



ABDA - Bundesvereinigung Deutscher Apothekerverbände
Postfach 08 04 63 · 10004 Berlin

European Commission
Pharmaceuticals Unit
DG Enterprise and Industry
Dr. Peter Arlett

Department for Drug Law and
Pharmacy Law, Professional Law
Tel.: 030 / 400 04-312
Fax: 030 / 400 04-313
aporecht@abda.aponet.de

Brussels

January 29th, 2008

Public Consultation on Legislative Proposals: „Strengthening and Rationalising EU Pharmacovigilance“

Dear Dr. Arlett,

on December 5th, 2007, the European Commission has published a consultation document on the future regime of pharmacovigilance.

The ABDA – Federal Union of German Associations of Pharmacists is the umbrella organisation of the 17 Pharmacists' Chambers and the 17 Pharmacists' Associations in Germany. Through its members, ABDA represents the interests of approximately 55.000 pharmacists.

Since pharmacists play an important role in the context of pharmacovigilance, especially because of their direct contact to patients, we have read your consultation document with great interest. We appreciate the aim of the consultation to improve the quality of pharmacovigilance. Nonetheless, there are some aspects which should be dealt with more deeply. Please find attached some remarks on behalf of ABDA. Furthermore, we endorse the comments of our European organisation PGEU – Pharmaceutical Group of the European Union.

Kind regards
ABDA – Federal Union of German
Associations of Pharmacists

Lutz Tisch

Deutsches Apothekerhaus
Jägerstraße 49/50
10117 Berlin
Telefon 030 40004-0
Telefax 030 40004-598
E-Mail abda@abda.aponet.de
<http://www.abda.de>

Remarks concerning the EU Commission's consultation on pharmacovigilance

- 1 It must be ensured that the existing, well-functioning systems of the EU Member States are not undermined by a re-structuring of the European directives. This is especially important insofar as the role of health professionals – for example pharmacists – is concerned. The consultation does not cover the role of these health professionals in detail, but only mentions them a few times.

Member States like Germany do have well-functioning rapid-alert systems and procedures for market withdrawal which include active participation of health professionals and their own pharmacovigilance institutions. For example, in Germany pharmacists annually report 6000 to 7000 cases of suspected adverse reactions and inadequate pharmaceutical quality not only to the competent authorities, but also to their own pharmacovigilance commission (*“Arzneimittelkommission der Deutschen Apotheker”*) which evaluates these reports and contacts the authorities by itself. This has proven to give an enormous amount of added value to the minimum legal standards envisaged by the European directives.

It must be ensured that these proven and reliable systems can be operated also under the new conditions. This is also required by the principle of subsidiarity.
2. It must be taken into account that not only new (prescription-only) medicines may show adverse reactions, but also existing OTC medicines. Concerning these medicines, pharmacists and their institutions are the most important control instance. **It is important that pharmacovigilance also covers OTC medicines**, but these are currently not sufficiently covered by the consultation text.
3. A specific remark concerning temporary suspensions (p. 29, Annex 1, Chapter 6, Art. 101k): It is very essential that maximum time limits are mandatory to notify competent authorities in those Member States where the medical product in question is also marketed. Experience shows that these notifications are transferred to the EMEA, but not to authorities of other Member States in due course.

A solution for this could be **re-structuring of the notification process**. The Member State who reports an incident should notify the EMEA, which then would notify the other Member States on its own. It would be important to ensure that these notifications are proceeded without delay, for example by stating exact dates and short time limits.
4. The database to which Art. 123 paragraph 4 relates is currently managed on an annual basis. It would be much more sensible if this **database**, which shall be run by EMEA in the future, **contained updated data on a daily basis** and would also be **accessible for all European members of the pharmacovigilance process**. Moreover, the database should not only cover drugs which are prohibited, but also drugs whose authorisation is temporarily suspended.