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European Commission
DG Enterprise & Industry
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April 7th, 2008

Public Consultation “Legal Proposal on Information to Patients”

Dear Sir or Madam,

in February 2008, you have published a document entitled “Public Consultation: Legal Proposal on Information to Patients”. We are one of the consulted stakeholders. Please, find our comments on this document as follows:

The ABDA – Federal Union of German Associations of Pharmacists is the main professional organisation of German pharmacists. Its members are the 17 Pharmacists’ Chambers (membership: all active pharmacists) and 17 Pharmacists’ Associations (membership: 90% of the pharmacy owners) of the federal states. The ABDA represents all 54.500 German pharmacists. On the European level, the ABDA is a member of PGEU – Pharmaceutical Group of the European Union.

We want to endorse the comments which have been sent to you by PGEU. They come to the conclusion:

> “*The Commission’s proposals are a missed opportunity. The legitimate concerns of patients could have been addressed while recognising the well founded concern about industry involvement in this area. Instead they offer a future in which the pharmaceutical industry can freely communicate information about its products in the mass media, but with a system of weak sanctions, conflicts of interest at national level, and a watered down system of quality criteria. It reads as a document which has little to do with the needs of Europe’s patients, and everything to do with the agenda of the pharmaceutical industry.*”

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We want to emphasise the legal environment in which the Commission's proposals have to be seen. According to the Treaty, **Member States are responsible** for the organisation of their health systems (Art. 152 EC). The EU can only take supportive action in this field, while harmonisation remains an exception. Furthermore, the **principle of subsidiarity** requests the Commission to refrain from any action unless Member States cannot reach the respective goals sufficiently on their own (Art. 5 EC). Both principles – national competence for health systems and subsidiarity – will be strengthened considerably by the Treaty of Lisbon.

This is the status quo as far as patient information is concerned. Of course, it leads to a situation where citizens of different Member States have different possibilities of access to information about medicinal products. These differences originate exactly from the national competence of the Member States and must not be taken as a justification for harmonising measures by the Commission, as it has been done in the "Report on current practices with regard to the provision of information to patients on medicinal products" (COM [2007] 862 final). **Otherwise, harmonisation would become a justification for itself**, which would pervert the principles of competence and subsidiarity.

Taking this legal environment into account, it is clear that **it is up to the Member States to develop models** which lead to a better patient information on medicinal products. The EU can help by sharing views on Best Practice, as it is done in the Pharmaceutical Forum. It should take **no further legislative measures** on Community level.

As an example for current activities on the national level, we want to draw the Commission's attention to the work which is undertaken by ABDA together with the National Association of Statutory Health Insurance Physicians (*Kassenärztliche Bundesvereinigung*), the Drug Commission of the German Doctors (*Arzneimittelkommission der Deutschen Ärzteschaft*), and the Federation of German Consumer Organisations (*Verbraucherzentrale Bundesverband*), among others, with support from the Federal Ministry of Health to prepare a common project for independent, objective and constructive patient information on medicinal products. It is common belief of the above mentioned organisations that this information must be given to patients **independently from the pharmaceutical industry**.

Concerning some of the details of the consultation document (while emphasising the fact that **we do oppose the proposed Community action**), we think that:

- "*A clear distinction between advertising and non-promotional information*" (p.5), which is emphasised by the Commission, is not visible in the consultation document. There is no legal definition of advertisement at all in the document[1]; it is just said that anything which is not covered by this (hypothetical) definition should be regarded as information (p.6). If any Community action should be taken in the future, it should follow the opposite approach: **give a clear definition of information, and everything else would be regarded as advertisement**.

[1] The current definition in Art. 86 of Directive 2001/83/EC states that "advertising of medicinal products shall include **any form of door-to-door information,** canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; …". If this definition – which is absolutely appropriate – was kept, it would contravene most of the Commission's plans.

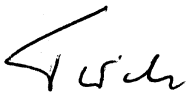
- "*Push mechanisms*" (p.6) should be regarded as a hint for promotional activity. This must not be a justification to enable more "*pull dissemination*" (p.7) by the industry, but **every way of dissemination should be regulated under the same standards**.

- Any "information" from the industry which is given directly to patients should be validated **ex ante** by **National Competent Authorities** or **independent bodies – without involvement of the industry** itself.

In conclusion, we call on the Commission once more to step back from its intention to allow direct-to-consumer information by the pharmaceutical industry. Instead, it should leave it up to the Member States to regulate how they want their patients to be informed about medicinal products. The German legislator has chosen to rely this task of independent information to independent health professionals – doctors and pharmacists –, not to the pharmaceutical industry.

Yours faithfully,

ABDA – FEDERAL UNION OF GERMAN
ASSOCIATIONS OF PHARMACISTS



Lutz Tisch