European Commission,
DG Health and Consumers,
Unit D5 'Medicinal products – authorisations, EMA'
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Response to the European Commission Concept Paper:
INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE

Statement/Commenter: Weleda Ges.m.b.H & Co KG, 1220 Vienna, Austria, a company specialized in natural medicinal products and natural organic cosmetics, SME.

Weleda Ges.m.b.H & Co KG welcomes the possibility to comment on the concept paper regarding the introduction of fees to be charged by the EMA for pharmacovigilance.

Preliminary remarks:
Weleda Ges.m.b.H & Co KG, Vienna, Austria is a company holding marketing authorisations for more than 200 different products authorised only on a national level (non-CAPs).

Weleda Ges.m.b.H & Co KG is holding many homeopathic marketing authorisations (§9b Austrian Drug Law (AMG) according to 2001/83/EC Art. 16.2.

The active ingredients of these products are of natural origin and have a well known safety profile. Most of them were placed on the market decades ago. ADRs are very rare and only in exceptional cases serious. There is no exemption for a PSUR for this kind of homeopathic marketing authorisation.

Regarding the general principles of this concept paper (2.3) we would like to highlight the following:

Proportionality:
The principle of proportionality between the amount (level) of the fees and the nature of the work/tasks to be carried out by EMA must be taken into account when fees are proposed, e.g. for the assessment of a PSUR for a well known substance or a combination thereof. That means that the factual workload of the assessors is to be taken into account which is assumed to be considerably lower with regard to PSURs for longstanding and well known products than for new chemical entities.

PSUR-exemptions exist for marketing authorisations like Well Established-Use (WEU), Traditional herbal registrations (THMP) and generics. Although there is no higher risk of ADRs for marketing authorisations based on Art. 16.2 of 2001/83/EC a PSUR is required. It is not to understand why a PSUR for marketing authorisations based on Art. 16.2 is required, even if the product has been in medicinal use within the Community for more than ten years, with recognised efficacy and an acceptable level of safety (criteria for well-established use).

Transparency:
Transparency is given by the proposed fees only regarding to what the fees correspond to. However, due to grouping it is not clear in advance how high the fees would be at the end. Example: If a PSUR is to be written for a product containing a substance from the URD list the MAH cannot know how many other MAHs will submit a PSUR for the same substance.

Equal treatment of MAHs:
In principle an equal treatment of MAHs is welcomed. However, the fees to be charged should distinguish between MAHs with few products having a high sales level and MAHs with many products having a low sales level. Weleda Ges.m.b.H & Co KG belongs to the latter category.
The products distributed by Weleda, which are based on a homeopathic marketing authorisation (16.2 of 2001/83/EC) have an average yearly turnover of about 25.000€. Production costs are high due to small amounts. If the proposed fees came into force we would have to withdraw all products from the market.

That means: Equal treatment of MAHs leads to unequal marketing conditions for MAHs.

3.1 Fee for assessments of Periodic Safety Update Reports
Consultation item no 1:

We do not agree with the proposed fee for single assessment of PSURs.

Explanation:
According to the long standing experience with the products and the PSURs submitted in the past to the national CA, the volume of such a PSUR is so small (for some of the products we did not receive one single ICSR in three years) that fees up to 80,300 € (or 40.150€) can never be justified. At the moment a fee of 100€ has to be paid. The proposed fee would be 400-800 times higher than now!!!

Moreover grouping with other MAHs is rather unlikely, because even within one company the products differ in the composition from country to country due to national traditions of the CAs in the different member states.

We propose:
First: No PSUR of homeopathic marketing authorisations (16.2, 2001/83/EG), especially, when the ingredients are in medicinal use within the Community for more than ten years, with an acceptable level of safety.

Second: Fees proportional to the risk of a product - measured e.g. on the number of serious ADRs per report period - should be charged.
Alternatively the fee of a PSUR could be connected with the yearly turnover (e.g. not higher than 3% of a yearly turnover).

Consultation item no 2:

Grouping is regarded as relevant, however it is not possible in advance to calculate the fees to be charged as the number of MAHs to submit a PSUR for the same substance is not known.

3.4 Pharmacovigilance Service Fees

Consultation item no 7:

We do not agree with the proposed pharmacovigilance service fee.

Explanation:
The submission of information on medicinal products under Article 57(2) of the Regulation is not done voluntarily by the MAHs. The administrative burden is extremely high for companies with many MA and the costs for personnel to carry out this work and for software are high as well. Therefore, it seems not acceptable to have to pay an extra fee on top. Literature monitoring has not yet started and although the list of substances for which the literature monitoring will be carried out by EMA in the future has not yet been published. We are very sure that hardly any of the substances used for the manufacturing of our products (more than 200 mostly of natural origin) will be part of this list. Furthermore, companies with low risk products and only a few numbers of ADRs will not benefit from signal detection carried out by the EMA with the help of the EudraVigilance database. No fees should be charged at all for this general service.