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Novartis May Be Fined for 'Fake' Doc

Drug Controller General of India cancels import licence and registration of the drug used for respiratory problems in animals

Bitter Medicine

SWISS PHARMA co Novartis may face penalties in India for submitting 'fake' papers to the DCGI for a veterinary medicine

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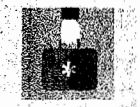

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The annual global sales of Novartis, out of which its Indian arm earns 900 crore yearly

SOMA DAS
NEW DELHI

Swiss drug innovator firm Novartis may face penalties in India for submitting 'fake' document to the Drug Controller General of India (DCGI) for a veterinary medicine. The Indian arm of Novartis has admitted before the DCGI that it had submitted a document that was later found to be 'fake' with regard to its site of manufacturing for Tiamulin Hydrogen Fumarate (80% granule).

Top officials of Novartis India, who appeared during a hearing in the drug regulator's office last week, have 'tendered an unconditional apology for the commission of the act', according to an order passed by the DCGI and reviewed by ET.

The drug regulator has cancelled the import licence and registration for the drug used for respiratory problems in animals and ordered its immediate recall from the market, said the order.

The matter of furnishing a fake certificate to get registration of a drug has been forwarded by the watchdog to the health ministry for further 'legal action'.

A Novartis spokesperson told ET that its application for the re-registration of the drug has been rejected by the DCGI. "While we will reapply for the registration, Novartis had already stopped further marketing and distribution of the product," she said, adding that the company has a "strong code of conduct with zero tolerance for deviations".

The drug regulator has also identified another 26 of Novartis' imported products, documents of which are being assessed for their authenticity at present. The DCGI may follow up the investigation with inspection at some of the company's European manufacturing sites, according to another order of the drug regulator reviewed by ET.

Novartis has annual sales of $58 billion globally while its Indian arm, a listed entity, earns ₹900 crore yearly

The development comes at a time when manufacturing facilities of many Indian pharma companies have also been hauled up by the US drug regulator for 'data integrity' violations that has resulted in import ban on a number of plants. Novartis has annual sales of $58 billion globally while its Indian arm, a listed entity, earns ₹900 crore yearly.

The Indian drug regulator became suspicious of the document that claimed the drug was manufactured in one of its Austrian facility at Tyrol after it spotted another application of the company displaying an identical certificate number, but citing a different manufacturing site at Trento, Italy.

Subsequently on the drug regulator's request, director, European Directorate of Quality Medicine, Council of Europe, confirmed its suspicion and said that the certificate of Novartis claiming that the drug was manufactured at its Austrian site was 'fake'.

A DCGI team of four officials headed by deputy drug controller K Bangarurajan conducted an inspection at Novartis India's office in Mumbai for four days towards the end of January to get to the bottom of the matter.

"When the company officials were questioned by the officials during inspection to detail the trail of the 'fake' certificate, they claimed that the documents were sent from Novartis' headquarters in Basel, Switzerland. They, however, claimed that the documents were lost in transit, after which the India office received a scanned copy through email," an official said.

However, he added, when the company executives were asked to furnish a copy of the emailed version, they further claimed that such a mail was not retrievable since their system automatically deletes emails after 60 days.

Interestingly, towards the end of the inspection, Novartis executives communicated to the DCGI's team of having received a mail in this regard from its Switzerland office, stating that even the headquarter has 'misplaced' the document which is being requested for by the Indian regulator.

Regulatory