Ref. MA 10/12

28th June 2012

Subject: EU Commission Public Consultation on "Introduction of fees to be charged by the EMA for Pharmacovigilance"

Dear Sir / Madam,

The Medicines Authority wishes to draw your attention to the **EU Commission Public Consultation on** "Introduction of fees to be charged by the EMA for Pharmacovigilance"

The new pharmacovigilance legislation Regulation (EU) No 1235/2010 of 15.12.2010 and Directive 2010/84/EU of 15.12.2010 (OJ 31.12.2010, L348) enables the European Medicines Agency to charge fees for its new pharmacovigilance activities.

With this public consultation, Directorate General for Health and Consumers within the European Commission intends to consult all stakeholders on the proposed structure and levels of fees for pharmacovigilance. Please find for your convenience the website address / links to the EU Commission web site to this published document for public consultation.

http://ec.europa.eu/health/human-use/latest_updates/index_en.htm
http://ec.europa.eu/health/human-use/pharmacovigilance/developments/index_en.htm
http://ec.europa.eu/health/documents/new_en.htm

The Commission invites comments on this consultation paper, and especially on the boxed "consultation items" by **15 September 2012** evening at the latest. Responses are sent preferably by email, **exclusively** to SANCO-FEES-PHARMACOVIGILANCE@ec.europa.eu, or by post to Directorate General for Health and Consumers, Unit SANCO/D/5, BE-1049 Brussels. The subject of the email/letter should refer to "PC/12/05 – Public Consultation on Pharmacovigilance fees". Stakeholders are also invited to carbon copy the Medicines Authority on consultations.medicinesauthority@gov.mt for information purposes.

Gavril Flores
Operations and Regulatory Affairs Manager
Medicines Authority