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Medical device sector delinked from pharma

Public Comments Sought On Revised Schedule

TIMES NEWS NETWORK

The government has accepted the long-standing demand of the medical devices sector to delink it from the pharmaceutical sector. The health ministry has agreed to delink schedule MIII of the Drug Rules, which deals with medical devices, from schedule M, which deals with drugs and pharmaceuticals.

The revised schedule is being put up on the website of the Central Drugs Standards Control Organisation (CDSCO) inviting comments from the public after which a notification will be issued through the law ministry for changing the Drug Rules.

Schedule MIII provides requirements of factory prem-

ises for manufacture of medical devices under the Drugs and Cosmetics Rules (DCR), 1945. However, it relates only to three medical devices, namely sterile perfusion and blood collection sets and syringes and needles. A large number of notified devices are currently being regulated under the provision of DCR, 1945.

The Drugs Technical Advisory Board (DTAB) in its August 2015 meeting recommended that Schedule MIII be incorporated under DCR 1945 and the rules amended so that it was exclusively for medical devices, while schedule M was applicable only to drugs.

"Nowhere in the world are pharmaceutical and medical device sector governed by the same set of legislations as has

been historically happening in India," said a statement of the Association of Indian Medical Device Industry (AIMED). This has had a detrimental impact on the medical devices sector, it added.

According to AIMED, imports account for about 70% of its roughly \$10 billion devices market. The lack of a regulatory framework along international lines, the industry body felt, has been a major factor as investors were discouraged by the initial move of 22 medical devices being regulated as drugs by CDSCO and state drug controllers. The government has taken the first step in the appropriate direction. But there needs to be a separate law book, separate rule book and separate regulatory authority.

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Regulatory / medical devices.