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

#### **LOK SABHA**

#### **STARRED QUESTION No. 192**

#### TO BE ANSWERED ON THE 29th November, 2016

#### **Pharma Sector**

\*192. SHRI HARI OM PANDAY: DR. RATNA DE (NAG):

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

- (a) whether the Government is satisfied with the performance of pharma industry in the country and if so, the details thereof;
- (b) the major initiatives taken in the pharma sector in recent times;
- (c) whether the Government proposes to amend the existing licensing policy for pharma sector in the country and if so, the details thereof; and
- (d) whether this proposal is likely to help in revamping the pharma sector as well as ensuring the growth and development of the said sector and if so, the details thereof?

#### **ANSWER**

### MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS AND PARLIAMENTARY AFFAIRS

(SHRI ANANTHKUMAR)

(a) to (d): A statement is laid on the Table of the House.

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# Statement referred to in reply to LOK SABHA STARRED QUESTION No. 192 to be answered on 29<sup>th</sup> November, 2016 regarding Pharma Sector

- (a): Yes, Madam. The Indian Pharmaceutical Industry is witnessing a robust growth. In the beginning of 11<sup>th</sup> Plan in 2007 it stood at approximately Rs. 71000 crores which has now risen to approximately Rs. 2,00,000 crores as per data of Pharmatrac and Pharmaceutical Export Promotion Council (Pharmexcil) upto 2015-16.
- (b): The Government has taken various initiatives to help the Pharma Sector grow and this is an ongoing process. Some of the major initiatives taken by the Government are as under:
  - (i) Withdrawal of exemption of Customs Duty on certain categories of drugs/medicines to promote domestic manufacturing of these medicines;
  - (ii) Implementing 'Cluster Development Programme for Pharma Sector (CDP-PS)' in Public Private Partnership made through Special Purpose Vehicle (SPV) through one time grant –in- aid to be released for creation of identified infrastructure and common facilities in the form of Common Facility Centers (CFC).;
  - (iii) Financial support for research and development under Drugs & Pharmaceuticals Research Programme (DPRP) of the Department of Science & Technology;
  - (iv) Section 35 of Income Tax Act grants weighted deduction for expenditure on scientific research.
  - (v)The Drugs (Price Control) Order, 2013, Para-32 (iii) provides exemptions from price control to a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India;
  - (vi) Foreign Direct Investment (FDI) Policy has been liberalised whereby Pharmaceutical Companies for Greenfield Pharma Projects can invest 100% FDI through automatic route and for Brownfield Pharma Projects foreign investment upto 74% is allowed under automatic route and beyond that the companies have to come through government route.

(c) & (d): Under the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder, the manufacturers/Importers are required to obtain license from Drug Controller / State Drug Controllers. The Drugs and Cosmetics Rules 1945 are amended from time to time to streamline the regulatory process with respect to manufacturing, import, sales and distribution of Drugs & Cosmetics.

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