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Press Office

Press release

GVK Biosciences review: some Member States suspend marketing authorisations for concerned medicines

Update on review of studies performed at GVK Biosciences site in Hyderabad, India

Some Member States have decided to suspend the marketing authorisations of medicines that have been authorised on the basis of studies conducted at the GVK Biosciences site in Hyderabad, India.

The European Medicines Agency (EMA) is currently reviewing findings of non-compliance with good clinical practice at this site and determining their impact on medicines authorised on the basis of studies performed at the site. These suspensions taken at national level are precautionary measures until the review is finalised.

EMA started the review in September 2014 following an inspection carried out by the French medicines agency at the GVK Biosciences site which raised concerns about the reliability of studies conducted at the site between 2008 and 2014.

As part of the review, the EMA's Committee for Medicinal Products for Human Use (CHMP) is identifying, together with Member States of the European Union (EU), which medicines are affected by the inspection findings. The review will provide a robust scientific assessment of all data and determine the impact of the findings on the concerned medicines, enabling Member States to take adequate EU-wide action to protect patients' health.

EMA will issue a recommendation on whether the marketing authorisations of the concerned medicines should be maintained, varied, suspended or withdrawn across the EU. The recommendation is expected in January 2015. Detailed information on the ongoing review is available on the EMA website.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. EU legislation gives Member States the possibility to take precautionary or temporary measures while reviews are ongoing at the EU or national level.

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3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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