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Start of a review concerning the conduct of studies at the Alkem Laboratories Ltd site, Taloja, India

The European Medicines Agency (EMA) has started a review of medicines for which studies have been conducted at the Alkem Laboratories Ltd site in Taloja, India. This follows a good clinical practice (GCP) inspection of this site which raised concerns regarding study data used to support the marketing authorisation applications of some medicines in the EU. The inspection was carried out jointly by the German and Dutch authorities in March 2015 in the context of a routine evaluation of applications for nationally authorised medicines.

Having considered the inspection findings, the German medicines agency (BfArM) has requested EMA to assess the impact that these findings may have on the benefit-risk of medicines authorised in the EU on the basis of studies performed at this site. It also has requested EMA to look at the impact on medicines which are currently being evaluated for authorisation purposes and which use study data from the site.

The Agency will now determine which medicines are concerned and will review the available data to determine whether any action is necessary to protect public health.

More about the medicines covered by this review

The review covers medicines authorised via national procedures in individual EU Member States, whose marketing authorisation applications included data from studies conducted by Alkem Laboratories Ltd, Department of Bioequivalence, C-17/7, MIDC Industrial Estate, Taloja, Dist. Raigad – 410208 India. It also includes ongoing marketing authorisation applications for medicines which use study data from the site.

More about the procedure

The review has been initiated at the request of the German medicines authority (BfArM), under Article 31 of Directive 2001/83/EC.

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 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.