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GVK Biosciences: European Medicines Agency recommends suspending medicines over flawed studies

Medicines considered critically important for patients to remain available

A number of medicines for which authorisation in the European Union (EU) was primarily based on clinical studies conducted at GVK Biosciences in Hyderabad, India should be suspended, says the European Medicines Agency (EMA). The recommendation is based on findings from an inspection that raised concerns about how GVK conducted studies at the Hyderabad site on behalf of marketing authorisation holders.

Upon the request of the European Commission, EMA's Committee for Medicinal Products for Human Use (CHMP) looked at over 1,000 pharmaceutical forms and strengths of medicines studied at the GVK site. For over 300 of them, sufficient supporting data from other sources were available; these will therefore remain on the market in the EU as EMA is satisfied with the available data.

For medicines that lack data from other studies, the CHMP recommended suspension unless they are of critical importance for patients because alternatives will not be able to meet patients' needs. There is no evidence of harm or lack of effectiveness linked to the conduct of studies by GVK Biosciences.

The decision on whether a medicine is critical for patients lies with the national authorities of EU Member States depending on the situation in their country. For medicines that are considered critical, companies are given 12 months to submit additional data.

The full list of medicines for which the CHMP recommends suspension can be found here.

The inspection of GVK that led to the CHMP's recommendation was carried out by the French medicines agency (ANSM). The inspection revealed data manipulations of electrocardiograms (ECGs) during the conduct of some studies of generic medicines. These manipulations appeared to have taken place over a period of at least five years. Their systematic nature, the extended period of time during which they took place and the number of members of staff involved cast doubt on the integrity of the way trials were performed at the site generally and on the reliability of data generated at that site.

EMA and national authorities work closely with international partners to ensure that studies underpinning marketing authorisations in the EU are carried out to the highest standards and that the companies involved comply fully with all aspects of Good Clinical Practice (GCP).

The CHMP's recommendation will be sent to the European Commission for a legally binding decision. This decision will apply to all Member States irrespective of whether or not they have taken interim measures to suspend medicines.

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Information to patients and healthcare professionals

A number of medicines are being considered for suspension in EU countries following concerns about how studies may have been conducted at GVK Biosciences' site in Hyderabad, India. Patients and healthcare professionals are advised of the following:

- There is no evidence of harm or lack of effectiveness with any of the medicines linked to studies conducted by GVK.
- Some medicines, for which insufficient alternatives are available to meet patients' needs, will remain on the market in some countries as new data are being awaited.
- National authorities in the EU will consider the availability of individual medicines in their countries and make final decisions on whether to suspend or allow continued availability, while new data are awaited.
- Patients should continue to take their medicines as prescribed.

More about the medicines

The review covered nationally authorised medicines whose marketing authorisation applications included clinical data from studies conducted by GVK Biosciences at its Hyderabad site.

More about the procedure

The review was initiated at the request of the European Commission, under Article 31 of Directive 2001/83/EC in relation to findings by the French medicines agency (ANSM) of non-compliance with Good Clinical Practice (GCP) at the GVK Biosciences' site in Hyderabad, India.

The review was carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which adopted an opinion on the marketing authorisation of these medicines. The CHMP opinion will now be forwarded to the European Commission, which will adopt a legally binding decision.

The CHMP opinion allows for national authorities to take decisions on how critical individual medicines are in their countries.

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