

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA  
UNSTARRED QUESTION NO. 128  
TO BE ANSWERED ON 2<sup>ND</sup> FEBRUARY, 2018**

**MANUFACTURING OF GENERIC MEDICINES**

**128. SHRI VISHNU DAYAL RAM:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether India is the biggest manufacturer and exporter of generic medicines in the world;
- (b) if so, the details thereof;
- (c) whether the Government has devised any uniform system to issue licenses for manufacturing generic medicines in the country;
- (d) the names of companies to which licenses have been issued, State-wise; and
- (e) the steps taken/ proposed to be taken by the Government to safeguard the interests of such generic drug manufacturers from the multi-national companies?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) & (b): India is one of the biggest manufacturers and exporters of generic medicines in the world. It is 4<sup>th</sup> largest in terms of volume and 10<sup>th</sup> largest in terms of value in exports.

(c): The manufacture for sale of any drug in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder. Licenses for manufacture of sale are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. Requirements for grant of such licences are prescribed under the said Act and Rules which are required to be followed uniformly across the country.

(d): As stated in (c) above, manufacturing license is granted by State Licensing Authority. Data in this regard is not maintained centrally.

(e): The Medical Council of India (MCI) has amended its code providing for generic prescription by the doctors. Further, Department of Pharmaceuticals is operating a Scheme 'Pradhan Mantri Bharatiya Janaushadhi Pariyojana' (PMBJP) in which quality generic medicines are being made available to the Indian masses at affordable price.