



Ministry of Health and Family Welfare

New Regulatory Regime for 8 Medical Items under Drugs and Cosmetics Act



Transition time of 6 months allowed for ensuring supply chain continuity and access while **in** implementing their regulatory order under Medical Devices Rules (2017)

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Adopting a proactive and sensitive approach to address the needs of the Indian Industry, the Union Ministry of Health & Family Welfare has taken a significant decision for ensuring continued access of eight regulated medical devices today.

The Ministry had earlier notified the following medical items to be regulated under the Drugs and Cosmetics Act which was to come into effect from 1st April, 2021 (as per S.O. 775(E) dated 08th February, 2019 under Medical Devices Rules 2017):

1. All Implantable Medical Devices;
2. CT scan equipment;
3. MRI equipment;
4. Defibrillators;
5. PET Equipment;
6. Dialysis Machine;
7. X-Ray Machine; and
8. Bone marrow cell separator.

Accordingly, as per the said order the importers/manufacturers are required to take import/manufacturing licence from Central Licencing Authority or State Licencing Authority, as the case may be, for import/manufacture of above devices, w.e.f. 1st April, 2021.

In order to ensure supply chain continuity and access to these Medical Devices, while implementing smooth transition into the new regulatory regime, Union Ministry of Health and Family Welfare has now decided that in case an existing importer/manufacture who is already importing /manufacturing any of these devices, has submitted application to Central Licencing Authority or State Licencing Authority, as the case may be, for grant of import /manufacturing licence in respect of the said device(s) under the

provisions of MDR, 2017, the said application shall be deemed valid and the importer/manufacture can continue to import /manufacture the said device(s) up to 6 months from issue of this order or till the time, the Central Licencing Authority or State Licencing Authority, as the case may be, takes a decision on the said application, whichever is earlier. Order in this regard has been issued by Drugs Controller General (India) on 18th April 2021 through CDSCO website.



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HFW/Med Equipment-Transition Time 6 months/18thApril2021/4



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