

Not only Combiflam, more drugs under scanner

Himani Chandna

✉ letters@hindustantimes.com

NEW DELHI: A day after French major Sanofi announced a recall of some batches of its popular painkiller Combiflam, India's drug regulator said over 102 medicines have been highlighted for quality concerns and withdrawal in the past five months. The list includes several popular painkillers.

The Drug Controller General of India (DCGI), the country's apex drug-regulation body, every month prepares a list of medicines that have some quality issues.

In the past five months, about 102 medicines have failed the tests and are under the category of spurious, substandard, adulterated, or misbranded medicines.

Some of the medicines that appear on the monthly alert list issued by the government include Cipla's CIP-ZOX, Macleods Pharmaceutical's Orcerin, Indian Drugs and Pharmaceuticals Ltd's

ON ALERT LIST

- ✉ In the past five months, about 102 medicines have failed the tests and are under the category of spurious, substandard, adulterated, or misbranded medicines
- ✉ The Drug Controller General of India (DCGI) prepares a list of medicines every month that have some quality issues
- ✉ Some medicines that appear

on the monthly alert list issued by the government include Cipla's CIP-ZOX, Macleods Pharmaceutical's Orcerin, Indian Drugs and Pharmaceuticals Ltd's Pantoprazole, Ipca Laboratories' Zerodol-SP and Karnataka Antibiotics & Pharmaceutical Ltd's Norfloxacin

Pantoprazole, Ipca Laboratories' Zerodol-SP and Karnataka Antibiotics & Pharmaceutical Ltd's Norfloxacin.

"All drugs listed under the alert list should be recalled with immediate effect. We have found some serious problems with the making of the drugs because of which we have highlighted quality concerns. Hence, recall is necessary for all companies," GN Singh,

DCGI, said. "All these companies do recall the problematic batches from the market, but they do it silently, simply to keep their brand image unhurt," he added.

Both Indian Drugs and Pharmaceuticals Ltd and Karnataka Antibiotics & Pharmaceutical Ltd are run by the government to produce cheap generic drugs.

Cipla's drug CIP-ZOX, which

is used to treat muscle spasm, has been highlighted due to its failure in disintegration test, similar to the failure of Combiflam, as per the drug alert list of February 2016.

Disintegration tests are used to assess the time it takes for tablets and capsules to break down inside the body and are used as a quality-assurance measure, according to the US Food and Drug Administration (FDA).

Macleods Pharmaceutical's Orcerin, which is used to treat diseases in the joints such as osteoarthritis, failed the test for "related substances" in April 2016. The test shows presence of impurities in the drug.

Ipca Laboratories' Zerodol-SP tablets, used for relief of pain and moderate fever, failed the test for 'Identification and Assay' in December 2015, which measures the clinical impact and efficacy.

The mails sent to the companies are awaiting response.

Regulatory