



*Representing the Consumer  
Healthcare Industry*

Directorate General for Health and Consumers  
Unit SANCO/D/5  
BE-1049  
Brussels

14<sup>th</sup> September 2012

Dear Sir or Madam,

The Proprietary Association of Great Britain (PAGB) is the UK national trade association representing the manufacturers of non-prescription medicines of chemical and herbal origin. PAGB is in general agreement with the response to the Commission's Concept Paper submitted by the Association of the European Self-Medication Industry (AESGP).

However, we would like to raise some points from a national perspective in addition to the concerns raised by AESGP.

- The Concept Paper does not explain how the establishment of the infrastructure required by EMA is to be funded or how the predicted operating costs have been determined. There is a major discrepancy between the Commission's anticipated increase in fees payable to EMA and industry's assessment of the costs that the proposals will incur. The proposed fee levels are disproportionate and there is no explanation of how the Commission has reached these figures or why the 2012 proposed fee levels are so much higher than those anticipated in 2008.
- PAGB firmly believes that the funding structure needs to be set up in such a way that the infrastructure required to establish and support the new system is assured. Another issue of concern to us relates to the need to ensure that the fee structure will not adversely impact the financial stability of national competent authorities. Once EMA fees are in place we are assuming that national competent authorities will no longer charge fees for pharmacovigilance (so as to avoid double charging). However, if a significant part of a competent authority's income is unpredictable and unduly dependent on EMA and the volume of pharmacovigilance work it can attract there is a real risk that this could have an impact on the long term sustainability of national competent authorities, staff retention and expertise.
- We suggest that further consideration is required in relation to the balance of fees raised on the basis of work activity vs. service fees, between pre and post market assessments, and the apportionment of costs between NCEs vs established products.

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Registered Address: Vernon House · Sicilian Avenue · London · WC1A 2QS ·  
Tel: 020-7242 8331 · Fax: 020-7421 9317  
E-mail: [info@pagb.co.uk](mailto:info@pagb.co.uk)