28 January 2022
EMA/38808/2022

Start of a review concerning the conduct of studies at Synchron Research Services, India

EMA has started a review of medicines for which studies have been conducted by Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, India.

This follows a Good Clinical Practice (GCP) inspection and analyses of study data carried out by the United States Food and Drug Administration (FDA), which in September 2021 led the FDA to reject all studies conducted at the CRO. Taken together with irregularities identified during previous EU inspections of the CRO, these findings have raised serious concerns about the validity of study data generated at Synchron Research Services.

Having considered the findings, national medicines regulatory authorities in several countries (Belgium, Denmark, Finland, the Netherlands and Sweden) requested EMA's human medicines committee (CHMP) to assess their impact on the benefits and risks of medicinal products which were authorised on the basis of studies performed at Synchron Research Services sites. EMA has also been requested to look at the impact on medicines currently being evaluated for authorisation which use study data generated at the CRO.

EMA will now review the available data to determine if any action is necessary to protect public health.

More about the medicines

The review covers medicines authorised or currently being evaluated via national or mutual recognition procedures on the basis of studies conducted by Synchron Research Services, India, on behalf of marketing authorisation holders.

More about the procedure

The review has been initiated at the request of the medicines regulatory agencies of Belgium, Denmark, Finland, the Netherlands and Sweden under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

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 An agency of the European Un on