Single-window portal for medical devices goes live

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In a move to streamline the import, clinical investigations, and testing of medical devices, the Centre has launched the National Single Window System (NSWS).

In a notice dated January 1, Rajeev Raghuvanshi, drugs controller general of India, said the NSWS has been established as a "genuine single-window system, which acts as a one-stop shop for all the approvals required by the investor and facilitates ease of doing business". *Business Standard* has a copy of the document.

The NSWS portal, distinct from the existing SUGAM and cdscomdonline portals, has been developed by Tata Consultancy Services (TCS). It facilitates applications for the certificate of registration and licences to manufacture or import medical devices for various purposes, including clinical investigations, tests, evaluations, demonstrations, and training. The existing portals will be disabled by January 15, the notice stated.

Finance Minister Nirmala Sitharaman had previously announced the creation of an investment clearance cell (ICC) during her Budget speech on February 1, 2020. The proposed ICC, now developed as the NSWS, enables investors to identify, apply, track, and obtain the necessary approvals before starting any business operations in India, eliminating the need for investors to visit multiple IT platforms and authorities, the Central Drugs Standard Control Organisation (CDSCO) notice read.

India's demand for medical devices is projected to reach $50 billion by 2030. Currently, the country produces approximately $7.6 billion worth of medical devices, exporting roughly $3.4 billion. The annual demand for medical devices in India is estimated at around $12 billion, with imports accounting for close to $7.6 billion, or over 60 per cent, of the domestic requirement.

However, the draft New Drugs, Medical Devices and Cosmetics Bill, 2023, expected to be tabled in Parliament soon, has triggered opposition from medical device makers, patient interest groups, and hospitals. They are advocating for a separate Bill for medical devices, distinct from drugs.

In a statement dated December 12 from medical device manufacturers' lobby groups, patient advocacy groups, hospital industry bodies, and others, Malini Aisola, co-convenor of the All India Drug Action Network (AIDAN), noted: "There are no clearly defined norms for conducting clinical investigations, particularly for high-risk devices that go into the body of a patient or have higher potential to cause harm, leading to some very poor study designs and insufficient or dubious data.

THE FINE PRINT

The portal aims to:
Provide an interface for approvals to start a business and give efficient, convenient, transparent, and integrated electronic services to investors

■ India's **70%** of domestic medical gear needs are met by imports

Sources: Govt websites

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