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Directorate General for Health and Consumers
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**Regarding PC/12/05 – Public Consultation on pharmacovigilance fees**

EQL Pharma AB is a pharmaceutical company falling within the EU definition of a SME. EQL Pharma has taken part of the Concept Paper "Introduction of fees to be charged by the EMA for Pharmacovigilance" submitted for public consultation, and wishes to comment on Consultation item n°8.

**Consultation item n°8:** 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.

**Comment:** EQL Pharma would like to draw the attention to the implications of the proposed PSUR fee. For pharmaceutical products with limited availability in terms of the number of markets where the product is present, limited revenues relative to the proposed PSUR fee may lead to the conclusion that there are no financial incentives to continue to market the product. Usually these products are quite small sales wise with revenues below 0,5 million Euros, due to local therapeutic traditions. Despite that, these products serve a number of patients very well and need to be kept available for them. In addition, if the number of MAH's for the product within the EU is limited, or more likely there is only one MAH, the benefits of grouping (in order to reduce the fee per MAH involved) doesn't apply at all. Since the benefits of grouping for these kind of products are not possible we are afraid that these fees might affect the possibility to maintain these products on the market. Hence EQL Pharma pleads to the EMA to reconsider the fee reduction for SMEs bearing the above in mind. One proposal might be to consider the revenues for the products when deciding about the fee, to assure that the product can bear the cost of the PSUR and stay on the market.

Please be informed that EQL Pharma does not wish its comments to be made public once the consultation period is over.

Best regards,
EQL PHARMA AB

Charlotte Enochsson
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