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Comments from Gilead Sciences International Limited in response to the Concept Paper “Introduction of fees to be charged by the EMA for pharmacovigilance”.

Thank you for the opportunity to comment on the aforementioned concept paper.

Much is made of the MAH having to pay for services it may theoretically benefit from, but in reality still has to do, for example, literature searching. This also affects certain but not all MAHs and largely the generics companies.

Regarding section 3.1, which references basic fees of 80,300 Euros for a PSUR and then states there will be a maximal amount equivocal to the renewal fees, this is not transparent nor helpful to MAHs needing to plan budgets to account for this additional and extensive costs. If 80,300 Euros is the maximum this should be clearer. In addition, where an MAH is required to submit multiple PSURs simultaneously due to a common active ingredient, such a fee structure seems punitive and will result in duplication of assessments. The grouping concept does not help in such a situation. A single fee for a PSUR seems inappropriate where there are multiple submissions expected of an MAH. Grouping will only benefit a subset of MAHs.

Regarding section 3.2 on PASS, it seems unusual that whether PRAC or a Member State reviews the protocol the cost of 80,300 Euros is the same. It is also interesting that this fee is the same as that for a PSUR which will require more analysis – the fee for PASS review seems high. There is no differentiation on costs for voluntary vs. imposed PASS. How will the validity of imposed PASS be assured when the MAH has to fund what is requested?

Regarding section 3.3 on referrals, the maximum amount seems prohibitive.

The annual fee is confusing and the basis is unclear.

Overall, these costs for regulatory review of pharmacovigilance activities and oversight is extensive and could adversely affect access to medicines in EU if the maximum fees are payable. The fees will impose significant financial burdens on MAHs going forward.

It would be useful to determine a typical income generated from a typical MAH with a given number of products and how this compares with agency costs and fees as the fees appear burdensome, high and not transparent in their application.