From: **Kappler Pharma Consult GmbH (DE)**
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Sent: 12 September 2012 11:14
To: SANCO FEES PHARMACOVIGILANCE
Subject: PC/12/05 - Public Consultation on pharmacovigilance fees

Dear Mr. Ziogas,

We are a company eligible as SME. We have only non-CAPs.

We want to give you some comments in course of the public consultation on pharmacovigilance fees:

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

The fees seem to us by far too high for most of the products. It may be acceptable for products with a substantial turn over but not for products with a small turn over or with a small market or for products which are not on the market.
These fees will drive small companies which have a couple of products with a small market to bankruptcy.

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

Grouping may be helpful to reduce costs but the difficulty is that companies have to disclose to each other substantial information and the procedure needs a coordinator. The procedure seems to be not appropriate.

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

We think that the fee is by far too high. The evaluation procedure should be done in a more efficient way.

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

Grouping is only applicable if several MAH have the same substance approved. This is a rare case for new products but quite normal in case of generics for which usually no PASSes are required.

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.

The maximum fee is not justified as this fee is in the region of the fee for a new application.
New applications are not only requiring assessment of safety and efficiency updates but as well review of complete pharmaceutical, pharmacological, toxicological and clinical dossiers.
The minimum fee of EUR 80,300 is too high as a standard minimum because there are cases which require only minimum efforts.
The fee structure should go in parallel with salaries of qualified people in pharmaceutical companies, SMEs and national authorities. EMA should consider subcontracting evaluations to less expensive countries.

Consultation item n°6: Do you agree with the concept of grouping as proposed? If not, please explain and/or suggest alternative.
Grouping seems to be o.k. in this case.

Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.
It is unclear why and for what purpose this fee is charged and which service is provided to a company. The pure existence of a database at EMA does not justify such fee.

There should be a differentiation whether products are on the market or whether these products are just kept for future marketing activities.

We assume that finally a fee will be charged. But this fee should be charged per substance and marketing authorisation holder and no extras should be charged for additional strengths, formulations or pack sizes.

Consultation idem 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.

We agree on the proposed reduction of the fee for SMEs but we want to point out that we do not agree on the fee structure and on the excessive high fees.

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

Sounds theoretically good but the services of EMA are not in place.
In addition it should be remembered that the services for literature search etc. were proposed to lower the burden for pharmaceutical companies. Consequently this argument cannot be used to justify new fees.

Consultation item n°10: What other aspects would you like to raise? Do you have additional comments?
No, we do not have additional comments.

Best regards

Dr. Joachim Kappler

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