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GVK Bio under the European regulatory scanner

03 October 2014 | News | By BioSpectrum Bureau

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The European Medicines Agency (EMA) has started a review in connection with findings of alleged non-compliance with good clinical practices (GCP) at a facility owned by GVK Biosciences, said reports.

The regulatory body's action comes after French medicines agency (ANSM) raised concerns over study data used by GVK Bio to support the marketing authorization applications of generic medicines.

"The review will cover nationally authorized medicines whose marketing authorization applications included clinical data from studies conducted by GVK Biosciences. 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," said the European drug regulator in a statement.

The company said that it has submitted necessary clarifications to the French authorities. "We are in the resolution stage and hope to close the matter to their satisfaction at the earliest. We are expecting the closure (of the matter) by October 26," said a company official.