## GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

# LOK SABHA

## **UNSTARRED QUESTION No. 1792**

# TO BE ANSWERED ON THE 8<sup>th</sup> March, 2016

#### Slow Down in Launching of New Drugs

1792. SHRI GODSE HEMANT TUKARAM:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether it is a fact that the measures being taken by the Government since the year 2011, for drug price control have resulted in a drastic slow-down in launching of new drugs in the country by drug manufacturing companies;
- (b) if so, the details thereof and the reaction of the Government thereto;
- (c) whether the Government proposes to impose custom duty on some life saving drugs; and
- (d) if so, the details and the reasons therefor?

# <u>ANSWER</u>

# MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a): As per information available, there has not been drastic slowdown in launching of new drugs by drug manufacturing companies.

(b): The new drugs are approved as per the Guidelines and requirements specified in Rule 122A, 122B, 122D, 122E and Schedule Y of Drugs and Cosmetics Rules, 1945. The numbers of new drug molecules (Non-biologicals and biologicals) approved by Central Drugs Standard Control Organization (CDSCO) during 2011 to 2015 (till 30.6.2015) in the country is as under:-

| 2011             | 41 |
|------------------|----|
| 2012             | 31 |
| 2013             | 16 |
| 2014             | 21 |
| 2015             | 11 |
| (till 30.6.2015) |    |

Contd-2

The launching of new drugs are done by the manufacturing companies taking into consideration all aspects including their business interest.

The National Pharmaceutical Pricing Policy (NPPP) was notified on 07th December, 2012 with the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "essential medicines" at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharma industry thereby meeting the goals of employment and shared economic well-bring for all.

(c) & (d): In order to provide a level playing field to the domestic pharmaceutical manufacturers, the Government had notified on 28 January, 2016, the withdrawal of exemptions granted to certain categories of drugs mentioned at list 3 and 4 of Custom Notification No. 12/2012-Customs, dated the  $17^{th}$  March, 2012.

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