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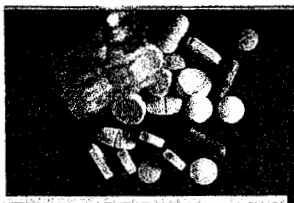
80 GVK-tested drugs face ban

Berlin, Dec. 10: Germany's drug regulator has banned the sale of 80 generic medicines with immediate effect on the grounds that their clinical trials conducted by India's pharmaceutical research company GVK Biosciences were "insufficient".

The Federal Institute for Drugs and Medical Devices said on Tuesday it had ordered drug manufacturers, wholesale dealers, medical stores and other outlets not to sell or use these medicines any longer. It also suspended the marketing authorisation given to the drugs concerned based on the data of clinical trials, supplied by the Hyderabad based contract research company.

The regulator said it had informed the drugs manufacturers about its decision on Monday and the ban on the sales of medicines came into effect on Tuesday.



BAN ON DRUGS

- EU's drug regulator believes that GVK Bio has been systematically manipulating its studies.
- Among the medicines affected are those for treating high BP, depression, migraine, epilepsy.

GERMANY'S DRUG REGULATOR HAS BANNED THE SALE OF 80 GENERIC MEDICINES ON THE GROUNDS THAT THEIR CLINICAL TRIALS CONDUCTED BY GVK BIO WERE "INSUFFICIENT".

Among the medicines affected by the ban are those for treating high blood pressure, depression, migraine, epilepsy and Parkinson's disease and they involved the products of 16 pharmaceutical companies. Patients still using these medicines have been advised to consult their doctors. In a press statement, the regulator said it did not expect its ban to cause any shortage of supplies as similar generic versions of these medicines by other manufacturers as well as their original branded versions are available in the market.

The regulator investigated the marketing authorisation of 176 medicines by 28 pharmaceutical companies after an inspection of GVK Biosciences' facility in Hyderabad revealed "substantial deficiencies" in carrying out the clinical trials of the generic medicines and in the validity of its data to support marketing authorisation applications, the statement said.

Meanwhile, refuting the media reports GVK Bio's CEO said, "The regulatory authorities have themselves stated that "this decision is taken out of precaution. No element at this stage has led to establish a true risk for human health or a lack of efficacy of these drugs".

We believe that the conclusions of the ANSM and the subsequent actions by the EMA are highly disproportionate to the actual risk posed to human health. At the same time, we respect and honor the conclusion made by the regulators and are working to provide new data. — *PTI*

Regulatory