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

LOK SABHA
UNSTARRED QUESTION NO.†353
TO BE ANSWERED ON 03RD FEBRUARY, 2023

INCREASING CASES OF SUB-STANDARD MEDICAL IMPLANTS

†353: SHRI RAMCHARAN BOHRA:

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

(a) whether the Government has taken cognizance of the increasing cases of sub-standard medical implants in the country;
(b) if so, the details thereof;
(c) the measures being taken by the Government to make the manufacturers and importers accountable for sub-standard medical implants; and
(d) the details of the Rules and regulatory conditions for ensuring safety of the patients in this regard?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (d): As per provisions of Medical Device Rules (MDR), 2017 Central Drugs Standard Control Organisation (CDSCO) investigates individual complaints as and when received for further action.

Manufacture and import of medical devices in the country are regulated under the provisions of the MDR, 2017. The manufacturer and importer of medical devices is required to fulfill the requirements as per the said rules which includes conditions of the manufacturing/import license, manufacturing information, safety data, labeling and instruction for use, post marketing surveillance data etc.

The products are required to conform to the standards prescribed under Rule 7 of the MDR, 2017. As per the rule, a manufacturer has to comply with the Bureau of Indian Standards (BIS). If these are not available then manufacturer has to comply International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standards. If ISO/IEC standards are not available then manufacturer has to comply with pharmacopoeial/ manufacturer validated standards.

Further, manufactures/ importers of the medical devices needs to comply with the requirements of Quality management System as prescribed under Fifth Schedule of the MDR, 2017 including the requirement of plant master file and device master file etc.

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