Ref: MA 11/11

16th September 2011

RE: Public consultation on the implementing measures in order to harmonise the performance of the pharmacovigilance activities in Directive 2001/83/EC and Regulation (EC) NO 726/2004.

The European Commission has submitted a concept paper on the above measures for consultation. The document provides details on:

- pharmacovigilance system master files;
- the quality system for the performance of pharmacovigilance activities;
- the use of internationally agreed terminology, formats and standards;
- monitoring data in the EudraVigilance database;
- the electronic transmission of suspected adverse reactions;
- electronic periodic safety update reports and risk-management plans;
- post-authorisation safety studies.

The paper is available on: http://ec.europa.eu/health/human-use/pharmacovigilance/developments/index_en.htm

Stakeholders are invited to comment on this consultation paper by 7 November 2011 at the latest. Responses should be sent preferably by e-mail to sanco-pharmaceuticals@ec.europa.eu , carbon copying the Medicines Authority on info.medicinesauthority@gov.mt.

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