Aurobindo Pharma Limited
Hyderabad, India

From: Gita Rao <gitarao@aurobindo.com>
Sent: 07 September 2012 08:48
To: SANCO FEES PHARMACOVIGILANCE
Subject: PC/12/05-Public Consultation on pharmacovigilance fees

Dear Sir/Madam

Thank you for giving us an opportunity to comment on the concept paper on Introduction of fees to be charged by the EMA for pharmacovigilance.

I work in Aurobindo Pharma Limited, India, a generic drug product manufacturer with a large number of marketing authorizations in Europe which are non-CAPs. Our company does not fall under the EU definition of SME.

We would like to comment on Fee for assessments of Periodic Safety Update Reports

Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and or suggest alternative.

We do not agree with the proposed fee for single assessment of PSURs. Unlike innovator products, there are no new studies conducted by generic product MAHs for evaluating risk/benefit. The data which is included in generic product PSURs is that which is accumulated from published literature and from reported cases which invariably would be much less in volume as compared to those for innovator products. Given this significant difference in the volume of data to be evaluated in innovator product PSUR versus generic product PSUR, MAHs of generic products should be made to pay lower fees than those proposed under this heading. It would be more appropriate to charge 1B variation fees from MAHs of generic products.

Kind regards
Gita Rao
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