EAMG
EUROPEAN ALLERGEN MANUFACTURERS GROUP

European Commission
Health and Consumers Directorate-General
Unit D5 "Medicinal products - authorizations, EMA
Sanco-fees-pharmacovigilance@ec.europa.eu

14/9 2012

Re: Concept Paper "Introduction of Fees to be charged by the EMA for Pharmacovigilance

Dear Sir.

On behalf of the European Allergen Manufacturers Group (EAMG) which is an association of 8 major manufacturers of allergen extracts for specific immunotherapy and allergy diagnostics in Europe (www.eamg.com) we kindly ask you to consider the following comments.

Considering the diversity and limited market of allergen products we would like to make the point, that the proposed concept and fees to be charged by EMA for Pharmacovigilance according to the concept paper for our specific industry would be unreasonable high and imply a risk for the future of the industry.

Allergen extracts/vaccines are used for specific immunotherapy and specific diagnosis of allergic diseases. Allergen extracts are aqueous solutions of allergenic source materials, such as pollens, animal hair and dander, house dust mite bodies or cultures, insect venom, mould mycelia and spores. Any immunogenic protein (antigen) has allergenic potential, why subject over Europe becomes allergic to many different substances driven by the natural environmental exposure and biological conditions.

Allergen extracts are complex mixtures of characterised allergens (enzymes, other proteins, and compounds) derived from natural allergen sources. Biological potency and reproducibility of the active substance is ensured by implementation of different standardisation procedures defined by the **European Pharmacopoeia 6.6: Allergen Products** (01/2010:1063) and EMA guideline: **Guideline on Allergen Products: Production and Quality Issues.** EMEA/CHMP/BWP/304831/2007).

These products are used in a variety of applications, including diagnostic skin testing, provocation testing and allergen specific immunotherapy treatment. Different application forms and different administration routes are used for specific immunotherapy - subcutaneous and sublingual administration being the most widely used.

Diversity in products including CAP and non-CAP, the use of products for diagnostics respectively immunotherapy treatment and the different application forms as well as a relative large amount of NPP products on the European market makes it unlikely to integrate this very unique field of medical practice into the proposed concept. Due to the medical and biological nature of allergic diseases the use of different species (sources) for production of allergen extract differs between climatic regions of Europe and as a consequence hereof, Pan European suppliers of allergen extracts often market different

products (biological species causing allergy) in different regions. This is a unique situation compared to the pharmaceutical industry in general and it makes it impossible to implement allergen extracts for diagnosis and treatment into concept for fees for Pharmacovigilance as proposed by the Commission.

Although the draft proposal offers the possibility of a fee reduction for micro, small and medium sized enterprises (allergen extracts manufacturers belong to the small/medium size companies within pharmaceuticals) most manufacturers do exceed the staff headcounts of 250 mainly caused by the high demands in production and quality control in allergy products.

The proposed 'grouping' for products which are parts of the same single assessment procedure is not applicable for allergen extract manufacturers.
The drug substances differ between the manufacturers because of different raw material sources, different ways of extraction, different production pathways with regard to the final products and different administration routes of the preparations. An allergen extract from the same source is not comparable between manufacturers - neither in quality nor in clinical documentation. Further to this many manufacturers are marketing different product lines for one allergen in order to satisfy the medical need for individual patient compliance.

With the many products that allergen manufacturers must be able to market in order to fulfill the need for diagnosis and treatment of the growing number of allergic patients in Europe, the proposed fees would constitute an inadequate financial burden. It becomes obvious that the proposed new fees are at least in the specific field of allergen products not useful and we therefore propose to include an additional general proposal which can meet the specifics of a unique medical field. With regard to manufacturers of allergen extracts the special situation as described above should be taken into account and an adjusted fee schedule developed.

We look forward to your reply and to discuss further how we can find a solution which can ensure a reasonable situation for the industry represented by allergen manufacturers in Europe.

Lars Jacobsen
Executive director, EAMG

Lars Ingemann
Chairman, EAMG

Re: “consultation items” - please see below

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

We do not agree - please see above

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

This proposal is not relevant for allergen products - please see above

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 do not agree - please see above

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

This proposal is not relevant for allergen products - please see above

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.

We do not agree - please see above

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

This proposal is not relevant for allergen products - please see above

Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.

We do not agree - please see above

Consultation item 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.

This proposal is not applicable for allergen manufacturers - please see above

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

This proposal is not applicable for allergen manufacturers - please see above

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

Since the concept proposal is not applicable to allergen extracts as described in details above, we recommend including justified alternatives to the concept paper.

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