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India Wants USFDA Chief to Treat Clinical Volunteers on a Par With US Counterparts

UFDA chief Margaret Hamburg

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NEW DELHI

India's drug regulator may urge the chief of US Food and Drug Administration, Margaret Hamburg, on her visit to the country next week to ensure that the drugmakers from the United States conducting clinical trials here treat the volunteers on a par with their counterparts back home.

"US and other global drugmakers who conduct clinical trials at different locations across the globe need to be made responsible in their home country for their objectionable conduct in clinical trials elsewhere," an official told ET, adding that the Drug Controller General of India, GN Singh, was likely to raise the issue with Hamburg on Monday.

"While conducting trials, drugmakers cannot discriminate on the basis of nationality, because patient safety is top priority for every regulator — US or India" he added.

There is already a law in place in the US that makes companies accountable at home if they are found to be indulging in corruption overseas.

Hamburg is set to arrive in India on a week-long visit that comes at a time when several top Indian drugmakers have been hauled up for quality issues by the US drug regulator. Besides her Indian counterpart, she is likely to meet the ministers of health and commerce, and top bureaucrats in the two ministries. There is, however, no official confirmation of the details of Hamburg's visit.

A US FDA spokesperson did not respond to an ET query sent last week seeking confirmation of Hamburg's visit.

India's drug regulator may also try to understand from Hamburg the gaps in the good manufacturing practices prescribed in the two countries and subsequently explore the possibility of upgradation of mandated quality standards while keeping in mind the dynamics of the Indian context.

"There are three parameters to judge the drugs in the Indian context — quality, safety and affordability. India cannot compromise by reducing access to drugs while thinking of bridging this gap," said the official, requesting anonymity.