Comments from the FAMHP on the European Commission proposal on pharmacovigilance

The FAMHP fully supports the Commission's proposal to strengthen and rationalize the EU pharmacovigilance system and the comments that were discussed by the Pharmacovigilance Working Party (PhVWP) of the EMEA, at their meeting in January 2008.

Please find here after some additional or strengthened Belgian comments on the:

1. Notification of single adverse drug reactions (ADR's).

We fully agree with the proposal to give to the EMEA the task to scan the literature and to enter the case reports from the literature in Eudravigilance.

We also support the intensive monitoring of some medicinal products. Nevertheless, we think that intensively monitored drugs should be reported also to the national authorities and not only to the marketing authorization holder (MAH). Some patients could be afraid to contact a pharmaceutical company and to report to the national authority would ensure a more standardized feedback to patients. Additionally, promotional messages to patients by the MAH could not be controlled.

2. Periodic safety update reports (PSUR's).

The FAMHP supports the concept of work-sharing as well as a legal basis for the PSUR work-sharing program and agrees with the proposal to adapt the periodicity of the PSURs to the knowledge on the medicinal product.
However, the proposal to suppress PSURs for generics, traditional herbal medicinal products and homeopathics other than referred to in article 14(1) is questionable. The provision proposed by the Commission is not applicable to innovators (reference medicinal products) authorized since a long time. Therefore, discrimination between innovators and generics may emerge from this situation. Additionally, the PSUR is a useful tool for periodical reevaluation of the benefit-risk balance of all medicinal products.
Consequently, the FAMHP prefers to keep the idea of a 3-years PSUR cycle for all sorts of medicinal products but with the possibility of a derogation based on a case-by-case evaluation and this equally applicable to all sorts of medicinal products.

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3. Public communication

We support the need to enforce the harmonization of safety communication in the EU. However, we would like to point out the complexity of harmonization in case of urgent situations on safety issues, e.g. media concern.

4. Codify oversight of non-interventional safety studies

The proposal of the PhVWP to ensure non-interventional post-authorization studies (when conducted in different Member States) having health objectives rather than promotional objectives, is welcomed . In this regard it is essential to harmonize the detailed definition of "non-interventional trial" between the different Member States and to foresee the necessary resources at the level of the National Competent Authorities : in some Member States, as is the case in Belgium, non-interventional trials (prospective) only need an authorization of the Ethics Committees .

5. Transparency

We support the proposal to increase the transparency in pharmacovigilance by providing on request the case reports from EudraVigilance.

Nevertheless, we think that the content of the information provided must be carefully evaluated at European level, e.g. information provided by active substance or by trade name. General communication concerning the content, the objectives and the limits of the EudraVigilance database should also be provided in order to avoid or to limitate misunderstandings.

6. Resources by national authorities

Some aspects of the proposal (e.g. mandatory patient reporting, reporting of all cases by the MAH, and repeated audits of the pharmacovigilance systems of the national authorities) will increase the workload for each Member State, raising concerns about the financial resources for all these new tasks.

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