Comments from the Spanish Agency of Medicines and Medical Devices to the concept paper submitted for public consultation entitled "Introduction of fees to be charged by the EMA for Pharmacovigilance"

Consultation item nº1: Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative.

The proposed fee for assessments of periodic safety update reports should be based on the expected amount of new data to be assessed during the period covered, and not on the arbitrary 2-years period. So, all six-monthly PSURs should have the same fee, and PSURs with longer period another fee.

A lower fee is proposed for 6-monthly PSURs. From the experience gained, although this PSURs cover just 6 months, the time for their evaluation is not half of the PSURs covering longer periods of time. This is due to the fact that during the first years of the medicine commercialisation, the information gathered on ADRs is normally higher, and the previous knowledge of the medicine safety profile is low. With time, safety profile of the medicine is better known, and evaluation is less complex. Taking this into consideration, to charge half the fee for 6 montly-PSURs does not seem reasonable, since the workload for the assessment could be higher than for a longer period PSUR.

Regarding the amounts to be charged, the adequateness will depend on the proportion of the fee that will be remunerated to PRAC rapporteurs and co-rapporteurs, since it should cover for the work to be performed.

Consultation item nº2: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative

We do not support the concept of grouping as proposed. A PSUR covering information of different medicines containing the same active substance will require more time for assessment since obviously it will have more data. Therefore, the remuneration to both PRAC rapporteur and co-rapporteur should be higher. The Commission proposes to charge an administrative fee of 500€ for each additional MAH in a group, but this is considered an administrative fee that would be retained by EMA. Considering that the EMA is already retaining a proportion of the basic fee for administrative and managerial purposes, it seems disproportionate to also assign the additional fee for each MAH to EMA. This fee should be incorporated to the proportion paid to PRAC rapporteurs/co-rapporteurs, since the assessment will increase in complexity proportionally to the number of products involved in the PSUR assessment.

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Consultation item nº3: Do you agree with the proposed fee for the assessment of PASSes? If not, please explain and/or suggest alternative.

It is not possible to agree on the proposed fee, since it is not stated which proportion of the fee will serve to remunerate the PRAC rapporteur/co-rapporteur.

It is not understood why the protocol assessment of a required study is not subject to fees, since this was foreseen in the initial legislative financial statement. It can be argued that the assessment of PASS protocols is a part of the assessment of the risk management plan in a marketing authorisation application where fees are already requested. Nevertheless, the new legislation (DIR Art.22a) allows competent authorities to request a PASS after the granting of the marketing authorisation independently from any marketing authorisation application. These PASS protocols will be assessed by the PRAC. The assessment of the results of the PASS will normally take place some years after the assessment of the protocol, and therefore the PRAC Rapporteur assessing the study results may well be different from the one who assessed the protocol. The latter will not receive any fee in many cases. Furthermore, a more effective way to encourage the performance of join PASS by various MAHs (DIR Art.22a 1.(a)) is by grouping fees at the very beginning of the procedure (i.e. protocol assessment) rather than grouping the fees for the later assessment of the PASS results. Therefore, we propose that a fee for reviewing the PASS protocol is established for PASS requested after marketing authorisation.

Consultation item nº4: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.

In the case of studies, it is less clear the rational for charging an extra fee, if the study has been performed by more than one MAH.

Consultation item nº5: Do you agree with the proposed fee for the assessment of pharmacovigilance referrals? If not, please explain and/or suggest alternative.

It is not possible to agree on the proposed fee, since it is not stated which proportion of the fee will serve to remunerate the PRAC rapporteur/co-rapporteur.

Consultation item nº6: Do you agree with the concept of grouping as proposed? If not, please explain and/or suggest alternative.

We do not support the concept of grouping as proposed. The complexity of the assessment of the referral increases with the number of medicinal products involved, even if data are presented in a unique report. Therefore, the remuneration to both PRAC rapporteur and co-rapporteur should be higher. The Commission proposes to charge an administrative fee of 500€ for each additional MAH in a group, but this is considered an administrative fee that would be retained by EMA. Considering that the EMA is already retaining a proportion of the basic fee for administrative and managerial purposes, it seems disproportionate to also assign the additional fee for each MAH to

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EMA. This fee should be incorporated to the proportion paid to PRAC rapporteurs/co-rapporteurs, since the assessment will increase in complexity proportionally to the number of products involved in the referral procedure.

Consultation item º7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.

We do not agree with the pharmacovigilance service fee per year. The legislation already envisages an annual fee to be paid to EMA for centrally authorised products and for NCA for nationally authorised products (including mutual recognition and decentralised procedure).

The concept paper includes this new fee, which was not envisaged in the legislation or in the legislative financial statement. The concept paper states that this fee is intended to cover general activities related to the new pharmacovigilance tasks of the agency, including operation of specific ICT tools. However, the ICT tools mentioned (EV database and psur repository) were already envisaged from the very first draft of the Commission proposal.
It is also stated that other activities relating to both CAPs and non-CAPS that the EMEA will cover with this fee include literature monitoring and monitoring the effectiveness of public health measures. However, literature monitoring was also envisaged from the very first text of the legislation proposal, and the legislative financial statement did not envisage a specific annual fee service for this task. The other activity to be covered by this annual service fee for both CAPs and non-CAPs is the monitoring of the effectiveness of public health measures. It has to be stated that this activity has to be performed in a collaborative way by both EMEA and national competent authorities (see Article 107h of Directive and Article 28a of Regulation), so that it is not fair that only EMA will charge for this task. However, again, this monitoring of the effectiveness of regulatory measures was envisaged from the beginning both in the Directive and the Regulation, and no service fee was included in the legislative financial statement.

Furthermore, this new fee is difficult to be understood in a framework where an annual fee for the maintenance of pharmacovigilance activities is already in place.

Consultation item nº8. 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 agree in maintaining the full maintenance fee for SME.

Regarding the proposed reduced pharmacovigilance fees for SMEs, it is considered that the evaluations that have to be carried out by the experts of national competent authorities for medicines owned by SME will not be reduced as compared to the evaluations to be carried out for products of larger companies, and therefore the reduced fee should be received entirely by national competent authorities.

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Consultation item nº9. Do you agree with the proposed approach with regard to the pharmacovigilance service fee for SMEs (point 3.5.2.)?

See answer to consultation item nº7.

Madrid, 31st August 2012

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