis of any advertising is to increase consumption, advertising for medicines is to be rejected.

Point 1. The procedure of the consultation.

I strongly appreciate that by this procedure the consultation has, as explicitly said in point 1.2.of the consultation document, been addressed to all citizens and organisations, and that it has not been restricted to the specialised European lobbying groups.

However, the consultation document has been made available only by the end of February with a deadline of 7 April. It is evident that such period is too short to permit the document to reach a wide range of citizens, professionals and organisations and give them the possibility to study and translate it, to assess its consequences and to prepare an adequate answer.

Moreover, I could, on my request, not receive this document, with its highly technical content and its possibly severe consequences for the future, in Dutch, which is an official language of the European Union. In a good working democracy, respecting equally all its citizens, I strongly had expected to find such a document in my own language.

Preparing this answer has been a difficult and time consuming effort. I hope that the Commission will take it effectively in consideration in the further preparation of this proposal.