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GVK Bio under European drug regulator scanner

HYDERABAD: The European Medicines Agency (EMA) has started a review in connection with the findings of alleged non-compliance with good clinical practice (GCP) at a facility owned by GVK Biosciences. The European body's action follows an inspection by the French medicines agency, ANSM, which raised concerns over study data used by GVK Bio to support the marketing authorisation applications of generic medicines.

"The review will cover nationally authorised medicines whose marketing authorisation applications included clinical data from studies conducted by GVK Biosciences Pvt Ltd, Hyderabad. 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," a European drug regulator statement said.

When contacted GVK, a company official said that from May 19 to 23, a regulatory inspector from ANSM inspected their Hyderabad Clinical facility and the company had submitted necessary clarifications to the French authorities. "Further, we were invited by the European authorities, GVK BIO met the European authorities in-person last week, presented the data and demonstrated how we have optimised our processes internally. We are in the resolution stage and hope to close the matter to their satisfaction at the earliest, the official said." — PTI

Company