

GVK's trials doctored, stop drugs' sale: European body

TIMES NEWS NETWORK

The European Medicines Agency (EMA) has recommended suspension of the sale of hundreds of medicines for which authorization was given on the basis of clinical studies conducted at GVK Biosciences in Hyderabad.

The decision was taken following inspection carried out by the French medicines agency (ANSM), which revealed data manipulations of electrocardiograms (ECGs) during the conduct of some studies of generic medicines.

"These manipulations 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

UNDER SCANNER

➤ French drug agency ANSM inspects GVK health devices, revealing data manipulation of ECGs

➤ European Medicines Agency (EMA) says data cast doubt on integrity of trials performed

➤ Over 1,000 medicines tested at GVK Biosciences in Hyderabad

cast doubt on the integrity of the way trials were performed at the site generally and on the reliability of data generated at that site," said a statement issued by EMA on Thursday.

EMA's Committee for Medicinal Products for Human Use (CHMP) looked at over 1,000 pharmaceutical forms and strengths of medicines studied at the GVK site.

For over 300 of them, sufficient supporting data from other sources were available; these will therefore remain on the market in the EU as EMA is satisfied with the available data.

The EMA statement said that the agency and the national authorities worked closely with international partners to ensure that studies underpinning marketing authorisations in the EU were carried out to the highest standards and that the companies involved comply fully with all aspects of Good Clinical Practice (GCP).

The EMA also stated that national authorities in the EU would consider the availability of individual medicines in their countries and make final decisions on whether to suspend or allow continued availability, while awaiting new data.

Clinical trials.