MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

Information memo

Agencia Española de Medicamentos y Productos Sanitarios
AEMPS

VOLUNTARY HARMONISATION PROCEDURE: PILOT STUDY TO INCLUDE THE OPINION OF THE ETHICS COMMITTEE IN THE CLINICAL TRIAL ASSESSMENT RESULT

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The AEMPS starts a pilot study to include the opinion of the Ethics Committee (EC) in the assessment conclusions of Clinical Trial Applications undergoing the Voluntary Harmonisation Procedure. The VHP guidance document has been updated.

The Voluntary Harmonisation Procedure (VHP), coordinated by the *Clinical Trials Facilitation Group* (CTFG), dependent on the EU Heads of Medicines Agencies (HMA) network allows for simultaneous assessment of the same clinical trial by the national competent authorities in all participating Member States. This procedure provides the Sponsor with a result achieved by consensus, simultaneous and integrated in the trial assessment by all national agencies. A revised guidance document regarding this procedure has just been published and it is available on the "Clinical Trials Authorisations (CTAs)" section of the CTFG website http://www.hma.eu/ctfg.html.

Taking into account the future changes derived from the new legislation on clinical trials, currently under discussion, the Spanish Medicines and Medical Devices Agency (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS) has considered necessary to gain experience on what could be the future authorisation process of a clinical trial, in which the opinion of the Ethics Committee (EC) should be included on the assessment report of the so called part I that this Agency sends the Sponsor.

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The aims of this pilot test are:

1. To assess the feasibility of adding the EC assessment to that of the AEMPS regarding the Protocol and Investigator's Brochure within the specified timelines for the VHP.

2. To evaluate the impact in terms of effort/cost by the AEMPS and the EC, as well as the benefit regarding the speeding-up of the processes.

3. To analyse to what extent repetitive assessments can be avoided and advancement towards a complimentary evaluation by the EC and AEMPS can be made.

Clinical trial Sponsors that have opted for the VHP are requested to indicate in the cover letter of the VHP application which the EC will be the one to provide the single opinion in Spain. In addition, it is recommended that the application containing the same document versions is simultaneously sent to the VHP coordinator and to the EC.

The participation of the EC in this pilot test will be voluntary. To this end, the AEMPS will ask the EC agreement to participate and will send the Protocol and Investigator's Brochure if the formal application has not yet been received by the EC.

For the purposes of this pilot test, the AEMPS informs that the EC's opinion for the VHP is not the final single EC's opinion regarding the trial.

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