14 September 2012

Submission of comments on 'EU Concept paper on the Introduction of Fees to be charged by EMA for Pharmacovigilance' (Ref. Ares(2012)723154

Comments from:

Name of organisation or individual
Pfizer Contact Name: Julie O'Brien (E-Mail julie.obrien@pfizer.com)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

General comments

Company	Comments
	Pfizer welcomes the opportunity to provide feedback on the concept paper on the Introduction of Fees to be Charged by the EMA for pharmacovigilance. In addition, to our specific comments outlined below, we are also broadly supportive of the consolidated comments from the research-based pharmaceutical industry that are being provided by EFPIA. We acknowledge the greater role for the EMA in pharmacovigilance under the new pharmacovigilance legislation and also acknowledge the need to adequately fund pharmacovigilance activities within the EU for the benefit of public health. We believe it is reasonable and justified that industry pays a contribution towards the costs incurred to conduct these activities. There are, however a number of aspects contained within the concept paper where we believe further consideration and indeed re-evaluation is merited. The four guiding principles of proportionality, transparency, equal treatment of MAHs and minimal additional administrative complexity are outlined in the concept paper. It is our view that accountability to these principles should be provided to MAH's as an integral component of the proposed fee structure to ensure adherence to the aforementioned principles. We would welcome a system whereby fees are not paid until it is demonstrated that the guiding principles have been adhered to and would ask that a mechanism for managing this be considered as part of the proposed fee structure.

Consultation item n°1: Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative

Company	Comments
	Proportionality between the level of the fees and the nature of the work/tasks actually carried out by the EMA is outlined as one of the general principles of the concept paper. In line with this we believe a form of scaling of fees for PSURs would be fairer and more in line with the principle of proportionality than the two discrete fee levels proposed (i.e. products authorised for more than two years and products authorised for less than two years). For example, for PSURs where a product is better understood and well defined it would be reasonable to charge a lesser fee based on the fact that any assessment of the PSUR in such a case would require less input than that of a less well defined and more complex product. This principle has already been acknowledged for referrals where a scale will apply depending on the workload required. Please also see paragraph 2 of our comments on consultation item no. 7, regarding the relationship between reduced administrative burden and fee levels.

Consultation item n°2: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative

Company	Comments
	We generally support the concept of grouping as outlined in the concept paper. However, clarification on the definition of "same MAH" and "different MAH" is required. Additionally, grouping between different MAHs requires further consideration in relation to the practical implementation of how such groupings would be agreed and how the costs would be shared. In the absence of clarification on these practical aspects grouping may not be easily implemented resulting in additional administrative complexity for MAHs. It is also important to highlight that as outlined in the concept paper products for which a MA is granted under the provisions relating to generics, well established-use, homeopathic products or traditional use herbal products will not be required to submit PSURs unless there is a specific requirement to do so. This will result in the innovative pharmaceutical industry bearing the burden of costs for PSUR fees and to a large extent removes the benefit of grouping for PSURs.

Consultation item n°3: Do you agree with the proposed fee for the assessment of PASSes? If not, please explain and/or suggest alternative

Company	Comments
	As with that proposed for PSURs under consultation item no. 1 above we believe a form of scaling of fees for PASSes would be in line with the principle of proportionality as stated concept paper.

Consultation item n°4: Do you consider relevant the concept of grouping as proposed, if not, please explain and/or suggest alternative

Company	Comments
	Please see paragraph 1 in response to consultation item no. 2 above.

Consultation item n°5: Do you agree with the proposed fee for the assessment of pharmacovigilance referrals? If not, please explain and/or suggest alternative.

Company	Comments
	We believe that the proposed fee levels and structure for referrals in the format outlined in the concept paper merits re-evaluation on a number of aspects as follows: • Different levels of referral fee along a scale are proposed in the concept paper depending on the workload involved. We welcome this approach which reflects the amount of work involved in a particular referral assessment and is in keeping with the concept of proportionality. However, no detail is given on how, and at what point in the process, the fee level in a particular case will be determined. Transparency on this aspect is needed. • It is envisaged the proposed maximum referral fee will be charged in cases where a full benefit risk evaluation is conducted. It is difficult to agree that this equates to the nature and amount of work involved in a new MAA as per the concept paper. The assessment of a new medicinal product requires an evaluation of far greater scope in comparison to a referral procedure which focuses on a particular issue. • At the opposite end of the scale the lowest referral fee proposed (Euro 80,300) relates to referral procedures which assess specific parts of the MA e.g. introduction of new contraindications. This proposed fee of Euro 80,300 exceeds the current referral fee of Euro 66,000, with no justification provided for such an increase. • Transparency of the workload that has been conducted by the PRAC and the EMA needs to be provided given the levels of fees being proposed. Additionally, greater transparency is also required in relation to the triggers for Referrals. • Clarification would be welcome on whether an appeals mechanism for MAHs dissatisfied with the fee proposed by the EMA will be put in place. In the case of a referral where a national competent authority takes unilateral pharmacovigilance action with regard to a product, such as suspension of marketing, and the matter is referred to EMA in order to reach a harmonized, EU position on the matter the purpose of the referral is both the protection of public health and the proper functioning of the internal market by reaching a harmonized decision. In this scenario it is reasonable that at least some of the fee should be borne by the public purse as it is related to the functioning of the single market.

Consultation item n°6: Do you agree with the concept of grouping as proposed? If not, please explain and/or suggest alternative

Company	Comments
	Please see paragraph 1 in response to Consultation Item No. 2 above.

Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative

Company	Comments
	It is proposed to charge an annual service fee of Euro 1,000 per year per product (CAPs and non-CAPs). An annual service fee is already charged by the EMA, a proportion of which it is proposed should be continued. It should be noted that similar service fees are being charged by Member States for both CAPs and Nationally Authorised Products and thus greater transparency into how these fees are being spent is required to ensure duplication of charges is not occurring. Additionally, in the consultation document, the explanatory section on proposed fees notes that, 'The submission of ADR reports by both MAHs and NCAs exclusively to EV in the future represents a considerable simplification and reduction of administrative burden for the MAHs compared with the current system (where ADR reports are sent by MAHs to the NCAs and in some cases also to the EV and where NCAs submit serious ADR reports to the other MS and EMA).' Just as duplication of charges between the EMA and NCAs should not occur, the reduction of bureaucratic burden on NCAs outlined here should arguably result in reduced service fees to said NCAs. The EMA may thus wish to formally note this anticipated outcome (please see comments under consultation item no. 10 regarding the importance of proportionality in fees).

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

Company	Comments
	As outlined in the concept paper SMEs will benefit from fee reductions of the order of 50%. We believe in addition to SMEs, orphan medicinal products should also benefit from fee reductions. Specific provisions for orphan drugs are not covered in the concept paper. In practice in some cases these would be covered under section 3.5. However many larger MAHs would not benefit from the reduced fees outlined in this section. Given the particular benefit to society of developing and marketing orphan drugs for unmet medical needs, as recognised in the Orphan Drug Regulation, we believe it is reasonable to propose fee reductions specific to all orphan products in the context of this proposal, in alignment with the purposes of that Regulation.

Consultation item n°9: Do you agree with the proposed approach with regard to the pharmacovigilance service fee for SMEs (point 3.5.2)?

Company	Comments
	The proposed approach for Pharmacovigilance Service Fee for SMEs in our view represents a reasonable approach to sharing the costs of the system amongst stakeholders.

Consultation item n°10: What other aspects would you like to raise? Do you have additional comments?

Company	Comments
	Fees and their relationship to health, innovation and investment in Europe Authorised medicinal products – the quality, safety and efficacy of which are continually monitored by the EU's pharmacovigilance systems – underpin the broadly high levels of health enjoyed in the EU. Such levels of health are a necessity for the EU's strong economic performance; meanwhile, a strong economy is also required to guarantee continued high levels of health. The innovative pharmaceutical industry contributes doubly to these areas, as both the creator of these socially and economically valuable products, and as a significant economic actor. However, the innovative industry is under intense pressure due to cost containment measures enacted by European governments that are under unarguable financial constraints. At such times, the principle of proportionality is of critical importance. The cost of doing business in Europe significantly affects the innovative pharmaceutical industry, as with any enterprise, and has consequences for both innovation and investment. Given the interlinked nature of health and economic performance, Pfizer would thus strongly encourage the EMA and Commission to reflect on how proportionality can be fully applied at this critical time. Such consideration would reflect, and be coherent with, the Commission's overarching goal of smart, sustainable and inclusive growth based on innovation, as expressed in the interlinked EU2020 and Innovation Union strategies. The fees proposal thus represents an opportunity for the Commission and EMA to demonstrate that these principles do indeed apply throughout their work. **Benefit/Risk and the new pharmacovigilance legislation** The new pharmacovigilance legislation introduces additional tools for regulators to manage the Benefit/Risk of medicinal products on the market in the EU. The implementation of such additional tools to monitor Benefit/Risk during the lifecycle of a medicinal product presents a fresh opportunity to explore ways of assessing the Benefit/Risk of a product during the MA approval process to align more closely with patient needs for timely access to new medicinal products. Such an approach would also be likely to have a positive impact on innovation and investment in the EU. **Proposed fees in the Concept paper greatly exceed those in the Commission's Impact Assessment on this legislation** The rationale for this discrepancy is outlined in the concept paper as relating to the fact that additional tasks were entrusted to the EMA in the new pharmacovigilance legislation that were not foreseen at the time of the initial impact assessment. No detail is given on these activities and we believe it is reasonable to request further granularity on such additional activities. **Transparency** Greater transparency should be available for MAHs into how their fees are being spent. It is not unreasonable that MAHs should have access to and regular insight on, the EMA's activities regarding pharmacovigilance of their products. Although stated as a general principle of the concept paper no details are given on how transparency will be provided to MAHs and we would request clarification on this; such transparency is the means by which the EMA and Commission can demonstrate their consideration of proportionality, as outlined above.