

EMA Recommends Suspension of 700 Generic Medicines



A committee of the European Medicines Agency (EMA) has made recommendations that the sale of four dozen generic drugs should be suspended. These include generic medicines for diabetes, depression and hypertension. The recommendations have been made on the grounds that the approval of these drugs was based on flawed clinical studies that had been conducted by GVK Biosciences, a contract research organisation in Hyderabad, India.

Some familiar generic drugs included in this list are candesartan, donepezil, escitalopram, esomeprazole, and metformin. Many of these drugs are marketed individually in multiple European Union nations and are sold in various dosages as well. Among the many manufactures involved in this scrutiny include Abbott Laboratories, Actavis, Dr. Reddy's Laboratories, Mylan Pharmaceuticals, Sandoz and Takeda Pharmaceuticals.

The EMA's recommendation for suspension of these drugs will apply throughout the European Union. Some countries including France, Germany, Belgium and Luxembourg have already initiated measures to stop the sale of 25 of these drugs.

An inspection of GVK Biosciences revealed that over the course of at least five years, electrocardiogram data had been manipulated during the conducting of some studies of generic medicines. This systematic and prolonged manipulation casts doubt on the integrity of the trial methodology as well as the reliability of the data that had been generated.

GVK Biosciences has called the EMA recommendation "unprecedented and highly disproportional" and is working toward ensuring an appropriate and quick resolution of these issues.

The FDA has not taken any action against these allegations. In a statement, the FDA has said that the agency had inspected GVK Biosciences in September 2014 and had found no evidence that affects the safety or efficacy of drug products that had pending applications or those that had already been approved in the US. However, the FDA has promised to take swift action if it is able to identify any issues concerning GVK Biosciences that relate to products that have been approved by the agency.

The EMA investigation included 1000 individual generics in various forms and strengths as individually approved in 29 European Union nations. The EMA found that only 300 of these generics had supporting clinical data that warranted their sale in the market but 700 generics should be suspended. The EMA however specifies that individual countries can make an exception for drugs that are clinically important and do not have any alternatives.

The recommendations will go the European Commission for a legally binding decision.

Source: [European Medicines Agency \(EMA\)](#)

Image Credit: European Medicines Agency

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