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.

(c) if so, the details thereof and if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (c) No such report has been received that business of manufacturing spurious medicines is flourishing in different parts of the country.

The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provisions of the Act and Rules.

In order to ensure the quality of drugs in the country, both the Central Drugs Standard Control Organisation (CDSCO) and the State drug regulators pick up a large number of samples of drugs from all over the country and (have) get them tested and analysed in the laboratories of the Central and State Governments. In a few cases, the samples tested and analysed do not meet the prescribed standards. The details of the drugs that do not meet the standards are immediately notified by the Central or State regulator concerned.

The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.

Arresting rising trend of drug addiction

†2985. SHRI LAL SINH VADODIA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government is seriously considering to prevent growing trend of drug addiction in the country;

(b) if so, whether Government has taken any step in this regard, so far; and

(c) if so, the details thereof and if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) to (c) Yes. The Ministry of Social

†Original notice of the question was received in Hindi.