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European Commission, DG Health and Consumers,
Unit D5 'Medicinal products – authorisations,
European Medicines Agency (EMA)

By email to: SANCO-FEES-PHARMACOVIGILANCE@ec.europa.eu

7 September 2012

Re: European Commission Concept paper on fees for new pharmacovigilance activities

Dear Sir or Madam,

The Association of the British Pharmaceutical Industry (ABPI) is in general agreement with European Federation of Pharmaceutical Industries and Associations (EFPIA) submission to this consultation, which highlights some serious concerns about the content of the Commission Concept Paper, in particular:

- The principle that the pharmaceutical industry should finance all pharmacovigilance activities at the EMA.
- The apparent disproportionate level of proposed fees for which there has been no clear justification.

In addition to these overarching themes, many National Competent Authorities also charge fees for pharmacovigilance which would duplicate some of the proposed EMA fees in the Concept Paper. If a workable compromise could be reached that would enable the implementation of the proposed EMA fees for pharmacovigilance, the ABPI would expect the corresponding EU National Competent Authorities to reduce their fees accordingly to avoid double charging the same work.

Many thanks for the opportunity to comment and we look forward to hearing from you.

Yours sincerely,

Dr Esteban Herrero-Martínez
ABPI Head of Regulatory Affairs & acting Head of Medical & Innovation