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# GVK Biosciences: European Medicines Agency confirms recommendation to suspend medicines over flawed studies

## Medicines considered critically important for patients to remain available

On 21 May 2015, the European Medicines Agency (EMA) confirmed its recommendation to suspend 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. This is the outcome of a re-examination requested by marketing authorisation holders for seven of the medicines concerned.

EMA's Committee for Medicinal Products for Human Use (CHMP) had adopted its original recommendation in January 2015 following an inspection of GVK Biosciences' site at Hyderabad by the French medicines agency (ANSM) that raised concerns about how GVK Biosciences conducted studies at the site on behalf of marketing authorisation holders.

The inspection revealed data manipulations of electrocardiograms (ECGs) during the conduct of some studies of generic medicines, which 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 conduct of trials at the site generally and on the reliability of data generated.

During the re-examination, the CHMP concluded that concerns about reliability of the clinical studies remain and therefore maintained its recommendation of January 2015 to suspend medicines for which no supporting data from other studies were available. This is with the exception of one medicine included in the re-examination for which concerns about studies were addressed. This medicine was removed from the list of medicines recommended for suspension.[1]

As a result of the CHMP's January 2015 opinion and the re-examination, around 700 pharmaceutical forms and strengths of medicines studied at the Hyderabad site were recommended for suspension. For around 300 other pharmaceutical forms and strengths, sufficient supporting data from other sources had been provided; these medicines will therefore remain on the market in the EU.

The updated list of medicines for which the CHMP recommended suspension is available on the EMA website.

[1] Bivolet (nebivolol) 5 mg tablets (marketing authorisation holder: Neo Balkanika EOOD); the product has now been removed from the list of medicines recommended for suspension.

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The CHMP noted that there is no evidence of harm or lack of effectiveness linked to the conduct of studies by GVK Biosciences at Hyderabad. Some of these medicines may remain on the market in some countries if they are of critical importance for patients because alternatives cannot meet patients' needs.

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

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 was sent to the European Commission for a legally binding decision. The Commission has issued its decision which applies to all Member States irrespective of whether or not they have taken interim measures to suspend medicines.

**Information to patients and healthcare professionals**

A number of medicines are being considered for suspension in EU countries following concerns about how studies had 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 Biosciences.
- Some medicines considered critical for patients will remain on the market in some countries pending the submission of new data.
- National authorities in the EU will consider how critical individual medicines 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 doctor or pharmacist if they have any questions.

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**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 on 25 September 2014 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 in January 2015 an opinion on the marketing authorisation of these medicines.

Following a request from some marketing authorisation holders, the CHMP re-examined its January 2015 opinion. The CHMP's final opinion was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 16/07/2015.

National authorities will decide if some of the medicines recommended for suspension are critical in their countries.

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