

Ref: MA 04/11

28th April 2011

RE: Public consultation on a concept paper on the revision of the 'Clinical Trials Directive' 2001/20/EC.

The European Commission is planning to put forward, in 2012, a legislative proposal to revise the Clinical Trials Directive 2001/20/EC.

A concept paper has been put out for public consultation by the Commission. It presents:

- a 'preliminary appraisal' of which option appears to be the most suitable one to address some of the key concerns of the Clinical Trials Directive, on the basis of the current state of the impact assessment; and
- the main figures that are being used to evaluate the impacts of the different policy options.

The paper is available on: http://ec.europa.eu/health/files/clinicaltrials/concept_paper_02-2011.pdf

Stakeholders are invited to comment on this consultation paper by 13 May 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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