From: Rita Mendes [mailto:r.mendes@benefarmaceutica.pt] ***Regulatory Affairs Director***

Sent: Monday, September 17, 2012 12:04 AM
To: SANCO FEES PHARMACOVIGILANCE
Subject: Public consultation - Introduction of fees to be charged by the EMA for pharmacovigilance
Importance: High

Dear Sir/Madam,

Bene Farmacêutica, Lda. is the Portuguese Affiliate of Germany Company, Bene Arzneimittel GmbH. Bene company is composed only by these two sites, which main business is marketing products in its own countries. Approximately 90% of its marketed products are Nationally Authorised Products (NAP).

Regarding the public consultation of the document mentioned above, our comments are listed below.

Before listing the comments to each item, we would like to notice that the values presented in the document should consider the economic situation in Europe.

Item #1:
We do not agree with the proposed fee since for National Companies (at least in Portugal) this value is too high. All products of Bene Farmacêutica, Lda. are NAP or MRP/DP and in these cases for a variation type II we pay a fee of 1585.65€ (for NAP we have 40% discount) plus 511.50€ for each strength or pharmaceutical form involved. As you can see it is a significant increase of costs for us. Therefore, in our opinion this should not be applicable irrespective of the route of authorisation, otherwise, National Companies will have a negative impact in their business.

Item #2:
Is this concept also applicable for generic, well-established use and hybrid products for different MAHs? Can it be grouped by active substance irrespective of the MAH?
Bearing in mind that the value of 80 300€ is already too high, so the proposed of the administrative of 500€ for some countries, as Portugal it can be too high for the extra work of adding a new MAH.

Item #3:
We have the same comment as for the PSUR assessment. If we want to compare an assessment of PASS against a variation type II, it should be created different fees according to different countries specificities.

Item #4:
It is absolutely relevant to have a concept of grouping as proposed. Our concerns are: if the MAHs concerned by the procedures in article 107q of the Directive will reach an agreement to perform only one single PASS. For this EMA should implement mechanisms that will ensure such an agreement between all MAHs.

Item #5 and #6:
According to our comment on item #1 it should be different fees for products authorised by CAP, NAP or MRP/DP. It is mentioned in this concept paper that the fee would be subject to grouping and the costs per applicant or MAH may therefore be substantially lower, however in our opinion it can also be higher. Though, we consider that EMA should differentiate all the cases as much as possible, for example, by the workload.

Item #7:
All these years, all the companies had costs with different pharmacovigilance services and we never received any fee from EMA or
other Agency. Our opinion is that the phamacovigilance service fee should also be subjected to grouping by MAHs with the same active substance. Moreover, this pharmacovigilance service fee is also acceptable if anyhow it will take away costs from the MAHs.

Item #8:
We are not sure that the majority of all MAHs of non-CAPS are SMEs. In our opinion this should be subject of an intensive impact study in each country. We are also of the opinion that a reduction of 50% is not enough.

Item #9:
For this item, please see my comment on item #7.
Regarding the annual fee for SMEs with non-CAPs, we agree with the proposal.

Kind regards,

Rita Mendes
Regulatory Affairs Director
bene farmacêutica
TEL: ☎ (00351) 21 191 44 55
FAX: 🖷 (00351) 21 096 74 19. **E-MAIL**: ✉ r.mendes@benefarmaceutica.pt