

DGCI orders Abbott to test Phensedyl syrup

SIDE EFFECTS Regulator calls for nationwide inspection of cough medication, says will take strict action in case of deviation

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NEW DELHI: The apex drug regulatory body, Drug Controller General of India (DCGI), has ordered testing of Abbott's cough syrup, Phensedyl, samples across the country. Several inspections at the company's manufacturing plants are likely to happen.

Following concerns of the regulators in West Bengal and Himachal Pradesh who alleged that Phensedyl contains excessive levels of a codeine, the DCGI has asked state drug controllers to check nationwide samples.

"A well-defined drill has been set in place to understand if other samples comply with the required specifications and standards," GN Singh, DCGI told *HT*. "I have been updated by the state drug controllers that samples (of Phensedyl) across India are being picked. Team of inspectors may also visit the company's manufacturing plant to check the new batches."

As per the industry estimates, Abbott's largest-selling brand, Phensedyl, accounts for about a third of the Indian cough syrup market.

"Considering the popularity of the drug, any negligence could be harmful. Hence, we will take strictest possible action in case any deviation will be found," Singh said.

Abbott did not reply to the

SORE THROAT

Phensedyl, which is Abbott's most successful brand in India, was the seventh highest selling drug in 2014

MEDICINE, COMPANY	ANNUAL SALES
① Mixtard, Novo Nordisk India	450
② Augmentin, GSK Pharma	330
③ Glycomet GP, USV	314
④ Monocef, Aristo	281
⑤ Corex, Pfizer	262
⑥ Becosules, Pfizer	258
⑦ Phensedyl, Abbott	247
⑧ Lantus, Sanofi India	241
⑨ Janumet, MSD Pharma	236
⑩ Spasmo Proxyvon Plus, Wockhardt	234 (₹ Cr)

CODEINE DECODED

- Codeine is a morphine derivative that acts as an analgesic and makes the patient sleepy
- Codeine-based medicines, especially cough syrups, are

widely used as recreational drugs due to their availability

- Due to this Bihar had imposed a restriction on sale of Phensedyl in 2013

Source: AIOCD-Awacs

mail sent by *HT* till the time of going to press.

In March, the drug regulator in Himachal Pradesh, where the syrup is manufactured, sent a "show-cause" notice to the company. The suspect sample, which contained a higher level of codeine in the syrup, was picked up and tested in West Bengal.

"The authenticity of the

sample tested has not been established. And if the government comes across any such incidents, the companies would definitely like to work with the government," said DG Shah, secretary general of the industry body Indian Pharmaceutical Alliance.

Abbott India is a unit of the US-based Abbott Laboratories.

Regulatory