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Press Office

Start of community reviews

CHMP meeting of 25-28 April 2016

Table 1. Start of reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
Semler		Article 31 of Directive 2001/83/EC	Procedure triggered by Denmark, Germany, Netherlands, Spain and United Kingdom in relation to findings of non-compliance with good clinical practice (GCP) at the Semler bioanalytical and clinical facilities in Bangalore, India. This follows inspections by the FDA and the WHO which raised serious concerns in relation to the suitability of the quality management system at these sites and the reliability of data submitted in support of several marketing authorisations and marketing authorisation applications in EU Member States.

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