Adverse events following use of medical device

2983. SHRI NARESH GUJRAL: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware of the medical device and adverse events reports which reveal that deaths from faulty medical devices has increased from 40 in 2014 to 556 in this year alone, if so, Government's reaction thereon;

(b) whether it is a fact that major global pharma companies are in a nexus with doctors to promote, sell and implant medical devices in an unregulated medical device industry; and

(c) whether there is no comprehensive legislation on regulation of medical device industry?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) The Government has not received such reports that death from faulty medical devices has increased from 40 in 2014 to 556 in this year alone.

Adverse reactions/malfunctioning in medical devices may happen due to various reasons like improper usage, improper size, electrical and mechanical problems and defective medical devices. It may or may not be related to the device.

The Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare regulates the import, sale and manufacturing of notified medical devices including breast, knee and hip implants, pelvic meshes, coronary stents under the provisions of Drugs and Cosmetics Act, 1940 and Medical Device Rules, 2017 thereunder. More than 350 medical devices and more than 250 in- vitro diagnostics have been brought under regulation. Under these rules, import of all classes of Medical Devices as well as manufacture of Class C and D Medical Devices are regulated by CDSCO, while manufacture of Class A and B Medical Devices are regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments.

Further, Ministry of Health and Family Welfare has approved the commencement of "Materiovigilance Programme of India (MvPI)" with Indian Pharmacopoeia Commission (IPC), Ghaziabad as the National Coordinating Centre having dedicated functional Medical Device Adverse Event Monitoring Centres (MDMCs) all over the country. All the Adverse Drugs Reaction Monitoring Centres (AMCs) under Pharmacovigilance

Programme of India (PvPI) have also been entrusted to report adverse events due to the use of medical devices.

(b) and (c) To have comprehensive regulatory provisions for import, manufacture, sale and distribution of medical devices based on risk based criteria, the Government of India has notified the Medical Device Rules, 2017 which have become effective from 01.01.2018. For import or manufacture of any medical device, the applicant is required to submit details of design, specification, non-clinical as well as clinical data of safety and performance of the devices. In case of new Medical Devices, the safety, quality and performance data are evaluated by CDSCO in consultation with the Subject Expert Committee in the relevant therapeutic areas. Under the said rules, there are provisions that subsequent to approval of a medical device, the applicant is required to closely monitor the device for its clinical safety. The applicant is required to submit Periodic Safety Update Reports (PSURs) to CDSCO.

The Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) announced by the Department of Pharmaceuticals in December, 2014 which is in operation since 01.01.2015 for voluntary adoption by pharma industry provides that the manufacturers should not use any unethical practices for luring doctors to boost sales of their products.

Further, Clause 6.8 (Code of Conduct for doctors in their relationship with pharmaceutical and allied health sector industry) of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prohibits doctors from taking gifts, travel facilities, hospitality and case or monetary grants from pharmaceutical and allied health sector industry. The said regulation empower the Medical Council of India and respective State Medical Council to award punishment to a doctor against any act in violation of Code of Ethics.

Clamping down manufacturing of spurious drugs

†2984. SHRI LAL SINH VADODIA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that business of manufacturing spurious medicines is flourishing in different parts of the country;

(b) if so, whether Government is contemplating to take any concrete and effective steps to control it; and

†Original notice of the question was received in Hindi.