18 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:

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

General comments

Comments
While we acknowledge that Recital 24 of Regulation (EU) No 1235/2010 provides for fees to be charged by the EMA for the conduct of pharmacovigilance activities, the legislation is primarily about strengthening the EU Pharmacovigilance system and protecting public health. It is suggested to define clearly which pharmacovigilance activities contribute to the strengthening of the EU system and the protection of public health and thus fall under the responsibility of the European Commission, vs. EMA. The interpretation of the new legislation by the European Commission is that **all** costs of pharmacovigilance activity should be funded by the pharmaceutical industry and not at present by a subvention from Community funds augmented by the annual service fee for centrally approved products. We consider that pharmacovigilance activities should receive at least some **Community funding**, on the grounds that these activities serve public health and cannot be considered a unique service to industry. Such an approach would also contribute to further strengthening the transparency, objectivity and independence of the assessments.
We have significant concerns about the **level of fees** proposed in the Commission's concept paper. The proposed fees for PSUR and PASS assessment are significantly higher (>10x) than those proposed in the Commission's Financial Statement and the Impact Assessment that accompanied the initial 2008 proposals for the pharmacovigilance legislation: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0665:FIN:en:PDF http://ec.europa.eu/health/files/pharmacos/pharmpack_12_2008/pharmacovigilance-ia-vol1_en.pdf http://ec.europa.eu/health/files/pharmacos/pharmpack_12_2008/pharmacovigilance-ia-vol2_en.pdf The 2008 Financial Statement and Impact Assessment indicated that all costs associated with activities from the proposal should be recouped through fees. It was then estimated that the (lower) suggested fees would generate an additional annual income to EMA of €10.596M. The estimated costs to the EMA (including payments to rapporteurs) of performing the new activities were €10.084M, leaving a surplus of around €0.5M per year. Based on the proposals in this June 2012 concept paper, and the same expected workload as in the 2008 Financial Statement (with the exception of fees for Risk Management Plan assessment, which are no longer proposed), the estimated additional annual income from fees would be at least €65M: this figure is based only on the lowest proposed fees for PASS and PSUR assessments and referrals, and does not include annual service fees, as we do not know the numbers of active ingredients or MAHs registered in the list of products established under Article 57(2) of the Regulation. We estimate that an additional €6M at least would be paid in annual service fees.

While we recognise that the final adopted legislation is not identical to the 2008 proposal, and that costs may have increased due to inflation since then, the pharmacovigilance activities concerned are very similar and it is difficult to accept that the costs to EMA for fulfilling the covered duties have increased so substantially. It is reported that the EMA management Board has recently adopted the policy of "best available advice" to develop and take forward Pharmacovigilance issues. This should be applied in a pragmatic way to avoid significant additional costs being incurred, for example by the introduction of a new team of rapporteur and co-rapporteur.
For individual companies, the proposed fees would lead to a significant increase in fees budgets. For example, one company, with a broad portfolio of small and large molecules authorised through all regulatory routes, has calculated that its current annual EMA fees could increase between 35% and 115% (depending on the number of PSURs and PASS in a given year, and on the interpretation of the fees for grouping). This calculation would imply that the additional annual income to EMA could be even greater than the €65M estimated above.

These figures indicate that a fundamental review of the entire EMA fee structure (both current fees and the proposed new fees for pharmacovigilance) is required. The principle of proportionality between the fees and the nature of the work actually carried out should be applied (as advocated in section 2.3 of the concept paper). Whereas the 2008 Financial Statement and Impact Assessment were accompanied by an annex providing details of the calculations supporting the proposals, there is no such detail in this concept paper. Clarity should be provided on how the EMA fees are justified, particularly in relation to the expected cost increase. **A more detailed examination of the cost base for EMA activities should be conducted in order to set reasonable and appropriate fees**.

We welcome the general principles behind the proposed Pharmacovigilance fees as explained in the concept paper, namely:

1. Proportionality between level of fees and amount of work for EMA & the network
2. Transparency: fee corresponding to each task, so that MAHs could avoid double payments, more transparency on how the fees are calculated and used
3. Equal treatment of MAHs
4. Minimal additional administrative complexity

We would offer the following comments on these principles

Proportionality
Overall the proposed fees appear excessive and the justification provided is based on an analogy with existing tasks rather than time recording. These analogies do not seem to be supported by an **analysis of the actual tasks** carried out by the secretariat and the NCAs in each instance.
Therefore, we would like further clarity on how the proposed fees have been arrived at based on the scope and volume of documents to be reviewed/the PV-related activities to be undertaken (as applicable) and the number of assessors/agency staff involved.

Transparency
Although it is clear in Recital 24 of Regulation (EU) No 1235/2010 that: 'These fees should not cover tasks carried out by national competent authorities for which such authorities change fees in accordance with Directive 2001/83/EC', some Member States already charge fees for pharmacovigilance-related activities, and also for some activities related to centrally authorised products
The concept paper indicates that EMA fees are to be charged for products authorised via centralised, national, mutual recognition and decentralised procedures.
The proposal should also make clear that individual member states must not charge duplicative fees for pharmacovigilance activities linked to centralised marketing authorisations and it must be ensured that marketing authorisation holders are charged only once for same work.

Equal treatment of MAH

As stated on p.9 of the Concept Paper, PSURs for generic products as well as homeopathic and herbal products are not required typically. Similarly, Post Authorisation Safety Studies (PASS) are not required usually for these products either. Therefore under the current fee proposals companies developing new and innovative medicines will pay the majority of the fees required to support the new Pharmacovigilance legislation, whereas many objectives of the new Pharmacovigilance legislation apply equally to new medicines as well as establish medicines that have been in use for a long period of time. This appears at odds to the general principle of the proposed fee structure that aims for equal treatment of MAHs.

Similarly situated marketing authorisation holders should be treated alike. the issue of whether the product is an originator or a generic/biosimilar should not be relevant factor. We propose that the fees be fairly and equally divided among similarly situated MA holders.

Minimal additional administrative complexity

We note that ranges of fees are provided in this proposal to cover different levels of assessment workload that may be necessary for PSURs and for referrals. For PSURs, the range is clear, but the justification seems to be flawed. For referrals, there is a large variation in the fees for referrals (80,300€ to 267,400€), but it is not clear how the fee for a specific procedure would be established. For PASS, no range is proposed, despite the fact that the type of PASS, and the corresponding assessment workload, may vary.

To comply fully with the principle of proportionality, the levels of fees for different assessments would need to be adjusted to individual procedures or products. The application of such an approach would, however, clearly introduce complexity, which would not be desirable. Where it is appropriate for a fee to be charged, the Commission should set a fee or a simple range of fees based on well-defined and justified criteria for each procedure, at a level commensurate with the associated workload, taking into account an appropriate level of Community contribution.

Grouping

In context of grouping provisions proposed under the different consultation items, it is important to get a clarification with regard to the definition of "MAH". For example, with regard to the grouping and paying a single fee, it appears that one MAH has to pay the full fee, whereas other MAHs pay administrative fees. We assume that the definition will be in accordance to the Commission Communication 98/C229/03 (22 July 1998). "Applicants belonging to the same mother company or group of companies and applicants having concluded agreements or exercising concerted practices concerning the placing on the market of the relevant medicinal product have to be taken as the same marketing authorisation holder."

Revision of fees system

In addition we believe that the **revision of the fees system** should be done in a wider context to ensure the development of a sustainable and competitive regulatory framework in the EU.

The fees proposed are in isolation of the significant fees already imposed on industry and are duplicative, in the sense for each discrete pharmacovigilance activity, fees will need to be paid more than once. It is unclear how the fees would be applied across a portfolio of products and across multiple MAH holders It would be important to evaluate the global cost of the post-marketing activities (in particular with regard to the significant payment of fees for variations across the portfolio that are disproportionate to the importance of the change and the assessment required).

Alongside this concept paper, there needs to be a discussion about the overall fee burden that will be imposed on MAHs in order to register and maintain products on the market within the EU. Providing a full picture of the maintenance burden will, in particular, help inform MAHs' decisions around commercialisation of products of high therapeutic value but low volume (e.g. orphan medicine and medicine meeting unmet medical need)

As far as we are aware, at the current time EMA is the only Regulatory Agency in the world that will levy a specific service fee to the industry to discharge their statutory obligations with regard to pharmacovigilance, which would put pharmaceutical industry operating in Europe at a competitive disadvantage.

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

Comments

We do not agree with the proposed fees for the assessment of PSURs. The proposed fees have not been fully justified, do not reflect the real amount of workload required for the assessment of PSURs, and do not appear to be in line with the general principles for setting the fees described in the Concept Paper. We believe that levels of fees should be defined based on clear criteria and principles. The level of a basic fee for assessment of PSUR should be closer to the amount proposed in the 2008 legislative financial statement, and in any case should not be above what is currently charged for the assessment of a renewal application.

Comparison with 2008 Financial Statement
The proposed fees of €40150 to €80300 are significantly greater than that proposed in the Commission's Financial Statement from the 2008 proposals (€6100). No explanation for this increase has been provided, even though there is little difference between the PSUR single assessment procedure described in the 2008 proposal and that in the final adopted Directive. The Financial Statement also estimated that there would be 1000 PSUR assessments/year. If the proposed fees were to be charged for the same workload, this would equate to approximately 20-40% of the current total EMA budget, which seems excessive.

Proportionality
We consider that using the Type II variation as a benchmark for the assessment of PSURs is not appropriate. A direct comparison cannot be made of the data that will need to be assessed, as the range of data for both PSURs and for Type II variations will vary greatly between submissions. A direct comparison of the two procedures is also not possible, as there is not yet any experience with the PSUR single assessment.

A more appropriate benchmark would be the assessment of a renewal application. The renewal assessment is based on a re-evaluation of the benefit/risk balance of the product; similarly, PSURs are intended to provide an evaluation of the risk-benefit balance of a medicinal product. In addition, until July 2012, renewal applications were required to include a PSUR, so the cost of PSUR assessment must have been covered by the renewal fee. Even allowing for some additional costs in the new single assessment of PSURs, associated with the involvement of the PRAC, it is difficult to see how a significantly higher fee can be justified. Moreover, with the implementation of the pharmacovigilance legislation, the new PSUR format should include less data in line-listings and narratives, and more focus on the benefit/risk assessment, which, if done well, potentially makes the assessment task easier. The Concept Paper argues that assessment of PSURs is based on cumulative data. The Commission Implementing Regulation ((EU) No 520/2012), however, requires that the PSUR "shall focus on new information" since the data lock point (DLP) of the last PSUR. It is reasonable to expect, therefore, that the assessment would also focus on the new information. While we acknowledge that there will be a range of size and complexity of PSURS, the "normal" assessment required is likely to be no more than that for a renewal application (€13300).

The setting of fees based on 2 years from time of authorisation seems rather arbitrary: the size and complexity of PSURS are dependent not only on the age of the product, but also on several other factors, including the pharmacological properties of the individual product, patient exposure to the product, ongoing clinical trials and the need and nature of risk minimisation measures. For many products that have been authorised for more than 2 years, the assessment workload may be no higher than, or may even be less than, that for newer products. The charging of a higher fee (especially one of €80300) would be unreasonable for products that have been on the market for several years, where the benefit-risk profile is well established, new data are limited and several sections of the PSUR are not applicable (e.g. 'Summaries of the significant findings from clinical trials in the reporting period', as these products

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are no longer under clinical development). In addition, the frequency of PSUR submission should be taken into account. For many products, the 6 monthly submission of PSURs may continue beyond the first two years of initial MA, either because the product could not immediately be placed on the market, or based on a competent authority request. In those instances, the amount of data in the PSURs may be more similar to those during the first two years of authorisation, and a total annual fee of €160600 would be excessive, relative to the assessment workload. It would be interesting to know the percentage of PSURs that have historically resulted in a variation. For CAPs, charging one fee for PSUR assessment regardless of the need for a subsequent variation procedure might contradict the general principle of proportionality. **Transparency** PSUR assessment for CAPs is not a new activity, and so is presumably currently funded out of the annual fee. If a separate fee for this activity is now deemed necessary, a consequential reduction in annual fee for CAPs would be expected. For the most recently authorised products that will go through the renewal process, consideration should be given that the PSUR assessment will duplicate the 5-year renewal assessment. If evaluation of essentially the same information is subject to two charges (fee for the renewal and fee for PSUR), this would conflict with the principle of transparency. We believe that the Concept Paper's proposals will create some inequity between the registration procedures. For CAPs, if an action concerning the MA is recommended, there is no longer the need to submit a variation to implement the change, so there will be no additional variation fee. For non-CAPS, however, a separate variation will be still required, which would attract additional fees. The implementation of changes concerning MAs of non-CAPs would, therefore, be more costly than for CAPs. We propose that for all non-CAPs, the subsequent variation to implement changes to the MA following the assessment of a PSUR should be free of charge. As several Member States are already charging national fees for PSURs assessment, the Commission should clarify how it plans to manage this situation in order to avoid the same task being charged twice. **Equal treatment of MAHs** It should be recognised that, for products that have been on the market for many years, the originator will continue to have the obligation to submit the PSUR and pay the PSUR fee, while generic products that will likely have most of the market share may be exempted from the PSUR submission. In such cases, introducing a fee payable only by the originator MAH, when the originator MAH also has to bear all the other costs associated with the PSUR preparation and assessment, does not seem to comply with the principle of equal treatment of MAHs. Consideration should be given to dividing the total fee for the single PSUR assessment among all MAH for the concerned active ingredient, regardless of whether the MAH have submitted a PSUR or not. **Minimum additional administrative complexity** To comply fully with the principle of proportionality, the appropriate level(s) of fee(s) for PSUR assessment should be based on several criteria, as discussed above. The application of such an approach to individual PSURs or products would clearly introduce complexity, which would not be desirable. The Commission should, however, take these factors into account in setting a fee or a simple range of fees, at a level more commensurate with the associated workload.

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

Comments
The concept of grouping is welcomed. However, it should be explicit that MAHs belonging to the same mother company or group of companies and MAHs having concluded agreements or exercising concerted practices concerning the placing on the market of the medicinal product(s) concerned, should to be taken as 'the same marketing authorisation holder' (see Commission Communication 98/C 229/03 OJ C 229, 22 july1998) and should not be charged additional administrative fees as if they were separate MAHs. As stated on p. 9 of the Concept Paper, PSURs for generic products as well as homeopathic and herbal products are not required typically. Therefore under the current fee proposals companies developing new and innovative medicines will pay the majority of the fees required to support the new Pharmacovigilance (PV) legislation through PSURs. This does not appear to meet the principle of equal treatment of MAHs. From a practical point of view, it does seem **unrealistic to produce a single PSUR that will integrate all the information, data and analysis coming from independent companies**. Nevertheless, it is important to establish a model-based system for the fee assignment that complies with the principles of proportionality and equal treatment of MAHs, as well as with competition laws. For PSURs that concern different MAHs (not covered by Commission Communication 98/C 229/03), we propose that the total fee (including any administrative fees) is equally divided among all concerned* MAHs for the same active substance, whether they be an MAH for an originator or generic product as the MAH for the generic product will also benefit from the assessment of the PSUR. This would also mean that for the so-called PSUR "EU single assessment" procedure (the assessment of PSURs for medicinal products subject to different marketing authorisations containing the same active substance or the same combination of active substances whether or not held by the same marketing authorisation holder and for which the frequency and dates of submission of PSUR have been harmonised in the list of EU reference dates), the total fee for the single assessment (including any administrative fees) is equally divided among all concerned MAHs for the same active substance, whether they be an MAH for an originator or generic product. *A concerned MAH is an MAH for product(s) containing the active concerned regardless of whether they have submitted a PSUR.

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

Comments
We do not agree with the proposed fee for the assessment of PASSs, as the fee seems unreasonably high and does not seem to be aligned with the general principles for setting the fees described in the Concept Paper. **Comparison with 2008 Financial Statement** The proposed fee for the assessment of PASS (80,300€) is far higher than that proposed in the 2008 legislative Financial Statement (6,100€). No explanation for this more than ten-fold increase has been provided. **Proportionality** We do not concur that the assessment of all PASSes is comparable to the data being assessed in the context of a Type II variation. The procedure for PASS concerns an assessment of a single report, whereas Type II variation applications may include two or more studies, and may be much more complex, for example, including proposals to revise several sections of the product information. The Commission's justification in the concept paper also appears to be based, at least in part, on an assumption that all PASS will result in changes to the marketing authorisation. Many PASS, however, may not result in changes to the MA, particularly those with the aim of "confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures". PASSes may adopt different designs depending on their objectives and therefore the amount of work required for the assessment of each final PASS report may vary. As for the PSUR, the proposed PASS fee will apply to any product, irrespective of the registration procedure that was used for granting the MA. We believe that this creates some inequity between the registration procedures (i.e. for CAPs if an action concerning the MA is recommended, there is no longer the need to submit a variation for implementing the change, while for non-CAPS, a separate variation will still be required). We propose that, for all non-CAPs, no separate variation fee should be required for the implementation of changes to the MA following the assessment of a PASS final report. **Minimum additional administrative complexity** To comply fully with the principle of proportionality, the appropriate level(s) of fee(s) for PASS final report assessment should be based on several criteria, such as the methods used for PASS (as described in Appendix 1 of GVP Module VIII), and the amount and/or type of data collected. The introduction of complexity should be avoided, but the Commission should define a fee or a simple range of fees closer to the amount proposed in the 2008 legislative Financial Statement and at a level more commensurate with the associated workload.

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

Comments
The concept of grouping is welcomed although its possibilities for PASS' for new active substances will be extremely limited. However, it should be explicit that MAHs belonging to the same mother company or group of companies and MAHs having concluded agreements or exercising concerted practices concerning the placing on the market of the medicinal product(s) concerned, should to be taken as 'the same marketing authorisation holder' (see Commission Communication 98/C 229/03 OJ C 229, 22.7.1998) and should not be charged additional administrative fees as if they were separate MAHs.

We recognize that the concept of grouping may facilitate the collaboration between independent MAHs to conduct PASS' jointly, as is foreseen in the pharmacovigilance legislation. However, in order to encourage the joint conduct of a PASS, it is important to establish a model-based system for the fee assignment that complies with the principles of proportionality and equal treatment of MAHs, as well as with competition laws. For a PASS conducted jointly by different MAHs (not covered by Commission Communication 98/C 229/03) and providing a single final study report, we propose that the total PASS fee (including any administrative fees) is equally divided among all concerned MAHs for the same PASS, whether they be an MAH for an originator or generic product.

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

Comments
We do not agree with the proposed fee for the assessment of pharmacovigilance referrals when the referral is initiated by a Member State or the Commission. Although we acknowledge that Recital 24 of Regulation (EU) No 1235/2010 states that 'The Agency should be enabled to fund these activities from fees charged to marketing authorisation holders', it is not implicit that the MAH should be the only stakeholder to fund the enhanced pharmacovigilance requirements particularly when the activity serves public health. We would view the assessment of pharmacovigilance referrals especially when initiated by a Member State or the Commission as a public health service. As such, mandating payment by MAHs could be perceived by some as leaving the Agency less independent because they are reliant on the fees gained for an imposed service. We therefore believe it is more appropriate for the Community to fund the assessment of pharmacovigilance referrals. Should pharmacovigilance referrals not be supported by full or partial Community funding we do not agree with the levels proposed for the referral fees. Currently, a referral fee of €66700 applies for referrals initiated by the MAH, but there is no clear justification for the higher fees proposed in the concept paper. We would suggest that the fee proposal is an overestimate of the workload required for the assessment of a referral, in particular for the maximum referral fee being proposed. A fee of €247600 is proposed for referrals requiring "full benefit/risk assessment", based on a comparison with a new MAA. This comparison does not stand up to scrutiny: assessment of a new MAA entails a review of not only clinical data, but also CMC information and nonclinical data. At the time of a new MAA, the assessment is conducted with the assessors having little prior knowledge of the product or its properties – the dossier must be reviewed in its entirety. In a referral, the focus of the assessment is on the new information that gave rise to the referral (albeit in context of what is already known), so the workload (and the fee) should be significantly lower. The proposal to have a (large) range of fees also raises concerns about the transparency and predictability of the costs that companies might face and companies' ability to budget. Referrals cover a wide range of circumstances and so there will be a broad continuum in the level of complexity. If the MAH is to be charged a fee, we believe that a single fee should be applied (as was proposed in the Commission's Financial Statement from the 2008 proposal). Whilst the workload required by the Agency to assess each referral will vary, when taken across several procedures the net income from fees should be

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covered. A referral could be initiated as a result of another ongoing procedure (e.g. variation, PSUR assessment) and as such it would seem unreasonable for the MAH to be charged for the referral when the Agency has already assessed the data and the MAH incurred the cost of the original procedure. Similarly a separate variation fee should not be charged by the EMA for the implementation of changes to the MA of CAPs following the conclusion of a referral procedure Furthermore, the threshold for initiating article 107i referrals is subjective (when a MS or the Commission "considers" that certain actions are necessary) and could be rather low. There have been instances where safety concerns by individual Member States upon referral were not shared by the CHMP. It would not seem fair to leave the MAH with the financial burden in cases where no action is deemed necessary upon conclusion of a referral or where only minimal amendments to the SPC are needed. According to the appointment principles for PRAC Rapporteur and Co-Rapporteur in case of pharmacovigilance referral (as defined in the EMA document (EMA/315258/2012) of 28 June 2012), the co-rapporteurship is automatically granted to the Member State triggering the referral when non-CAPs or mixture of CAPs and non-CAPS are involved. Considering that the scientific assessments by PRAC Rapporteur and Co-Rapporteur should be subject to payment of half the fee (as mentioned in the 2008 legislative financial statement), a special attention should be given for not creating a bias in the system by setting up very high referral fee that may be unduly seen as a potential important source of revenue that can be disproportionate to the importance of the scientific assessment required.

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

Comments
Should pharmacovigilance referrals not be supported by Community funding, the concept of grouping is welcomed. However, it should be explicit that MAHs belonging to the same mother company or group of companies and MAHs having concluded agreements or exercising concerted practices concerning the placing on the market of the medicinal product(s) concerned, should to be taken as 'the same marketing authorisation holder' (see Commission Communication 98/C 229/03 OJ C 229, 22.7.1998) and should not be charged additional administrative fees as if they were separate MAHs. Should pharmacovigilance referrals not be supported by Community funding , it is important to establish a model-based system for the fee assignment that complies with the principles of proportionality and equal treatment of MAHs, as well as with competition laws. For pharmacovigilance referrals that concern different MAHs (not covered by Commission Communication 98/C 229/03), we propose that the total referral fee (including any administrative fees) is equally divided among all concerned MAHs for the same active substance or class (in the case of class referrals), whether they be an MAH for an originator or generic product.

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

Comments
In principle, the concept of an annual service fee for certain routine pharmacovigilance activities is acceptable, provided that it is clear what those activities are, those activities are a service to MAH, and the fee is proportionate to the cost of those activities. With regard to the specific proposals in the concept paper, however, there are several considerations which need to be addressed. Annual fees are already in place in most of the Member States for non-CAPs, to cover all aspects of routine dossier management and maintenance, including the work associated with on-going pharmacovigilance activities. The proposed new pharmacovigilance service fee could duplicate the national fees, which is not compliant with the Commission's general principle of transparency (same work being not charged twice). Similarly, CAPs are already subject to a substantial annual fee of €95500, of which 30% (€28770) is foreseen for pharmacovigilance and inspection staff costs. The Commission proposes to continue to charge this fee, but the Concept Paper includes no analysis of the use of the revenue from that fee, and does not clearly stipulate the additional activities that are above and beyond those currently performed that will be funded by the new annual fee. The concept paper does list some activities that should be financed by the proposed pharmacovigilance service fee. As these include public health activities ("monitoring the effectiveness of public health measures"), we propose that these activities should be at least partly financed by Community funds.. It should also be noted that the EMA's literature monitoring will not benefit all products or companies, so it seems unfair to include the cost of this service in the fees paid by all companies. It should also not be forgotten that MAHs have already invested significant amounts of money and resources in ensuring that internal systems are ready and that relevant personnel are trained in compliance with the new legislation. For example, MAHs are likely to have expended budget to allow the development of internal databases to draw down data, which is then fed into EU Agencies' databases. Further imposing fees in order to allow the Agency to implement parallel systems could mean that the MAHs are paying twice to support the same activity.
We believe that an overall review is necessary in order to have more transparency on what tasks the different annual fees correspond to, in order to be able to form a firm opinion on the acceptability of an annual service fee and the appropriate level of such a fee. If a pharmacovigilance service fee is introduced, it must be explicit that MAHs belonging to the same mother company or group of companies and MAHs having concluded agreements or exercising concerted practices concerning the placing on the market of the medicinal product(s) concerned, should to be taken as 'the same marketing authorisation holder' (see Commission Communication 98/C 229/03 OJ C 229, 22.7.1998) and should not be charged additional service fees as if they were separate MAHs. [*EMA website – "Funding" page - http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000130.jsp&mid=WC0b01ac0580029336]

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

Comments
We welcome that a reduced fee level be introduced for micro-enterprises and for SMEs, but consider that this reduction should go further and also cover orphan-medicinal products and other low volume/low sales products which might otherwise be withdrawn from the market due to the additional costs associated with post-marketing activities

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

Comments

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

Comments