

(b) The Drug (Prices Control) Order, 2013 follows a market based methodology and not cost based methodology.

(c) to (e) The Committee constituted by the Department of Pharmaceuticals to look into the issue of high trade margins for pharmaceutical and medical devices has proposed graded trade margins with reference to the Price to Trade (PTT) and it has *inter-alia* recommended 35% margin for medicines with MRP above ₹ 50/-.

The recommendations are being examined in consultation with other Government Departments including Department of Legal Affairs and Competition Commission of India. As such, no time-frame can be given.

#### **Making life-saving drugs available free of cost to poor people**

2288. SHRI P. BHATTACHARYA: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether Government proposes to bring life-saving drugs under control;
- (b) if so, the details of action taken by Government in this regard; and
- (c) the arrangement made by Government to make life-saving drugs free of cost to the poor and helpless people in Government as well as in private hospitals?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAMAHIR): (a) and (b) The prices of drugs are controlled under the provisions of the Essential Commodities Act, 1955 where drugs are referred to as per their definition in the Drugs and Cosmetics Act, 1940. However, there is no definition of life saving drugs either in the Drugs and Cosmetics Act, 1940 or in Drugs (Price Control) Order, 2013. At present, the ceiling prices of medicines of various strength/ dosages form as declared by Ministry of Health and Family Welfare included in National List of Essential Medicines (NLEM), 2015, are fixed by National Pharmaceutical Pricing Authority (NPPA).

(c) There is no such arrangement made by Department of Pharmaceuticals in providing life-saving drugs free of cost to the poor and helpless people in Government as well as in private hospitals.

#### **Provision for penalty for overcharging in DPCO**

2289. SHRI A.W. RABI BERNARD: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether the National Pharmaceutical Pricing Authority (NPPA) has proposed changes to the existing Drugs (Prices Control) Order, 2013 (DPCO) seeking provisions to impose a fine on those violating pricing norms, if so, the details thereof;

(b) whether Government has decided to introduce hefty penalties for companies overcharging on sale of drugs, if so, the details thereof; and

(c) whether Government intends to take this initiative with an aim to protect consumers as there is need for a tougher law to discourage drug makers from over charging, if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAMAHIR): (a) Yes, Sir. NPPA has suggested certain amendments in the provisions of DPCO, 2013 including imposing fine on those violating the pricing norms.

(b) and (c) The Government receives various suggestions from the stakeholders including NPPA regarding various provisions of DPCO, 2013. The final view on the same is taken after consulting all the stakeholder and on the merits of the proposals which is an ongoing process.

#### **Measures to improve quality of drugs and manufacture of APIs**

2290. SHRI A.U. SINGH DEO: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the details of domestic production and import of pharmaceutical and medical devices during last year;

(b) whether Government has taken measures/plans to take measures to improve infrastructure facilities, regulations and tariff structure of pharmaceutical sector;

(c) if so, that details thereof and timeline for implementation, if not, the reasons therefor; and

(d) whether Government has introduced measures to improve quality of drugs and for creation of APIs manufacturing capabilities, if so, the details thereof and if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAMAHIR): (a) The annual turnover of the Indian Pharmaceutical Industry was 1,65,202.3 crores during the year 2014-15 and India imported 29,336.1 crores worth of bulk drugs, drug intermediates, drug formulations and biologicals during same period. The imports made by the companies are not mainly restricted to availability but also due to economic considerations. However, in the case of medical devices the country is mainly dependent on imports in case of high-end medical devices especially for those used for stents/implants.