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Press Office

Start of union reviews

CHMP meeting of 17-20 July 2023

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

Name	INN	Type of procedure	Scope
Synapse	various	Article 31 of Directive 2001/83/EC	Procedure triggered by Spain in relation to findings of non-compliance with good clinical practice (GCP) at Synapse Labs in Pvt. Ltd., a contract research organisation (CRO) located in Kharadi, Pune, India. This follows an EU inspection, which raised serious concerns related to the suitability of the quality management system and the overall reliability of data generated at Synapse and submitted in support of marketing authorisations and marketing authorisation applications in EU Member States.

