DAWN

Drap asks nine firms to recall 'contaminated medicines' used to treat high blood pressure

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ISLAMABAD: The Drug Regulatory Authority of Pakistan (Drap) has directed nine pharmaceutical companies to recall medicines of high blood pressure, manufactured by them, as contaminated raw material used in these medicines can cause cancer.

The directive has been issued after getting an alert from the European Medicating Agency (EMA) which pointed out that the raw material was contaminated.

"Though the directive has been issued and pharmaceutical companies have started recalling the medicine, the incident has exposed the flaws in Drap as in Pakistan 95 per cent medicines are made with imported raw material but there is no mechanism to check the quality of raw material. Companies get licences, for imports, by paying a few hundred rupees and start importing raw material. We should be thankful to the United Kingdom because we have learnt about the issue only because of that country," an official of Drap, who requested anonymity, told Dawn.

Regulatory authority says raw material used in these drugs can cause cancer

However, Drap spokesperson Sajid Shah said that the prompt action to recall the medicine was proof of the authority's performance. He claimed that Drap was taking all possible steps to safeguard people's health.

According to a recall letter issued by Drap and available with Dawn, it has been informed that EMA has detected an impurity — N-Nitrosodimethylamine (NDMA) — in the valsartan active ingredient which the company supplied to manufacturers in some areas of the European Union (EU) and in Pakistan.

The letter claims that NDMA is classified as a probable carcinogenic (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is sought to be related to changes in the way the active substance was manufactured.

National authorities across the EU are recalling the medicines containing valsartan supplied by Zheijiang Huahai. Valsartan medicines are used to treat patients with high blood pressure in order to reduce complications such as heart attack and stroke.

Companies have been directed to recall the finished drug containing the valsartan manufactured by Zheijiang Huahai Pharmaceuticals, China. Moreover drug inspectors have also been directed to ensure recall of the drug and "not to dispose of" the same on prescribed form in the public interest till final decision by the competent authority.

According to the Drap letter, companies which imported raw material from the Chinese company are M/s Amarant Pharmaceuticals (Pvt) Ltd, M/s Efroze Chemical Industries, M/s High-Q Pharmaceuticals, M/s Pharm Evo (Pvt) Ltd, M/s Safe Pharmaceuticals (Pvt) Ltd, M/s Sami Pharmaceuticals (Pvt) Ltd, M/s Tabros Pharma (Pvt) Ltd, M/s Searle Pharmaceuticals and M/s Genetics Pharmaceuticals.

The drug inspectors and health departments have been informed that the recall shall also be implemented on all medicines containing valsartan manufactured by the Chinese company whether locally manufactured or imported ones, claims the letter.

Moreover, through the letter, healthcare professionals have been requested to take necessary measures in the treatment of patients using valsartan products to protect patients from the complications of NDMA.

According to the Drap official, it does not mean that the other products of companies are also unsafe. He suggested that patients should use other medicines of the said companies without any fear.

“In developed countries special focus is given on checking the quality of raw material, but in Pakistan there is no arrangement to check the quality of raw material. Drap mostly focuses on the quality of finished product. After the incident of Punjab Institute of Cardiology (PIC), then chief justice of Pakistan Tassaduq Hussain Jillani directed that Adverse Drug Reaction (ADR) reporting — which is done to analyse effects of medicines — be started, but the directive could not take practical shape,” he said.

It is pertinent to mention that in 2012 more than 200 patients died after they took contaminated medicine from PIC pharmacy.

The official suggested that the government appoint a permanent chief executive officer of Drap because only a full-time head can take steps to address such issues.

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