INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE

3.1. Fee for assessments of Periodic Safety Update Reports

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

FCIO comment:

In line with the benchmarking approach, it is proposed to charge (a basic) maximum fee of € 80.300 EUR for each assessment of PSURs. This maximum fee of € 80.300 is proposed for each assessment of a PSUR for products that have been authorized for 2 years or more and a lower fee of € 40.150 for products authorized for less than 2 years.

Currently, the submission of a PSUR for a nationally authorized product in Austria and as a result of an authorization in Austria as concerned member state is € 500. The submission of a PSUR due to approval in Austria as reference member state is € 3.600. Thus the proposed fee of EMA amounts more than 20-fold of the Austrian fee. The fees of the EMA shall apply to each type of authorization (EU procedures and national). The proposed fee for the PSUR assessment does not consider the real costs of work of the EMA. This is less if the product is approved and commercialized only for a few countries, and thus fewer side effects are reported. So the fee should be staggered (depending the number of side effects that arise for consideration in the PSUR).

Moreover it is completely unclear for what services € 40.150 or maximum € 80.300 will be levied.

In accordance to general principles in proposing fees for pharmacovigilance by the EMA the proportionality between the amount of the fees and the nature of the work / tasks actually carried out by EMA has to be consistent. In addition the EMA shall take care for transparency in order that marketing authorization holders (MAH's) know what tasks the fee corresponds and shall avoid that they are charged twice (by EMA and the member states) for the same work.

Products for which a MAH 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. It must be added that not all generic drugs are generally excluded from the PSUR submission. There remains a large number of active ingredients, for which the PSUR will continue to be necessary.

It is also unclear why the amount of € 80.300 for each assessment of PSUR should be a maximum amount, whilst the lower fee of € 40.150 is no maximum amount. Reasons for this difference are entirely lacking.

The “outdated” 2008 Financial Statement provides for the assessment of PSUR’s € 6100 (1000 PSUR’s/year). There is not the merest hint in the proposal why a single PSUR assessment is now charged with a fee of € 80.300.

We call for the amount of the proposed PSUR-fees a detailed statement about the people and administrative expenses and a precise statement of the services to be provided for the proposed fees.

The new pay rates could be life threatening for many pharmaceutical companies. Such an explosion of costs does not make sense also it is impossible to adjust the prices to an extent that would offset the additional costs.

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

FCIO comment:

Even the offered opportunity to reduce the fees by "grouping" would mean unreasonably high fees.
In addition, in the case of grouping administrative fees of € 500 per group participant are planned. It is totally unclear for what the additional charges of € 500 incurred. Therefore we call a statement about which work is carried out under the item “administration””.

3.2. Fee for assessments of Post-Authorisation Safety Studies

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

FCIO comment:

For the assessment of each final study report for PASSes, in line with the benchmarking approach, it is proposed to charge a fee of € 80.300.

The 2008 Financial Statement calculated a workload of 300 study assessments/year at € 6100 at the EMA. There is no justification presented why the assessment of each final study report for PASSes is now charges with a fee of € 80.300.

This would be a very new type of fee which does not currently exist. Neither the reason nor the amount of this fee for the assessment of each final report of a PASS is traceable. Again, we ask for a detailed list of all services that are included in this point. Here, too, a graduated fee is thinkable, since the workload is not equally at each PASS.

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

FCIO comment:

Here, too, the same arguments are necessary like executed to item n° 2.

3.3. Fee for Assessments of Pharmacovigilance Referrals

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.

FCIO comment:

For Pharmacovigilance referrals it is proposed to charge a pharmacovigilance referral fee ranging from € 80.300 to a maximum of € 267.400.

The 2008 Financial Statement calculated a workload of 20 assessments/year at € 72.800 at the EMA. There is no justification presented why the assessment is now charged with a fee ranging from € 80.300 to € 267.400. The current proposal shall mandatory explain the basis of the calculation.

It is undisputed that vast resources and extensive expertise are required for a referral for safety. However, the underlying calculations for resources and expertise have to be made transparent. Here, too, a graduated fee is conceivable, since the workload is not equally with every referral. It is unclear who ranks the amount. It is not explained in which case the maximum costs of € 267.400 per referral have to be paid by the authorisation holder. EMA has to describe accurately, which services can be requested for this fee by the authorisation holder.

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

We don't agree with the concept of grouping as proposed for the same reasons as described under consultation item n° 2.
We assume clarification about the detailed services of EMA which are provided for the „administration fee" of € 500.

3.4. Pharmacovigilance Service Fee

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

FCIO comment:

In the Concept Paper it is proposed to charge an annual pharmacovigilance service fee of up to € 1,000 for each license holder and each medicinal product. There is no existing suitable benchmark for this type of fee. The level of fee will depend on the number of different authorized active ingredients (plus combinations). Through this brand new service fee that will be levied irrespective of a particular power would mean an added annual charge of € 100 000 for many pharmaceutical companies. An additional fee is not justified, since the individual pharmacovigilance activities are already billed separately. It is totally unclear what service shall be provided for this service fee by the EMA.
This service fee is intended to cover services such as literature monitoring and monitoring the effectiveness of public health measures (e.g. risk management systems, through outsourced studies of their outcomes using longitudinal patient databases). It was also made clear by EMA, that the legal obligation of the MAH's to monitor the scientific literature and to process literature reports on adverse drug reactions will remain unchanged. Therefore, literature monitoring by EMA does not shift any task from the MAH to the EMA and for that reason it cannot be regarded as a service.

This raises the question whether these benefits could not be serviced much easier by a Member State, which already has its own vigilance center.

In the Concept paper it is not described if there is only a maximum amount of € 1000 or whether it can also lead to reductions in favour of the authorisation holder.

For companies with a large range of drugs or drug combinations would mean the service fee an additional annual burden of € 100,000 and more. Then some products needed by smaller groups of patients would not be cost-effective. For these reasons the stated requirement is more than excessive. It is not justified to charge the industry with an additional lump sum for unspecified services.

On top of that, the current annual fee, which the Agency currently charges for centralised authorized products should continue to be charged by the EMA.

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

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.

FCIO comment:

In the concept paper it is proposed that the SMEs - irrespective of whether they have CAPs or non-CAPs - be granted a 50% reduction of the proposed full fees for PSUR single assessments, PASS assessments and pharmacovigilance referral assessments. The 50% reduction would only apply when SMEs are not involved in a grouping. In view of the amount of the proposed PSUR, PASS and referral fees a 50% reduction doesn't seem to be adequate.

In the post-authorization phase, SMEs with CAPs currently pay the full annual fee and the full variation fee. Fee incentives for SMEs are limited in this phase to a 90% reduction of the fees only for inspections, scientific advice and scientific services.
This 90 % reduction should also apply to fees for single PSUR assessments, PASS assessments and pharmacovigilance referral assessments. SMEs should also be provided a 90% reduction for that type of charges.

In addition it is proposed that micro-enterprises are totally excluded from any pharmacovigilance fees. Micro-enterprises are the smallest category of SMEs with less then 10 employees and a turnover equal to or less than € 2 mio.
This exemption is very welcomed. However, it must be carried out that the majority of all marketing authorization holders are SMEs and therefore would not fall under this exemption for micro-enterprises.

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

FCIO comment:

The proposed pharmacovigilance service fee would be charged yearly to marketing authorization holders of CAPS and non-CAPs. SMEs get absolutely no reduction of the service fee, but "will be only charged proportionally less than bigger companies, holding a larger product portfolio". It is not clear for whatever reason the SMEs shall receive no reduction of the proposed pharmacovigilance service fee, especially since it is planned not to reduce the full current annual fee to SMEs in the future.