GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
STARRED QUESTION No. 283
TO BE ANSWERED ON 19TH AUGUST, 2025

Scientific legislation for medical devices sector

283 Dr. Ajeet Madhavrao Gopchade:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Government is considering to enact a scientific legislation to tackle all issues related to the medical devices sector, given that such legislation is essential as this plays an indirect role in preserving human lives; and
(b) whether Government has examined the legislations from South Korea and Iceland, as these outline the responsibilities of medical device companies, establish a Medical Devices Industry Master Plan, create a Medical Devices Industry Promotion Committee, facilitate the certification and promotion of innovative medical devices, support the development of medical device software, enhance research and development, and impose penalties for non-compliance with standards, if so, the details thereof?

ANSWER

THE MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI JAGAT PRAKASH NADDA)

(a) and (b): A statement is laid on the Table of the House.

Statement referred to in reply to the RAJYA SABHA STARRED Q. No. 283 for answer on 19.8.2025, raised by Dr. Ajeet Madhavrao Gopchade, regarding Scientific legislation for medical devices sector

To regulate the import, manufacture, distribution and sale of drugs, including devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be notified by the Central Government, legislation is in place in the form of the Drugs and Cosmetics Act, 1940. Under the said legislation, Government has notified the Medical Devices Rules, 2017 in order to ensure quality, safety and performance of medical devices.

Act on Medical Devices, No. 132/2020 of Iceland is concerned primarily with measures to ensure quality and safety of medical devices. The aforesaid existing Indian legislation to ensure quality, safety and performance of medical devices, has been made considering international regulatory frameworks that cover import, manufacture, clinical investigation, distribution and sale of medical devices in the country intended for human or animal use.

The Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices of the Republic of Korea is concerned primarily with addressing issues concerning the policy framework to bolster medical device industry. The objectives this legislation seeks to achieve are being furthered in India through the National Medical Devices Policy, 2023 and various schemes launched by the Government of India. The said policy aims to facilitate growth of the sector and guide its development through a set of strategies across six key areas, namely, regulatory streamlining, enabling infrastructure, facilitating research and development and innovation, attracting investments in the sector, human resource development, and brand positioning and awareness creation. Further, to promote domestic manufacturing of medical devices and develop an ecosystem of manufacturing of medical devices, Government of India has launched the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, the scheme for Strengthening Medical Device Industry and the Scheme for Promotion of Medical Devices Parks. Some of the specific objectives sought to be achieved by the Korean legislation are being addressed in India through the following mechanisms and measures:

(a) The objectives sought to be achieved through the establishment of a Medical Devices Industry Promotion Committee in the Republic of Korea are being furthered in India through a National Medical Device Promotion Council having members from all stakeholder departments as well as representatives from medical device industry associations.
(b) The objectives of support for innovative medical devices companies and research and development in the Republic of Korea are being furthered in India through the Scheme for Promotion of Research and Innovation in Pharma-Med Tech Sector (PRIP) launched by the Government for providing financial assistance for research and innovation in medical devices to industry and startups and for setting up Centres of Excellence in the National Institutes for Pharmaceutical Education and Research (NIPERs). A Centre of Excellence in Medical Devices has also been set up under this scheme at NIPER, Ahmedabad.
(c) The objective of support for clinical trials in the Republic of Korea is being furthered in India through the Medical Device Clinical Studies Support Scheme for providing financial support for conducting clinical trials of medical devices in India.
(d) The objective of establishment of a foundation for safety management of innovative medical devices and support for standardisation in the Republic of Korea is being

furthered in India by way of identification of 214 priority medical devices for which Indian Standards are not available and in respect of which the Bureau of Indian Standards has been requested to develop standards on priority.

(e) The objectives of nurturing professionals by helping them secure qualifications required by the medical devices industry and providing support for promotion, exhibition and training in the Republic of Korea are being furthered in India under the following sub-schemes of the scheme for Strengthening of Medical Device Industry

(i) The Capacity Building and Skill Development for Medical Devices sub-scheme, which provides financial assistance for training programmes and capacity-building initiatives aimed at developing a skilled workforce in the medical device sector; and

(ii) The Medical Device Promotion Scheme, which provides financial support to industry bodies, industry associations and educational institutions to conduct meetings, seminars, workshops, events, roadshows, expos etc.

*****