Pharmis Biofarmacêutica, Lda.
EMA-SME number: **EMA/SME/056/11/R1**
Customer account number: **600553**
&
Color Pharma, Lda.
EMA-SME number: **EMA/SME/057/11/R1**
Customer account number: **600552**

Country: Portugal

03rd July 2012
Ref. Ares(2012)723154 - 18/06/2012

INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE

CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

Subject: Response to Consultation items

Consultation item n°1: Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative.
No. EMA wants to charge a fee equal to a CAP variation, which is unacceptable for the companies with non-CAPs'.
According to point 3.1 "Products for which a MA 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", however, this phrase is very ambiguous because according to the draft new list EU reference – dates, in public consultation until September 2012, most of the generic products have a "specific requirement" to present the PSUR.
Because most of the Pharmaceutical companies has non-CAPs' the proposed fees will lead to a financial disaster in Pharmaceuticals in the EU, as the commercial margins are crushed due to the aggressive Health policy in generic products.
Moreover, the majority of the SMEs have generic products in its portfolio, and even a reduction by 90% is not sustainable, especially in small EU countries.
Alternative: A fee of 1,000€ per MAH appears to be more than reasonable, as we have thousands of MAs per medicinal product (generic or well-established use) in the EU. Therefore, a number of 81 companies would be enough to achieve the maximum fee proposed of 80,300€.
In this case, the SMEs should have a 50% reduction.

Consultation item n°2: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.
Theoretically yes, but no in practice, because EMA cannot expect MAHs in different countries to be grouped. Even in the same country is not easy to group companies.
Moreover, from the grouped companies, who is going to pay the maximum fee? The biggest company? Even a big multinational does not want to pay a fee of such an amount.

If grouped companies decide to proportionally split the total amount according to their turnover or product portfolio, how EMA is going to invoice the companies?

Consultation item n°3: Do you agree with the proposed fee for the assessment of PASSes? If not, please explain and/or suggest alternative.
No, the proposed fee is too high considering all expenses related with the medicinal product (clinical studies, regulatory fees and PSURs).
Alternative: half of the proposed fee (40,150€) seems to be more sustainable.

Consultation item n°4: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.
Yes, but the same can happen as stated in the response of item nº2.

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.
No. We think that EMA should charge the basic fee applicable for a referral, 66,700€.

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

Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.
No. Some companies are already charged by their own local Agencies with a % over sales for the management of these and other activities by Health Authorities, like Portugal. Therefore, the proposed pharmacovigilance service fee goes against the principle of transparency, at least in some EU countries.
Please note that SMEs have fee incentives granted by EMA, but not by NCAs.
Alternative: if the pharmacovigilance service fee must be charged to the companies, then we propose a fee of maximum 500€ per year and per medicinal product, with a fee reduction by 80% for the SMEs; but national fees have to be revised to avoid violation of the principle of transparency.

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.
Yes, we fully agree as far as fees for pharmacovigilance procedures are revised by EMA as mentioned before.

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

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

As mentioned in item nº7, EMA must see with NCAs the fees already charged to the companies that already include the pharmacovigilance activities, to avoid duplication of fees; and it should be noted that SMEs do not have a fee reduction granted by NCAs for local fees.