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Start of a review concerning the conduct of studies at Micro Therapeutic Research Labs, India

The European Medicines Agency (EMA) has started a review of medicines for which studies have been conducted by Micro Therapeutic Research Labs at two sites in India. This follows a good clinical practice (GCP) inspection which raised concerns about the study data used to support marketing authorisation applications of some medicines in the EU. The inspection was carried out jointly by Austrian and Dutch authorities in February 2016 in the context of the evaluation of applications for nationally authorised medicines.

Having considered the inspection findings, several national medicines regulatory agencies (Austria, Bulgaria, Croatia, Denmark, Estonia, Finland, Germany, Hungary, Iceland, Latvia, the Netherlands, Norway, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom) requested EMA to assess the impact of these findings on the benefits and risks of medicines authorised in the EU on the basis of studies performed at the Chennai and the Coimbatore sites in India. EMA has also been requested to look at the impact on medicines which are currently being evaluated for authorisation and which use study data from these sites.

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

More about the medicines covered by this review

The review covers one medicinal product authorised centrally through EMA (Tadalafil Mylan), as well as medicines authorised by national procedures in individual EU Member States, whose marketing authorisation applications included data from studies conducted by Micro Therapeutic Research Labs at two sites in India:

- Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6, Kamarajar Salai, Selaiyur, East Tambaram, Chennai-600 059, Tamil Nadu.
- Micro Therapeutic Research Labs, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641 029, Tamil Nadu.

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The review also includes ongoing marketing authorisation applications for medicines which use study data from these sites.

More about the procedure

The request for review has been initiated by several medicines regulatory agencies – Austria, Bulgaria, Croatia, Denmark, Estonia, Finland, Germany, Hungary, Iceland, Latvia, the Netherlands, Norway, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom – 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 all questions concerning medicines for human use, which will adopt an 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.