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Start of a review on the conduct of studies at Semler Research Centre Private Ltd, Bangalore, India

The European Medicines Agency (EMA) has started a review of medicines for which studies have been conducted at Semler Research Centre Private Ltd, Bangalore, India. This follows an FDA inspection[1] that identified several issues at Semler's bioanalytical site, including the substitution and manipulation of subjects' clinical samples. The World Health Organization (WHO) has also raised serious concerns[2] regarding data integrity and manipulation of study samples, following its own inspections of Semler's bioanalytical and clinical sites.

Semler performs bioequivalence studies for medicines, including some medicines authorised in the United States and medicines included in the WHO prequalification programme. Bioequivalence studies usually form the basis for authorising generic medicines.

In the EU, several medicines have been authorised through national procedures on the basis of studies conducted at Semler.

The findings from FDA and WHO inspections question the reliability of all data generated at Semler, including data used to support marketing authorisation applications in the EU. Therefore, medicines agencies from Denmark, Germany, the Netherlands, Spain and the United Kingdom have requested EMA to assess the impact of these findings on the benefit-risk balance of medicines authorised in the EU. They have also requested EMA to look at the impact on medicines which are currently being evaluated for authorisation and which rely on study data from the site.

The Agency will now determine which medicines are concerned and will review available data to see whether any action is needed to protect public health. EMA will communicate further as appropriate.

[1] http://www.fda.gov/Drugs/DrugSafety/ucm495778.htm

[2] http://apps.who.int/prequal/info_applicants/NOC/2016/NOC_Semler12April2016.pdf

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More about the medicines covered by this review

The review covers medicines authorised via national procedures (including mutual-recognition and decentralised procedures) in individual EU Member States, whose marketing authorisation applications included data from Semler's bioanalytical site (Semler Research Center Private Ltd, 75A, 15th Cross, 1st Phase, JP Nagar, Bangalore 560 078, Karnataka, India) and from Semler's clinical site (PA Arcade, #21, 22, 23, Kodigehali Main Road, Sahakaranagar Post, Bangalore 560 092, Karnataka, India). It also includes ongoing marketing authorisation applications for medicines which use study data from these sites. No generic medicine authorised centrally via EMA was tested in these sites.

More about the procedure

The review has been initiated at the request of medicines agencies from Denmark, Germany, the Netherlands, Spain 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.