GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 2658

TO BE ANSWERED ON THE 1st August, 2017

Essential Medicines

†2658. SHRI KAUSHAL KISHORE:

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

(a) whether 108 of the total medicines produced in India are useful for the treatment of many serious diseases including cancer, diabetes, high blood pressure and heart disease have been delisted from the list of essential medicines by the National Pharmaceutical Pricing Authority;

(b) if so, the details thereof;

(c) whether this is being done to give benefits to foreign companies which are producing more costly medicines and if so, the details thereof;

(d) whether registration of some Indian pharmaceutical companies has been cancelled; and

(e) if so, the details thereof and the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) to (c): No, Madam. The Core-Committee constituted by the Ministry of Health and Family Welfare (MoHFW), Government of India to revise the National List of Essential Medicines (NLEM) through a series of meetings and consultations across the country, deliberated and revised the National List of Essential Medicines (NLEM) 2011. There were 348 medicines listed in NLEM 2011. A total of 106 medicines have been added, and 70 medicines have

been deleted while preparing NLEM 2015 which now contain a total of 376 medicines. NLEM 2011 and NLEM 2015 notified by MoHFW were included in Schedule-I of DPCO, 2013 by Department of Pharmaceuticals The apparent mismatch in the total number of medicines is on account of different name of the same medicine considered in NLEM 2011. The Core-Committee has also submitted the detailed recommendations and the procedure adopted for revision of the NLEM. As per NLEM recommendation committee, the criteria for deletion of a medicine are as under:

1. The medicine has been banned in India.
2. If there are reports of concerns on the safety profile of a medicine
3. If medicines with better efficacy or favorable safety profile and better cost-effectiveness is now available.
4. The disease burden for which a medicine is indicated is no longer a national health concern
5. In case of antimicrobials, if the resistance pattern has rendered a medicine ineffective.

(d): Manufacture, sale and distribution of drugs are regulated under provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 through a system of Licencing and inspection. Licence for manufacturing, sale & distribution of drugs are granted by the State Licencing Authorities appointed by respective State Governments. The existing regulatory provisions require the drug manufacturers to comply with all the conditions of license, which include compliance with Good Manufacturing Practices (GMP) as prescribed under Schedule 'M' of the said Rules, to ensure that the drugs manufactured by them are of standard quality. State Licensing Authorities are empowered to take action on violation of any conditions of such Licenses. Department of Pharmaceuticals has no information regarding cancellation of registration of Indian Pharmaceutical companies

(e): In view of reply to (d) above, does not arise.

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