EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2022
EMA/33473/2022
Press Office

Start of union reviews

CHMP meeting of 24-27 January 2022

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

Name	INN	Type of procedure	Scope
Synchron	various	Article 31 of Directive 2001/83/EC	Procedure triggered by Belgium, Denmark, Finland, The Netherlands and Sweden in relation to findings of non-compliance with good clinical practice (GCP) at Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, Gujarat, India. This follows inspections and analyses by the FDA, as well as previous EU inspections, which together raise serious concerns related to the suitability of the quality management system and the overall

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Name	INN	Type of procedure	Scope
			reliability of data generated at Synchron and submitted in support of marketing authorisations and marketing authorisation applications in EU Member States.

Table 2. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Daruph and Anafezyn	dasatinib (anhydrous)	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Daruph and Anafezyn. The procedure was initiated because of disagreements regarding the benefit-risk balance.