FDA India: A single regulator on the cards?

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The FDA Centre for Drug Evaluation and Research in Washington D.C., United States. Niti Aayog has proposed an Indian FDA to oversee food, medicine, and medical devices.

A single regulator for food, medical devices, and medicines is on the cards in India, as the government think tank Niti Aayog has proposed a body analogous to the Food and Drugs Administration (FDA) in the United States.

At present, food safety is overseen by the Food Safety and Standards Authority of India (FSSAI) and medicines by the Central Drugs Standards and Control Organisation (CDSCO). Assimilating these into a single body would serve to "restructure the regulators" according to an official quoted by *The Times of India (ToI)*, an objective they described as "important". Furthermore, the official said that Niti Aayog's proposal "has found favour with the PMO [Prime Minister's Office] and is likely to be implemented soon."

Central regulation of medical devices is already underway, with a Union Health Ministry gazette notification bringing all devices within the radar of the central government due to come into effect as of December 1st. The idea of having a central regulator to cover these sectors follows in the footsteps of this policy, which included provisions of "medical devices including software, equipment, accessories and contraceptives will be regulated under the Drugs and Cosmetics Act. Consequently, firms will have to seek approval from the Drugs Controller General of India to manufacture, import and sell any medical device in the country."

The Niti Aayog proposal would see a separate regulatory body for medical devices as, according to the official, "it is unfair to regulate medical devices as medicines." These would all be under the umbrella of a central FDA-style organisation.

"Much of these are pharmaceutical products or products concerning the health of people, they are different in their making, design, technology, usage as well as marketing and distribution," the official said. "It is important to have somebody overseeing them from a health perspective." At present, both the CDSCO and FSSAI report to a joint secretary within the Union Health Ministry.

The *ToI* reports that the proposal of an Indian FDA has been welcomed by the industry, quoting one medical device manufacturer as saying “an overarching body like FDA India will help enhance the brand value and establish a credibility by way of uniformity. It is often difficult and sometimes even embarrassing for us in other regulated markets to seek clearances for our products because they are certified by authorities or organisations with no global recognition.”