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BY E-MAIL

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Subject: Fee reduction for designated orphan medicinal products

Dear Madam, Sir,

IPFA and PPTA represent the manufacturers of plasma-derived medicinal products and their recombinant analogues. We have noted the new fee structure for designated orphan medicinal products (EMA760514/2011). While we appreciate that the previous incentives for Small Medium Enterprises (SME) are maintained we would respectfully like to oppose to the increase of fees for initial marketing authorisation application for non-SME sponsors.

The companies our organisations represent produce medicinal products derived from human plasma, a precious and scarce starting material. Due to the unique nature of this starting material, our members have a very different cost structure than classical pharmaceutical manufacturers, because the plasma already accounts for over 60 % of the overall manufacturing costs. Furthermore, most plasma protein therapies treat diseases with small numbers of patients. We would respectfully like to point out that although most of our members are non-SMEs we are nevertheless a small and unique sector with limited resources to support the development of medicines for small patient populations. However, we have been able up to now to also develop designated orphan medicinal products.

As you know, over the last years the financial pressure our members have experienced has led to a significant consolidation of companies, leaving only a limited number of players in the field.

The services EMA provides in protocol assistance, initial and follow up requests are of the highest quality and are very helpful to manufacturers. We understand that the agency needs to be appropriately reimbursed for their excellent support.

However, payment of 90 % of the full registration fee for a designated orphan medicinal product manufactured from human plasma would leave no incentive for our members to embark on the development of orphan medicinal products.

We believe that the change of the fee structure is against the policy of the European Union to provide patient access to novel therapies for clinical situations with real medical need. In addition, a significant increase of regulatory costs from 50 to 90 % for the initial MAA should have been announced with an appropriate implementation time to give manufacturers an opportunity to reconsider and adapt their financial and development strategy accordingly.

In our experience, EMA is one of the most transparent and open regulatory agencies we interact with pertaining to regulatory and scientific issues. We would greatly appreciate if this transparency and openness would also be applied to the development of fee structures.

We would respectfully request that, due to the specificities of the cost structure of our industry, the previous incentives of 50% fee reduction for non-SMEs of the plasma sector remain in place. We remain at your disposal for further discussion.

Yours sincerely,

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