FARMINDUSTRIA

Subject:	"PC/12/05 – Public Consultation on pharmacovigilance fees"
Respondent:	Farmindustria - The Italian Association of Pharmaceutical Enterprises
Respondent profile:	stakeholder association pharmaceutical industry association – originator products
Address:	3/8 Largo del Nazareno – 00187 Rome (Italy)
e-mail contact	moroni@farmindustria.it

Replies to concept paper submitted for public consultation: introduction of fees to be charged by the EMA for pharmacovigilance

General comment

Farmindustria welcomes the opportunity to submit comments on the concept paper released by the European Commission regarding the introduction of fees for pharmacovigilance to be charged by EMA.

Farmindustria does not agree with the maximum amounts of all proposed fees, which seem to be exceedingly high compared to the workload requested for the assessment especially of Periodic Safety Update Reports (PSURs), and Pharmacovigilance Referrals (specific motivations are reported below). Moreover we consider the fees exceedingly high in particular for those companies whose products are authorized only at national level or in a very limited number of Member States.

We agree that reduced fees should be foreseen for SMEs and should be considered also for orphan drugs, for which the Agency provides reduced fees for regulatory activities.

Consultation item n°1: Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative.

Farmindustria does not agree with the proposed fee for single assessment of PSURs, considering that the majority of the fees to support the new pharmacovigilance legislation through PSURs will be paid by companies developing new and innovative medicines.

Farmindustria does not agree with the proposed criteria to benchmark the fees proposed for the assessment of PSURs with the current fee applied for a Type II variation. In this last case the assessors usually evaluate completely new data (e.g. data from clinical studies) while in the case of PSURs - except for the first PSURs submitted to the Authority

- evaluation will be made also on the basis of previous assessments on PSURs previously submitted; this is particularly true for those products that have a consolidated benefit/risk profile (e.g. eye drop, dermatological product).

As for the different fee amounts proposed for new and old products (40.300 € for products authorized for less than two years and 80.300 € for product authorized for more than 2 years), we believe that the workload actually needed for assessment should be reconsidered. Even if PSURs for products authorized for more than 2 years contain more safety data compared to PSURs for new products, the workload in assessing PSURs for old products could be lower depending on the overall risk profile of the products.
Moreover we suggest that different fee levels should be considered and should take into account the following elements:

- Therapeuthic class;
- Active substance (if new chemical entity or not);
- Innovative product;
- Number of EU member states where the product is authorized;
- Volume of sales in EU;
- Eudravigilance data.

Consultation item n°2: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.

The possibility for MAHs of grouping for the purpose of paying a single fee providing a single PSUR would be positive in principle, but might be practically unfeasible for the following limitations:

1) Each company has its own standard operating procedures and this might result in differences (e.g. in case assessment) which could be difficult to be harmonized in a common PSUR.
2) Coordination activities related to the writing of a common PSUR by different companies is a demanding task that might impact on the PSUR timelines compliance. Above all, it might be a challenge for different MAHs (even for confidential reasons) to agree on the content of a common overall benefit-risk evaluation and conclusion.

Moreover, additional administrative fees should not be charged to MAHs belonging to the same mother company or group of companies, or to MAHs having agreements regarding the placing on the market of concerned medicinal products.

Consultation item n°5: Do you agree with the proposed fee for the assessment of pharmacovigilance referrals If not, please explain and/or suggest alternative.

We do not agree with the proposed criteria to benchmark the fee for the assessment of pharmacovigilance referral with the current fee for an initial MA application in the

centralized procedure; in our opinion the data to be assessed and the work involved is not comparable to an initial application since products involved in a referral are authorized products for which competent authorities have already performed an evaluation of the benefit/risk profile both at the time of the application and for PSURs assessments.

Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative

We do not agree with the proposed annual pharmacovigilance service fee charged to all MAHs.

Many MAHs will pay for the service but will not benefit from the pharmacovigilance activities carried out by EMA, i.e. screening of selected medical literature will be done by EMA only for the active substances included in the list monitored by the Agency. MAHs of the products not included in the list and others will continue to carry the burden of worldwide literature screening.
The EMA will screen only selected medical journals while other kinds of scientific publications (e.g. local journals) will always be under the MAHs responsibility and burden.

The annual fee covers the maintenance of the Eudravigilance database for the submission of all ADR reports from MAHs. To this regard, it should be considered that the number of ADR reports may be very low for certain active substances (e.g. less than 100 ICRSs yearly), depending on their risk profile and the distribution on the market, so a reduced fee should be considered.

Moreover the annual fee for pharmacovigilance would be added to the annual fee paid to the EMA and would duplicate the existing annual fees already paid at national level.

Consultation item n°8: Do you agree with the proposed approach for fee reductions for SMEs as regards the pharmacovigilance procedures at EU level (point 3.5.1)? If not, please explain why and provide suggestions how this could be improved

We do agree with the proposed approach for fee reductions for SMEs.

14th September 2012