EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Start of a review concerning the conduct of studies at GVK Biosciences site in Hyderabad, India

The European Medicines Agency (EMA) has started a review in relation to findings of non-compliance with good clinical practice (GCP) at GVK Biosciences site in Hyderabad, India. This follows an inspection by the French medicines agency (ANSM) which raised concerns about study data used to support the marketing authorisation applications of generic medicines.

As a result of the concerns, the European Commission asked the EMA to assess the impact of the inspection findings on medicines authorised on the basis of studies performed at the site.

The EMA's Committee for Medicinal Products for Human Use (CHMP) will now review available data to determine which medicines are affected by the inspection findings and issue a recommendation on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

More about the medicines

The review will cover nationally authorised medicines whose marketing authorisation applications included clinical data from studies conducted by GVK Biosciences Private Limited, Swama Jayanthi Commercial Complex, Ammeerpet, Hyderabad 500 038, India.

More about the procedure

The review of medicines for which studies have been conducted by GVK Bio has been initiated at the request of the European Commission, under Article 31 of Directive 2001/83/EC.

The review will be carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for all questions concerning medicines for human use, which will adopt a final opinion on whether the marketing authorisation for these medicines should be maintained, varied, suspended or withdrawn across the EU. The CHMP opinion will then be forwarded to the European Commission, which will adopt a legally binding decision.

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