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Indian drug regulator plugs quality gaps after drawing flak from USFDA

Organises workshops for its inspectors

OUR BUREAU
New Delhi, August 16

The Indian drug regulator, the Central Drugs Standard Control Organisation, is busy reforming itself and plugging all quality gaps by organising skills development programs for its officers and inspectors to make them more attuned to international standards.

The Indian drug regulator has been in the spotlight over the issue of quality concerns faced by the domestic manufacturers. Recently, instances of the US Food and Drugs Administration (FDA) taking action against Indian drug makers have become prominent.

While the US regulator called into question the quality of medicines being manufactured for the purpose of exports, many in the Government believe these sanctions are pressure tactics to get India in line with the US' patent regime. However, on its side the Indian drug regulator is clear that it would "strengthen its systems."

According to the official, the regulator has started inducting new inspectors to add to its highly constrained workforce besides conducting workshops for the existing employees on quality concerns and inspection modules. Further, the official added, the Drugs and Cosmetics (Amendment) Bill will also add more teeth.

Priority country

Earlier this year, several US advocacy groups had recommended that the United States Trade Representative designate India as a "priority foreign country." This had come close on the heels of several sanctions imposed by the USFDA on Indian drug makers.

Another Health Ministry official said that India would, in fact, maintain its position on compulsory licencing of drugs and IPR, adding that the US is trying to protect the interests of its own manufacturers threatened by India's cheap generics market.

"We need to ensure we can provide quality at the right price to our consumers," the official said. The official added that India is not violating or manipulating any national laws or international agreements in the pharmaceutical space. Recently, the Department of Industrial Policy & Promotion (DIPP) has denied compulsory license for cancer drug Dasatinib seeking more information on the urgency for making this drug available to the Indian citizen at cheap prices.

The Health Ministry had tried to get compulsory licence for the same medicine twice earlier too.

The issue of compulsory licencing has also been seen as a deterrent for innovative environment in pharma sector by the US even though it is allowed both under Indian law and Trade Related Intellectual Property Rights.

The US itself has invoked this in several cases.

Regulatory