Introduction of Fees to be Charged by the EMA for Pharmacovigilance

Concept Paper Submitted for Public Consultation

Actavis Group comments

September 14, 2012

Contents

1. Fee for assessment of Periodic Safety Update Reports

a. *Consultation item no. 1: Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative.*

We strongly believe that proportionality and transparency, as described in Section 2.3 of the Concept Paper, are key principles to be observed in connection with determining any fees for pharmacovigilance activities. The proposed (basic) fee of maximum Euro 80,300 appears to be high. It will represent a significant cost burden for a generic company which typically markets a very large number of different molecules (up to several hundred different molecules).

We also would like to highlight that the Concept Paper only proposes a maximum fee but does not give any information on any lower fees that may be applicable, and on what basis such lower fee levels would be determined.

The benchmark of a Type II variation used is a very general one and does neither provide any transparency on the specific amount of the work that would be involved in assessing PSUR reports, nor how the differences in workload for individual PSURs (e.g. based on data volumes to be assessed) would be taken into account.

It is mentioned that a lower fee of Euro 40,150 would apply to products that have been authorized for less then 2 years, and the maximum fee of Euro 80,300 would apply for products that have been approved for a longer period of time. While we do appreciate the concept of a range of fees to reflect different data volumes and consequently workload, this concept does not take into account that as a result of the normal product lifecycle, the volume of additional pharmacovigilance data usually decreases significantly several years after a product launch.
Based on the principle of proportionality, we believe that the fee for PSUR assessment should be reduced again 7-10 years after a product launch, or at the latest when the product becomes generic, to reflect the reduced workload for a PSUR assessment.

b. *Consultation item no. 2: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.*

We do support the concept of grouping. However, it should be considered to extend the possibility of grouping beyond MAHs of products being part of a same single assessment procedure, and to allow grouping of data from different MAHs at least those belonging to the same company group.

We believe that data consolidation by different MAHs from unrelated company groups would hardly be possible due to confidentiality reasons and because of differences in systems and infrastructures of different MAHs, and that such consolidation would have to be done by the authorities. Such grouping may nevertheless lead to a decrease of the EMA's workload and thus conduct to a reduction in fees.

2. Fee for assessment of Post-Authorization Safety Studies

a. *Consultation item no. 3: Do you agree with the proposed fee for the assessment of PASSes? If not, please explain and/or suggest alternative.*

The proposed (basic) fee of maximum Euro 80,300 appears to be high. The Concept Paper only presents a maximum fee of Euro 80,300, but does not give any information on any lower fees that may be applicable, and on what basis such lower fee levels would be determined. Again, the used benchmark of a Type II variation is a very general one and does not provide any transparency on the specific amount of work that would be involved in the assessment of the final PASS study reports, and how differences in workload for different studies would be taken into account.

We believe that the fee should reflect the amount of data to be assessed and different data volumes due to difference in study size.

b. *Consultation item no. 4: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.*

Grouping is only relevant here if it concerns a study imposed by the authorities on many MAHs.

3. Fee for assessment of Pharmacovigilance Referrals

a. *Consultation item no. 5: Do you agree with the proposed fee for the assessment of pharmacovigilance referrals? If not, please explain and/or suggest alternative.*

The Concept Paper presents a fee range between Euro 80,300 and Euro 267,400 per referral procedure, which is based on the fees for initial MA applications as a benchmark.

On this basis, we believe that also the existing concept of reduced fees for abridged initial MA applications should apply, reflecting the significantly lower amount of data to be assessed in connection with referrals involving products that have been approved based on an abridged application.

b. *Consultation item no. 6: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.*

We do not have any comment on this proposal.

4. Pharmacovigilance Service Fee

Consultation item no. 7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.

The proposed fee does not give any transparent information that would allow us to assess if the principle of proportionality is applied with respect to the workload and costs incurred by the authorities. Furthermore, taking into account that an average generic company has a portfolio of 1000 active

substances, this could mean that one generic medicines company could have to pay up to € 20 million on annual pharmacovigilance fees only. Consequently we feel that the proposed fee is very high.

5. Fee incentives for micro, small and medium-sized enterprises as regards pharmacovigilance

a. *Consultation item no. 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.*

We find it reasonable to reduce the fees for SMEs.

b. *Consultation item no. 9: Do you agree with the proposed approach with regard to the pharmacovigilance service fee for SMEs (point 3.5.2)?*

We find it reasonable to reduce the fees for SMEs.

*** * ***

Consultation item no. 10: What other aspects would you like to raise? Do you have additional comments?

The proposed fees represent a significant cost burden to MAHs, in particular for generic companies which typically market a much higher number of different molecules (up to several hundred different molecules), and would force generic companies to reduce the product portfolio offered. Due to this fact, the proposed fee structure would impose a significant negative impact on generic competition. It should be considered to avoid such disincentives in order to support competition in the pharmaceutical market for the benefit of consumers.