

EU to discuss ban on drugs tested by GVK Bio

January meet will examine India's stand that there was no data manipulation

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The European Union (EU) has agreed to meet Indian officials to sort out concerns related to the ban on 700 drugs tested by GVK Biosciences earlier this year and reach an understanding for the future.

"The meeting with officials from the EU's health and food safety department will take place in January. The EU had sent us an agenda and background paper for the meeting and we have already sent our comments on it, pointing out where we do not agree. This will be discussed in detail at the meeting," an official told *Businessline*.

While there is not much

chance of the ban on the drugs getting revoked soon, the January meeting will serve to set things straight for the future and ensure that bans are not enforced on the same grounds again, the official added.

In July, the EU had banned 700 generics (copied versions of off-patent drugs) tested by GVK following charges of manipulation of clinical trials for bio-equivalence testing (a test to prove that the generic drugs are as effective as the originals) made by French standard's agency ANSM.

In protest, India, which was ready to restart bilateral free trade talks with the EU in July, had called off the meeting.

However, last month, India de-

clared to relax its position and hold an initial stock-taking meeting with the EU on the free trade agreement, formally known as the Broad-based Trade & Investment Agreement (BTIA).

in January. "There is no formal connection between the relaunch of the India-EU BTIA and the meeting on GVK, but these are happening simultaneously. The EU has realised that if it wants healthy trade relations with us, it has to heed to our concerns," the official said.

French concerns

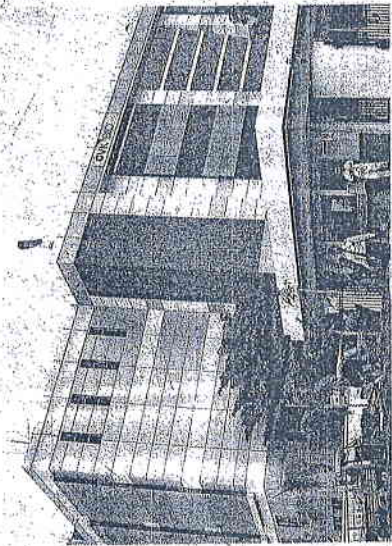
The ANSM had alleged that the electrocardiogram (ECG) data of volunteers examined between 2008 and 2014 by GVK was manipulated, and, hence, the tests were not reliable. The drugs tested by GVK during the period were withdrawn from all EU markets in August despite no evidence or complaints regarding the quality or efficacy of the medicines.

Interestingly, even the US Food and Drug Administration, which

insists on high standards, found no problem with the processes followed by GVK and has not taken any action against the drugs in its markets, the official pointed out.

"We are very clear in our assessment that there was nothing wrong with the ECGs and we have enough proof to back that. Some of our arguments and related documents have already been submitted to the EU. We hope to convince them when we meet," the official said.

In October, the Commerce Ministry had set up a six-member panel of experts from various departments, including drug regulators and cardiologists, to look into allegations made by ANSM. The panel confirmed GVK's assertion that there were no irregularities in the data, the official said.



The GVK Biosciences headquarters in Hyderabad. The EU had banned 700 generics tested by the company in July.

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