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EMA recommends suspension of medicines due to unreliable studies from Micro Therapeutic Research Labs

Medicines where suitable alternative data are available can remain on market

On 23 March 2017, the European Medicines Agency (EMA) recommended suspending a number of nationally approved medicines for which bioequivalence studies were conducted by Micro Therapeutic Research Labs at two sites in India. Bioequivalence studies are usually the basis for approval of generic medicines. The list of medicines recommended for suspension can be found here. The suspensions can be lifted once alternative data establishing bioequivalence are provided.

Alternative supporting data had already been provided for several of the medicines reviewed. Therefore, the Agency recommended that these medicines could remain on the market. The list of medicines recommended to remain on the market is available here.

The Agency also recommended that medicines not yet authorised but which were being evaluated on the basis of bioequivalence studies from these sites should not be authorised until bioequivalence is demonstrated using alternative data.

Micro Therapeutic Research Labs is a contract research organisation (CRO) which conducts the analytical and clinical parts of bioequivalence studies, some of which are used to support marketing authorisation applications of medicines in the EU.

The review of medicines studied by Micro Therapeutic Research Labs was started after inspections to check compliance with good clinical practice (GCP) by Austrian and Dutch authorities in February 2016. The inspections identified several concerns at the company's sites regarding misrepresentation of study data and deficiencies in documentation and data handling.

The review, by EMA's Committee for Medicinal Products for Human Use (CHMP), concluded that data from studies conducted at the sites between June 2012 and June 2016 are unreliable and cannot be accepted as a basis for marketing authorisation in the EU. However, there is no evidence of harm or lack of effectiveness of medicines authorised and being evaluated in the EU on the basis of studies at the sites.

Some of the medicines which have been recommended for suspension may be of critical importance (e.g. due to lack of available alternatives) in certain EU Member States. Therefore national authorities can temporarily postpone the suspension in the interest of patients. Member States should also decide whether recalls of the affected medicines are needed in their territories.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The CHMP's recommendation concerning these medicines was sent to the European Commission, which issued a legally binding decision valid throughout the EU.

Information for patients and healthcare professionals

- A number of medicines for use in the EU were approved based on studies carried out at two Micro Therapeutic Research Labs sites in India. The studies are unreliable because of problems in the way data and documents were managed at the sites. As a result, several medicines approved in the EU have been suspended.
- The list of medicines recommended for suspension can be found here.
- There is currently no evidence of unexpected harm or lack of effectiveness with any medicine approved on the basis of studies conducted at Micro Therapeutic Research Labs.
- Several medicines which were approved on the basis of studies conducted at Micro Therapeutic Research Labs can remain on the market in the EU. This is because during this review, alternative data were provided for these medicines.
- The list of medicines recommended to remain on the market can be found here.
- National authorities in the EU will consider how critical individual medicines recommended for suspension are in their countries and make final decisions on whether to suspend or allow them to remain available, while new data are generated.
- Patients should continue to take their medicines as prescribed and contact their doctors in case of questions or concerns.

More about the medicines

The review covered one medicine authorised centrally through EMA (Tadalafil Mylan), as well as medicines authorised by national procedures in EU Member States (including decentralised or mutual recognition procedures), 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.

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

More about the procedure

The review was initiated on 15 December 2016 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 was carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for all questions concerning medicines for human use, which adopted its opinion. The CHMP opinion was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 23 June 2017.