

HMA response on the fee regulation regarding pharmacovigilance activities

The HMA would like to thank the European Commission for the public consultation on the paper which lays down a proposed fee system for pharmacovigilance activities which includes current non-remunerated activities (such as a safety referral).

The European Medicines Agency (EMA) fee system is closely linked to and based on the activities conducted by the national medicines agencies on behalf of the EMA. It is clear that all National Competent Authorities (NCAs) would like to emphasise that any amended fee structure should reflect the NCAs right to an equitable proportion of that fee based on the contribution of the work provided by the NCAs. The pharmaceutical companies pay for a service which is provided by the EMA, using the expertise of the NCAs. The "network" model in which we operate— like a chain being only as strong as the weakest link – requires adequate resources for the entire network (EMA and NCAs). Stability is required in the fee structure to provide the highest possible degree of financial predictability at all stages of provision of services and to avoid variable remuneration for scientific services and the rapporteur assessments. Member States are the providers of scientific resources and their expertise for assessments which in the case of centralised procedures, are coordinated by the EMA. As most NCAs have a fee based funding model, fees need to be raised for all types of activities in their remit, including pharmacovigilance.

The HMA is presenting a general response on the consultation on behalf of the network and anticipates that individual National Competent Authorities may include more specific detail in their responses.

The following are general points which the HMA would like to comment on as a network:

- The proposed maximum fee of 80.300€ of a PSUR for products that have been authorised for 2 years or more while a lower fee of 40.150€ is proposed for products less than 2 years on the market: here we propose that the fee system follows the frequency of the PSUR assessment,.
- Regarding the SMEs, the work is done by the NCA also when it concerns a Centralised Procedure. To make sure that the principle, on the one hand, that SMEs are charged less is guaranteed and on the other hand that the work that has been done is remunerated fairly, HMA propose that the RAP/coRAP should receive both 50% of the regular fee amount which would have been paid if no reduction had been applied or the reduced fee in its entirety.
- EMA currently charges the MAHs an annual fee for CAPs. Is it correct that of the future annual fee, 30% is foreseen only for EMA pharmacovigilance activities excluding the costs for EMA with regard to pharmacovigilance inspection?

- Regarding the pharmacovigilance inspection costs the proportionality between the amount of fees and the nature of the tasks carried out by NCAs, in case of inspections, should be balanced. Therefore the HMA proposes that the current system of inspectors from the NCAs, taking part on the basis of their expertise, will be paid directly via a separate pharmacovigilance inspection fee (instead of the current situation in which the fee is going to EMA, however the HMA propose to share the fee among the Inspectorates of the Members States performing the inspection).The HMA want to stress the importance of pharmacovigilance inspectors being based in their NCA and Member State remaining intact.
- Whereas pharmacovigilance relates to the detection, assessment and prevention of adverse effects HMA welcome a yearly fee. Pharmacovigilance activities are difficult to link to every single registration of a product and it is difficult to capture this in one pharmacovigilance service fee. Further information is requested in regards to the new Pharmacovigilance Service Fee, as this currently seems disproportionately large and it is not clear in the proposal what will be the remuneration for the work done by the NCAs. As some of this work will certainly be performed by the NCAs, a transparent method of distribution of the funds should be proposed. Although the final impact assessment is not presented, the HMA urges the Commission to make sure the allocation of fees payed by MAH will be dealt with in a transparent and open way in order that the fees are fairly allocated to both NCAs and EMA.

On behalf of the HMA Management Group



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