EUROPEAN COMMISSION

Brussels, 9.4.2014
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Dear President,

The Commission would like to thank the Vouli ton Ellinon for its Reasoned Opinion on 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}. With regard to the concerns of the Vouli ton Ellinon regarding compliance with the principles of subsidiarity and proportionality, the Commission would like to make the following remarks.

As regards the suggestion by the Vouli ton Ellinon that those Member States who have been involved in the evaluation of nationally authorised medicinal products in the context of pharmacovigilance referrals will not be able to charge fees for this activity, it should be noted that the legal proposal does foresee a remuneration for the Member States that have conducted such evaluations as rapporteur or co-rapporteur. Hence, the fact that it will not be possible to charge a specific national fee for such evaluation work does not mean that the Member State having acted as rapporteur/co-rapporteur will not receive any funding for this activity.

As to the concern expressed by the Vouli ton Ellinon that Member States will be prevented from charging fees for post-authorisation safety studies that have been requested to be conducted in more than one Member State, the Commission would like to remark that the pharmacovigilance legislation foresees that the evaluation of such studies be carried out at Union-level, i.e. involving the pharmacovigilance risk assessment committee which justifies a fee payable to EMA. However, again it is proposed that the Member State acting as rapporteur (and co-rapporteur) will be remunerated for the evaluation of such studies.

The Vouli ton Ellinon expresses criticism regarding of the proposed annual fee, suggesting that this fee is only levied for the sole benefit of EMA although the fee is charged for nationally authorised medicinal products, while no fees are allegedly levied for centrally authorised products. The Commission would like to remark that EMA currently does charge an annual fee for centrally authorised products which is precisely why these products are exempted from the proposed annual flat fee. The Commission considers that the proposed annual flat fee is justified as it is intended to cover new activities and facilities that EMA is required to perform and provide under the revised pharmacovigilance legislation, notably in

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the field of information technology, for the benefit of marketing authorisation holders and also of the Member States.

In respect of the proposed proportionate reduction in rapporteurs' remuneration in case of fee reductions, it should be noted that this is already provided for in the Annex of the legal proposal. Concerning the suggestion to amend the well-established and widely used definition of a micro enterprise at EU level, the Commission would also like to point out that it would not be appropriate to re-define this definition only for the purposes of the payment of pharmacovigilance fees.

The Commission hopes that these clarifications address the comments and concerns raised by the Vouli ton Ellinon and looks forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President