BUNDESVERBAND DER ARZNEIMITTEL-HERSTELLER e.V. (BAH)
(FEDERAL PROPRIETARY MEDICINES MANUFACTURERS' ASSOCIATION

The Managing Director

To

Dr. Martin Terberger

Head of Pharmaceuticals Unit

Enterprise and Industry Directorate General

European Commission

1049 Brussels

Bonn, 11 April 2006

Harmonised compilation of Periodic Safety Update Reports (PSURs)

Dear Mr Terberger,

In your letter of 24 March 2006 to Dr. Cranz, you asked the AESGP (European Proprietary Medicines Manufacturers' Association) if it wished to take part in a study of the EU pharmacovigilance system.

In this context we should like to draw your attention to a problem which makes heavy demands on the resources of both the competent authorities and the industry, and which would not be necessary if the system were optimised.

The problem is with the Periodic Safety Update Reports (PSURs). A PSUR is a largely active-substance-related compilation of all information available worldwide over a reporting period of three years as a rule, and has to be completed by all holders of authorisations for the active substance. Since PSURs on substances with a well-known benefit/risk profile are usually based primarily on information from the available literature, it makes sense to compile these sections of a PSUR jointly. For this to happen, however, the dates for submitting a PSUR need to be harmonised, preferably to a single deadline per substance. Herein lies the challenge for which we are seeking your support.

As we see it, two things are necessary:

1.) fixed substance-related data deadlines;

2.) a procedure for meeting these deadlines.

For single data deadlines to be fixed, we feel that a list of dates needs to be compiled and made generally available in the near future. Since such a deadline will rarely agree with the date arising from the authorisation history of a specific product, an instrument is needed which is simple and cheap to administer and enables authorisation holders to meet this harmonised deadline. The high administrative and financial cost of the current instrument, a Type 11 variation, makes it largely unsuitable.

One solution to this problem is in the joint interests of the industry and the authorities. Together with the BfArM (*Bundesinstitut für Arzneimittel und Medizinprodukte* – Federal Pharmaceuticals Institute) we have arrived at effective solutions in Germany for national products. Given the increasing importance of European authorisations, however, a European solution also needs to be considered. In this context we welcome and support the efforts being made by a working party set up for this purpose by the Netherlands

authority. To help these efforts succeed more quickly and on a broader basis, we should welcome the chance to discuss our proposals with you.

The consultation planned for 27 April on the EU pharmacovigilance system, at which the BAK will be represented as part of the AESGP delegation, would offer an opportunity for such a discussion.

We should be delighted to receive a positive response to this suggestion.

Yours sincerely,

Dr. Bernd Eberwein

cc.: Dr. Hubertus Cranz, AESGP