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Comments from the Austrian Medicines and Medical Devices Agency (BASG / AGES Medizinmarktaufsicht) on the consultation paper "Introduction of Fees to be charged by the EMA for Pharmacovigilance"

Please see our comments in connection with the more general response of the Heads of Medicines Agencies.

Consultation item n°1:
It is unclear if the fee is proportionate to the costs incurred (administration and assessment). In AT we differentiate between PSURs for nationally authorized medicinal products and those where AT is RMS and, even though our national fee-regulation foresees a fee reduction of 50% under special circumstances (presented simultaneously by the same marketing authorization holder, active ingredients are of the same type, and their application is comparable with regard to the evaluation), we are able to cover our costs in the average. The proposal in question means a more than 20fold increase of fees as compared to the current national situation – this may be justifiable but requires additional information.

Consultation item n°2:
The concept of grouping as proposed seems relevant. However the additional charge of 500€ for administrative purposes seems to be quite high. Administration is expected to be widely automatized (e.g. electronic submission via PSUR repository) in future and as such the purpose of this fee should be made clear.

Consultation item n°3 and 4:
PASS assessment will require substantial resources and expertise. The concept of grouping as proposed seems relevant. However, an estimate of the average time and costs for administering, assessing and discussing a PASS at the EU-level would be helpful.

As above the additional Charge of 500€ for administrative purposes seems to be quite high and should be explained/justified further.

Consultation item n°5 and 6:
Pharmacovigilance referrals require substantial resources and expertise. The concept of grouping as proposed seems relevant. However, an estimate of the average time and costs for administering, assessing and discussing a referral at the EU-level would be helpful.

The range from 80,300€ to 267,400€ as proposed is extremely wide. Underlying calculations for minimum and maximum fees should be made transparent. Moreover a clear and detailed scale for the intermediate fee levels should be provided.

Again the additional Charge of 500€ for administrative purposes seems to be quite high and should be explained/justified further.

Consultation item n°7:
We strongly question the pharmacovigilance service fee as proposed. It is unclear which services are encompassed and what the resource requirements (and finally cost) of these services are. We can assume that there are about 3.500 to 4.000 distinct active substances in the EU in addition to a currently unknown number of fixed combinations of substances. It is currently, however, unknown how many MAH per substance/combination would have to pay this fee. Accordingly it is unclear, if this fee is excessive or appropriate.

In practice there will be substances, e.g. paracetamol, where in many MS there will be several national MAHs with an authorization seems inappropriate to charge each 1.000,- per year. Looking at Austria there are about 600 marketing authorization holders of which each holds authorizations for about 10 substances in the average. In light of the next paragraph this may sum up to 6 million Euro, which raises the question for which purpose these fees are designed. Moreover it should be taken into account that most of the administrative work (data input, data update) is done – as required by legislation – in fact by industry.

It is also unclear from whom the fee is levied in case of multinational companies despite the example given in the consultation paper. Here is a simplified example: substance S is authorized 10 times by 3 MAH (X1, Y1, Z1) in AT and 10 times by 3 MAH in another MS (W2, Y1, Z2) Y1 indicates multinational corporate group and Z2 is also part of a multination corporate group but as Z1 but another national branch): does that mean a total of 4.000 (W2, X1, Y1, Z1/2) or 5.000 (W2, X1, Y1, Z1, Z2)? In should be taken into account, that regulatory/company constructions like these reflect real life conditions.

Consultation item n°8:
The proposal as outlined in 3.5.1 is reasonable. Assuming that activities are in principle in a proper relation to the level of the fee, it is unclear who then pays for the incurred costs at the level of EMA (providing administration) and the NCAs (providing assessment)? Will that have to come from national sources or will it be covered by the Commission? If the former, are Member States informed that this will be required? It is our current understanding that there is no such budget in Austria.

Even though not a consultation item we would like to address the exemption for micro-enterprises: It is unclear how the micro-enterprise status is validated.

Consultation item n°9:
See also comment on item 7.

From the wording as proposed "As EMA will continue to carry out certain pharmacovigilanc activities also for SMEs with CAPs…it is proposed not to change the current annual fee to SMEs." it seems to be unclear whether this sentence refers to normal annual fees in general or Pharmacovigilance Service fees in particular. In other words: are SMEs subject to Pharmacovigilance fees or not?

Consultation item n°10:
We generally support that fees are to be raised for assessment activities for which EMA for administration and rapporteurs/co-rapporteurs for scientific assessment are currently not remunerated.

We support all the general principles in proposing fees and in particular we support the principle of proportionality (money for service) and transparency (what to pay for and not paying twice). Therefore it is rather difficult to comment on the level of some of the proposed fees as it is unclear what the amount of the generated revenues will be and likewise what the amount of expenditure will be. In terms of transparency it is difficult to comment for mostly the same reasons - it is unclear for what EMA charges, how the charged amount is constructed, and which part of it, if any might also be charged by NCAs.

We would also welcome a transparent system for the allocation of charges to EMA (for administrative efforts) and NCAs/(Co-)Rapporteurs (for assessments).