MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

Information note

Agencia Española de Medicamentos y Productos Sanitarios
AEMPS

1000TH APPLICATION FOR CLINICAL TRIAL AUTHORISATION IS REACHED IN THE VOLUNTARY HARMONISATION PROCEDURE (VHP)

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The Spanish Agency of Medicinal Products and Medical Devices informs about the submission of the application for clinical trial authorisation Nº. 1000 via Voluntary Harmonisation Procedure. AEMPS encourages sponsors to continue using this procedure that facilitates clinical trial authorization until the new clinical trial Regulation's effective application date, foreseen for October 2018.

The reception in the EU of the 1000th VHP[1] application for authorisation of a clinical trial highlights the great value of this procedure to reach a common position out of the coordinated assessment in all concerned Member States (MS) as it is foreseen in the Regulation (EU) No. 536/2014[2]. Spain has participated as a concerned Member State in 65% of the clinical trials submitted for VHP assessment since 2009.

It is foreseen that the Regulation (UE) Nº 536/2014 will be fully applicable in October 2018; all applications for authorisation of a clinical trial involving two or more Member States in the European Union will from that moment follow a coordinated assessment. The VHP procedure has served as proof of concept of this coordinated assessment and the Spanish Agency of Medicines and Medical Devices (AEMPS) encourages sponsors to use this procedure until new Regulation's application date.

It is important to highlight that this procedure, which initially focused on allowing the sponsor to quickly know the result of the common assessment on part I only by the competent Authorities in all concerned MS, permits Member States to involve Ethics Committees in the clinical trial assessment on a voluntarily basis since June 2016. This process is named as 'VHP

1 http://www.hma.eu/whatsnew.html#c5518
2 Regulation (UE) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

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plus' procedure and information on what Member States are currently participating may be consulted in the VHP guidance[3].

The AEMPS strongly recommends that sponsors involve the Ethics Committee (CEIm) in all VHP applications by indicating the name of the assessor CEIm to participate in the VHP assessment in the cover letter submitted with the application. In this case, the Spanish opinion on the VHP will be binding for both AEMPS and CEIm. However, after VHP ends, a national application for authorisation of a clinical trial or a part I and part II substantial modification needs to include the part II favorable opinion by the CEIm. Therefore, in order to be able to get the CT or substantial modification authorisation 10 days after a valid application is received by AEMPS, it is necessary to present the application for the Ethics Committee opinion on part II on the same date VHP application is submitted.

The documentation to be submitted to the CEIm when it participates in the VHP plus is the same already submitted to the VHP (except documents referring to quality or good manufacturing practice of investigational or auxiliary medicinal products) and the corresponding to part II. In this case, the AEMPS will send any possible updates of this documentation to the CEIm as a consequence of VHP process.

When the sponsor opposes to CEIm participation in VHP, the documentation to be submitted to the CEIm would be the same though the sponsor will be responsible for providing it any possible update of this documentation as a consequence of VHP process.

[3] Available in http://www.hma.eu/ctfg.html

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