Ref: MA 14/11

11th October 2011

RE: European Commission Public consultation paper on the review of Regulation (EC) 1234/2008 to the handling of variations to purely national marketing authorisations.

As part of the Better Regulation policy, in 2006, the European Commission initiated an ambitious project to revise the overall framework for variations to make the whole system simpler, clearer and more flexible without compromising public health. The final step to conclude the adoption of the variations' initiative will be the amendment of Regulation (EC) No 1234/2008 to enlarge its scope to include purely national authorisations, in accordance with the mandate given by Directive 2009/53/EC.

With this public consultation, Directorate General for Health and Consumers intends to consult all stakeholders on the following items:

- The extension of the scope of the Variations Regulation to purely national marketing authorisations.
- The adjustment of some of the procedures with a view to focus resources of the authorities on variations with the most impact on public health.
- Some workability concerns identified.
- Whether, in the light of the experience of last year, the procedure for the authorisation of vaccines in a pandemic setting should be amended.

The paper is available on: http://ec.europa.eu/health/files/betterreg/2011_09_21_public_consultation.pdf

Stakeholders are invited to comment on this consultation paper by 22 October 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 if deemed necessary.

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