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USFDA to fast-track approvals

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The US Food and Drug Administration (USFDA) is in the process of reorganising its structure and speeding up the process of approvals. This would help clear the backlog of inspections for Indian drug manufacturers who have applied for approvals from the regulator to export their products to the US, said USFDA commissioner, Margaret Hamburg.

The USFDA also plans to conduct workshops across India in the next one year in order to sanitise Indian drug companies about the changing quality requirements in the American market.

Ms Hamburg, who is on a visit to India, said that the FDA office in India has a mandate to conduct inspections of pharmaceutical manufacturing premises and was working towards bringing awareness about US regulatory requirements and standards amongst industry through capacity building workshops.

Strong and smart regulation in a clear, predictable and transparent ecosystem creates a level playing field for all players in the market, she said. She said that safety, efficacy and quality of the product are the three pillars of the regulatory framework and USA and India need to work in collaboration for getting affordable drugs made available to the patients not just from both the countries but also meet the global requirement.

She noted that India provides generic medicines to almost 200 countries and is the second largest exporter of generic medicines to the US.

She said USFDA was looking forward to enhancing ties with its India counterpart.

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