Teva Submission on the Concept Paper Submitted for Public Consultation on the Introduction of Fees to be Charged by the EMA for Pharmacovigilance

Teva welcomes measures that will improve patient safety and will harmonise and improve the efficiency of pharmacovigilance activities.

Teva has three key comments and concerns relating to the European Commission's proposals on the fees to be charged by the EMA.

1. Pharmacovigilance Service Fee

The basis and justification for this proposed fee is unclear

A key concern surrounds the purpose of, and justification for, the proposed Pharmacovigilance Service Fee. Teva's current assessment of available information is that it is not possible to determine whether the proposed Pharmacovigilance Service Fee of €1000 per MAH per product per year is reasonable. For example, the current proposal is not accompanied by an estimate of the amount of income that this fee is expected to generate and how much the EMA genuinely needs to generate the costs actually incurred and intended to be recovered by way of this fee.

The activities that the concept paper states that this fee will cover[1] are not expected to be available to the industry until 2016 –inclusion of these activities is not acceptable. . Further it is not indicated whether or not certain set-up costs are included, e.g. for IT systems to enable the EMA to undertake its new responsibilities. This fee should only cover the assessment part – any "set-up" costs should be paid for directly by funds from the EC or, if this fee does include "set-up" costs, this naturally implies that it should be reduced after the EMA's new systems are installed and up and running in 2013. At present the industry has no transparency in the true costs meant to be recouped by way of this fee.

A: This fee could cost EU pharma hundreds of millions of euros per year

Also the Pharmacovigilance Service Fee suggested in the concept paper is too high. To place the figures into context, the Commission anticipated the EMA generating between €10 and €11 million in fees from the industry per annum in its 2008 financial statement (last page). Teva anticipates the proposed new EMA fee structure will cost Teva alone between €6 and €30 million per annum. Clearly the EMA must anticipate a much greater income in fees from these services than was originally set out in the Commission's 2008 financial statement.

To introduce such a fee for a poorly defined service product where the overall fees gathered from industry could be around two orders of magnitude (i.e. 100 times) more than was anticipated in the Commission's 2008 Financial Statement runs the risk of being

[1] It is "intended to cover general activities related to the new pharmacovigilance tasks of the Agency, including operation of specific ICT tools". The ICT tools required include "the EV database and the PSUR repository" and the activities covered include "literature monitoring and monitoring the effectiveness of public health measures".

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seen as a unjustifiable tax on the EU pharmaceutical industry (also see further below on "Transparency").

B: The concept of charging per MA/by MAH is wrong

The concept paper suggests that the pharmacovigilance service fee should be charged per MAH per product per year. Our view is that, if any such fee can be justified at all, then it should be charged per pharmaceutical corporate group per product per year. Further, there seems no reason why the service fee should not be charged singly, per active, and shared across all MA holders (as defined above as their broader corporate groupings).

The concept paper states that, in proposing the fees, the principles of proportionality, transparency and equal treatment of MAHs should be respected. This will not be achieved if the services fee is not charged per corporate group rather than per MAH and across single actives as opposed to per corporate group. This is because companies will be treated differently on the basis of their corporate structure and where within that structure their MAs are held.

Companies having a structure where different entities within their group hold MAs will be disproportionately penalised when compared to companies that hold all their MAs in the same entity. In Teva's case it is estimated that this penalty would amount to more than €20 million per year. This additional cost will ultimately, at least in part, be passed on to patients and will contribute to increasing the price of medicines in Europe. It is likely Teva would seek to mitigate this new burden by varying many of its MAs to alter the MAH (also at great cost). This would obviously create a large administrative burden on the Agencies which would be unnecessary if the fee was charged by corporate group as suggested.

2. Grouping

A: Fees should be charged in line with the nature of Pharmacovigilance activities

It is not clear from the concept paper how "grouping" will work but Teva sees this as a vital concept for mitigating the impact on its business of the Commission's suggested fee structure.

The Commission has suggested that the fee for assessment of a PSUR is to be charged per assessment procedure, not per MAH[2]. However what was not made clear was whether or not such a "grouping" will apply even where different MAHs submitted separate PSURs[3]. This is an important concept and there seems to be no reason why the EMA should require new PSUR, PASS or service fees depending upon the number of MAH submitting data or to whom reports and communications need to be sent. Following the coordination of PSURs on particular actives across the EU due to the introduction of data lock dates, only one assessment procedure will usually be undertaken per active no matter how many PSURs are submitted. Also, the same data

[2] Questions and Answers relating to the Concept Paper on Introduction of Fees to be Charged by the EMA for Pharmacovigilance, dated 28 August 2012.

[3] In fact, the Commission concept paper suggests this is not the case.

set will be analysed and reported on by the EMA no matter how many PSURs are submitted for an assessment procedure. Hence, there can be no justification for the EMA charging multiple PSUR assessment fees where multiple MAH submit multiple PSURs in relation to a particular active.

B: The proposed "admin fee" for PSURs should amply cover costs of multiple submissions and could be applied also to PASS

Any cost associated with administering multiple PSURs during an assessment procedure should amply be covered by the proposed admin fee. As stated above, the same data set is analysed for each MAH and to permit the EMA to charge different MAH for the sole reason that they submit different PSURs to the EMA permits a significant amount of "double charging" by the EMA. The situation becomes more concerning as the number of MAH increases and the EMA "recycles" the same analysis to report to each MAH.

The Commission should confirm that the concept of "grouping" runs as broadly as stated above for PSUR assessment procedures and also applies to the PASS assessment fee and the pharmacovigilance referral fee.

C: Grouping should be permitted for the Pharmacovigilance Service Fee

Subject to there being any justification for introducing a pharmacovigilance service fee (see 1 above), our view is that this fee should be charged per corporate group, rather than per MAH. The inequity of an arrangement that sees fees, or shares of fees, calculated by MAH would see companies such as Teva penalised and subjected to disproportionate fee levies for pharmacovigilance as compared to companies holding one MAH for a product, even where cumulative sales per corporate grouping for these respective products might be comparable.

Teva reiterates that should its definition of "grouping" not be implemented, then it will strongly be incentivised to reduce the overall number of MAH for its products over a short period of time thereby imposing a significant administrative burden on the EMA and national agencies.

3. Transparency

A: The cost of these measures has risen almost a hundred fold

The Commission initially anticipated that the <u>total</u> annual income to the EMA from pharmacovigilance fees would be approximately €10.5 million[4]. Our calculations suggest that Teva's contribution alone could amount to 2-3 times more than the originally anticipated annual fee level across the entire industry. By this calculation, the EMA looks set to raise hundreds of millions of euros in fees each year from these proposed fee introductions.

It is, therefore, not possible to assess whether the proposed fees are reasonable and justifiable without a detailed explanation of why there are has been a dramatic increase in

[4] Proposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use, dated December 2008.

anticipated cost since 2008, how much the fees are expected to generate, and precisely where the funds from industry will be used. There is very little transparency as to the basis for the proposed fees and why they appear to bear little relation to the estimates that accompanied the original proposals for amending the pharmacovigilance legislation. The Commission needs to rectify this omission as a matter of urgency such that EU pharmaceutical companies can assess what the justification for the dramatic increase in fees required to cover the costs of the new EU pharmacovigilance proposals.

B: The Pharmacovigilance legislation may need to go back before the Parliament

Should it be demonstrated that the cost/benefit basis on which the legislation was approved in the European Parliament was fundamentally flawed, then it is also possible that the Parliament may wish to reopen its debate.

At the very least, the Commission and the EMA should release any new financial statements or projects that have been prepared and upon which the proposed fee structure is based in order to allow industry properly to assess whether the proposed fees are proportionate and what the new pharmacovigilance measures are likely to cost EU industry.

4. Summary

Teva is deeply concerned by the current version of the Commission's concept paper. The fee burden on the company could be markedly greater than was anticipated only a few years ago. Teva now seeks assurances from the Commission that these fees will not prove to be the burden on the EU pharmaceutical industry that they currently seem to be.

If the fee structure remains as described in Teva's worst case scenario above, Teva believes that the whole pharmacovigilance package should be placed before the Parliament again. This time the Parliament should be given the clear and transparent message that this package of measures could cost the EU pharmaceutical industry many hundreds of millions of euros per year. These costs will, inevitably further push up the price of pharmaceutical products in the EU at a time of financial austerity and will have an impact on the availability of affordable quality medicines for patients.