EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Congreso de los Diputados and the Senado for their Reasoned Opinion concerning the proposal for a Regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency (EMA) for the conduct of pharmacovigilance activities in respect of medicinal products for human use {COM(2013) 472 final}.

The Commission would like to make the following remarks.

The Commission welcomes the opinion of the Congreso de los Diputados and the Senado that the proposed Regulation does not imply an infringement of the principle of subsidiarity in relation to the establishment of the three fees for Union-wide procedures relating to pharmacovigilance. The Commission also concurs with the analysis of the Congreso de los Diputados and the Senado that the proposal is necessary since the tasks imposed by the pharmacovigilance legislation must be adequately financed.

The Congreso de los Diputados and the Senado further state that there may be an infringement of the principle of subsidiarity with regard to the proposed annual flat fee, due to a possible overlap between activities covered by that fee and a national annual pharmacovigilance renewal fee intended to cover all transversal activities at national level which are not subject to a fee, including pharmacovigilance activities. In this respect, the Congreso de los Diputados and the Senado argue that the proposed annual flat fee could be considered as a renewal fee.

The Commission would like to remark that the payment of the proposed annual flat fee by the marketing authorisation holder would have no effect on the renewal or the validity of the marketing authorisation of its products. It is proposed that only products with a valid authorisation be subject of the annual flat fee. Regarding a possible overlap of activities, whilst agreeing with the Congreso de los Diputados and the Senado that such an overlap should not take place, the Commission would like to remark that it has endeavoured to provide for maximum precision on the activities at the level of the Union to be financed by that fee, both in the legal text and in the financial statement of the proposal. The underlying assumption of that approach is that the precise and transparent enumeration of the activities carried out at the level of the Union that are to be covered by this fee will facilitate any

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adjustments, if necessary, of possible national fees. The Commission would like to remark that it has noted that the same approach has been followed in the currently on-going discussions in the Working Party on Pharmaceuticals and Medical Devices of the Council of the European Union. Therefore, the Commission considers that whereas the proposed fees are intended to cover only activities that are carried out at the level of the Union, the principle of subsidiarity is complied with.

As regards to remuneration of rapporteurs, the Congreso de los Diputados and the Senado state that fees are not fairly divided between the EMA and the rapporteur from the Member State and gives the example of the proposed fee for assessment of post-authorisation safety studies. The Commission would like to remark that the amount for remuneration of the rapporteur is included in the overall amount of the fee, therefore the part of the fee retained by the EMA is not equal to the overall amount of the fee. With respect to the statement that the remuneration of the rapporteur is not predictable, the Commission would like to remark that the proposed remuneration may be reduced where reductions and exemptions apply notably in respect of marketing authorisation holders that are small, medium-sized or micro enterprises (SMEs). It is proposed that the same rate of reduction is applied to the part for the EMA and the part of the rapporteur, because support to SMEs is a transversal policy of the European Union.

With respect to the remarks regarding the legal base for charging fees for pharmacovigilance, the Commission would like to draw the attention of the Congreso de los Diputados and the Senado to the Explanatory Memorandum of the legal proposal where the provisions and recitals of the pharmacovigilance legislation that are relevant in order to enable the financing through fees of EMA's pharmacovigilance activities, including activities undertaken by the rapporteurs of the Member States, are quoted.

With regard to the comments regarding the proposed delegation of powers, the Commission would like to remark that the intention of such a provision is to allow for flexibility in adjusting, where necessary, the level of the fees to the underlying costs. The cost-based approach on which this proposal is based means that the estimated average costs of remuneration of rapporteurs is included in the overall amount of the fee.

The Commission hopes that these clarifications address the comments and concerns raised by the Congreso de los Diputados and the Senado and looks forward to continuing our constructive political dialogue in the future.

Yours faithfully,

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Vice-President