GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA STARRED QUESTION NO.180 TO BE ANSWERED ON THE 21ST DEEMBER, 2018 REUSE OF DISPOSABLE MEDICAL DEVICES

*180. SHRI SANKAR PRASAD DATTA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether complaints/cases related to reuse of disposable medical devices/items, especially in cardiology and other super specialities in private hospitals of the country have been received/detected;
- (b) if so, the details thereof along with the number of such complaints received/cases detected during the last two years, hospital and State-wise; and
- (c) the corrective steps taken by the Government to safeguard the health of the patients along with the action taken against such hospitals?

ANSWER THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (c): A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.180* FOR 21ST DECEMBER, 2018

- (a) & (b) Health is a State subject and such complaints 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 is not maintained centrally.
- (c) 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 prescribe 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 and infection control practices including compliance to Bio-Medical Waste Management Rules. 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 falls within the ambit of the States/Union territories.

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