BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

MoHFW highlights guidelines regarding re-use of Medical Devices

13 February 2019 | News

The Government of India has enacted the Clinical Establishments (Registration and Regulation) Act, 2010 and notified Clinical Establishments (Central Government) Rules, 2012 for registration of Clinical Establishments.



According to a recent announcement by the Minister of State (Health and Family Welfare), Ashwini Kumar Choubey, the Government of India has enacted the Clinical Establishments (Registration and Regulation) Act, 2010 and notified Clinical Establishments (Central Government) Rules, 2012 for registration of Clinical Establishments with a view to prescribing the Minimum Standards of facilities and services provided by them.

Under the said Act, the National Council for clinical establishments has approved Minimum Standards for different levels of Hospitals. These minimum standards inter-alia provide that the hospitals should have adequate drugs, medical devices and consumables commensurate to the scope of services and number of beds. These standards further provide that the quality of drugs, medical devices and consumables shall be ensured.

The Hospitals are also required to follow standard precautions like practicing hand hygiene, use of personal infection equipment etc. and infection control practices including compliance to Bio-Medical Waste Management Rules to reduce high risk of healthcare associated infection. Currently, the Act has been adopted by 11 States namely, Sikkim, Mizoram, Arunachal Pradesh, Himachal Pradesh, U.P, Bihar, Jharkhand, Rajasthan, Uttarakhand, Assam and Haryana and all Union Territories except Delhi. The implementation and enforcement of the said Act fall within the ambit of the States/Union territories.

As per Constitutional provisions, ‘Health’ is a State subject and such issues would generally be addressed to the State/Union Territory concerned for taking appropriate action as per the provisions of Act and Rules applicable in the concerned State/UT. Data regarding the complaints received by States and action taken by the State to reimburse the affected patients is not maintained centrally.

Further, Central Government has published Medical Devices Rules 2017 effective from 01.01.2018. As per the said rules, Medical Device intended to be used for single use should be labeled appropriately.