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DCGI Questions Novartis Over Origin of Veterinary Medicine

Regulator asks pharma major to explain 'violations' in papers on drug manufacture

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India's drug regulator has asked Novartis to explain "violations" in papers relating to the manufacturing origin of a veterinary drug, with a European agency having ruled that the document the Swiss company submitted was fake. This has prompted the watchdog to begin a wider inquiry into the records submitted by the company to assess whether any of the other documents it has filed with the Indian regulator's office are "fraudulent" in nature.

The January 28 show-cause notice issued to the Swiss company by the Drug Controller General of India (DCGI) came after the European Directorate of Quality Medicine (EQDM) confirmed that the document showing the drug as having been manufactured at its Tyrol, Austria, facility was spurious. DCGI has suspended sales of tiamulin hydrogen fumarate (80% granule), used in poultry. It has sought an explanation for the "violation" in 10 days, apart from asking for detailed documentation for all imported products.

The drug regulator has identified another 26 products imported by Novartis and is checking their papers for authenticity. Any falsification of origin is "a grave violation", a DCGI official office told ET. "We would have to check and ensure that its documents on all other imported products are in order and real," Novartis has annual sales of $58 billion globally while its Indian arm, a listed entity, posted annual revenue of a little more than ₹900 crore in FY13. The Indian drug regulator's suspicions were aroused after coming across another application of the company displaying an identical certificate number, but citing a different manufacturing site at Trento, Italy.

"Subsequently, on our request, director, EQDM, Council of Europe, confirmed our suspicion and informed us that the certificate of Novartis claiming that the drug was manufactured at its Austria site is fake," said the official.

The Indian arm of the Swiss company confirmed that it had received a show-cause notice from DCGI alleging that one of the documents submitted along with an application for renewal of registration was not genuine.

"Novartis has a strong code of conduct with zero tolerance for deviations. Novartis has responded to the notice and shall extend full cooperation to the authorities," a company spokesperson said, without divulging the contents of its response. "The product is an anti-mycoplasma respiratory animal drug used for respiratory disease in the poultry industry. We do not as a policy disclose individual product sales," she added.

As part of its inquiries, a DCGI team of four officials headed by deputy drug controller K Bangarurajan conducted an inspection at Novatis India's Mumbai office for four days toward the end of January. "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, when company executives were asked for a copy of the emailed version, they said it wasn't retrievable as the system automatically deletes emails after 60 days.

Regulatory