To: European Commission 14 Sep 2012
Health and Consumers Directorate-General
Unit D5 "Medicinal products - authorizations, EMA
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Response to Public Consultation on Introduction of Fees To Be Charged By The EMA for Pharmacovigilance. Deadline 15th September 2012

**Consultation item No 1: Do you agree with the proposed fee for single assessment of PSURs? If not please explain and or suggest alternative**

The wish to keep safety of medicines on a superior level is highly appreciated. Therefore, all activities to gain transparency and scientific competency are supported. However, we doubt the advantage of transferring product specific know how from the responsible company to an authority. Highly specialized companies as allergen manufacturers have an experienced and knowledgeable understanding of their products. Taking over the responsibility for the PSUR and other current safety assessments will create more bureaucracy and costs; without any progression in quality.
Therefore, we would prefer to keep compilation in house using our current knowledge. This would avoid any extra cost for EMA and the need to charge fees; this is particularly relevant for such unique products.
We can appreciate that the system might be suitable for small molecular and chemical entities. However, allergen products are different. As an allergy company we have years of understanding our products and can see no reason to move this process to EMA.
In addition, as we supply to non European markets we would still need to perform this service in house and keep the existing personnel levels.

The responsibility of a European Commission is the supervision of safety in the European Union. It cannot be the function of a super-visionary body to take over tasks of commercial services.

**Consultation item No 2: Do you consider relevant the concept of grouping as proposed? If not, please explain and /or suggest alternative.**

In principle we have no issue with grouping for companies with small molecule products. However, for allergy therapy products which are unique it would not be possible to group products with any other company products. Therefore we would propose that the principle of grouping is only applied to certain types of products and that Allergy products are excluded from processing by EMA and that PSURs are maintained by the company.

**Consultation item No 3: Do you agree with the proposed fee for single assessment of PASSes? If not please explain and or suggest alternative.**

Given that a fee has already been paid for the MA the company does not consider that further fees should be paid for assessment of the PASS report. The company would prefer to meet the requirements of the protocol and assess compliance independently; such that the final report reflects the results from the study. The report can be approved by an independent clinical expert if required.

**Consultation item No 4: Do you consider relevant the concept of grouping as proposed? If not, please explain and /or suggest alternative.**

In principal we have no issue with grouping for companies with small molecule products. However, for allergy therapy products which are unique it would not be possible to group products with any other company products. Therefore we would propose that the principle of grouping is only applied to certain types of products and that Allergy products are excluded from processing by EMA and that PASS reports are reviewed by the company.

**Consultation item No 5: Do you agree with the proposed fee for single assessment of Pharmacovigilance referrals? If not please explain and or suggest alternative**

As the company would not qualify for grouping the proposed fee seems excessive for a company which is just above the current SME qualification .The company agrees that there should be a fee but feels it should be assessed determined on the company turnover and supply.

**Consultation item No 6: Do you consider relevant the concept of grouping as proposed? If not, please explain and /or suggest alternative.**

In principal we have no issue with grouping for companies with small molecule products. However, for allergy therapy products which are unique it would not be possible to group products with any other company products. Therefore we would propose that the principle of grouping is only applied to certain types of products and that Allergy products are excluded from processing by EMA.

**Consultation item No 7: Do you agree with the proposed Pharmacovigilance service fee? If not please explain and or suggest alternative.**

The general concept of taking fees for services is questionable as such, if the European Union gives guidance to the public and supervises the outcome this is both part of the legislatory function and control of it. However, the take over of service functions is a step to an integrated manufacturer itself which is not covered by any public interest. Instead we would propose to finance any of the public tasks by public funds, which means taxes.

Another most problematic issue is the fact that many of the products are not only distributed in the EU but outside the EU. Therefore, the proposed taking over of services and the collection of fees is clearly an over-engineered approach.

In practice, the company would prefer to maintain literature screening and risk management within the company as it will need to perform this task for Non European markets. Therefore it can see no reason to change from the annual fee for CAPs to the service fee.

**Consultation item No 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 and or suggest alternative.**

The company agrees that for SME's generally there should be a fee reduction. As many of the allergy companies fall just outside SME's and do not qualify for grouping, it might also be useful to consider another category which is between medium and large that allows some reduction in fees, so that allergy companies are not aligned with the global pharmaceutical companies.

**Consultation item No 9: Do you agree with the proposed approach with regard to the Pharmacovigilance service fee for SMEs (point 3.5.2)? If not please explain and or suggest alternative.**

As response No 8

**Consultation item No 10: What other aspects would you like to raise? Do you have additional comments?**

If the proposal were to go ahead the company would like the following considered.
Allergy products would not qualify under the grouping ruling therefore full fees would be required at a maximum of 80,000 euro. This fee is the same for national, MRP or DCP processes and as most allergy products are licensed under national registrations this fee would seem much too high. CROs can offer this service for a fraction of the cost.
If any, we would propose different levels of fees dependant on the number of countries involved. If a company has just one national registration the fee should be reduced to a much lower level.
Whilst we appreciate that it may be similar workloads for the agency for the company involved with one national the fee does not justify continued medicine supply.

As a general remark we would propose allergen diagnostics are excluded under well established use and thus do not require submission of a PSUR
We would also request considering any allergen homologous mixtures are treated as one active regarding the annual fee