

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION NO. 2514
TO BE ANSWERED ON 3rd December, 2019

Essential Medicines

2514. SHRI N.K. PREMACHANDRAN:

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

- (a) whether it has come to the notice of the Government that the price of about 100 medicines including medicines for Alzheimers, diabetes, hypertension and cancer could rise by up to 10% after they were removed from the National List of Essential Medicines (NLEM);
- (b) if so, the details thereof alongwith the action taken by the Government to control the price hike of medicines;
- (c) the details of the criteria adopted by the Government for removing those medicines from the national list of essential medicines;
- (d) the list of medicines included by the National Pharmaceutical Pricing Agency (NPPA) in the list of essential medicines; and
- (e) whether the Government proposes to include more medicines in the list of essential medicines so as to ensure the availability of medicines at a reasonable price and if so, the details thereof?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)**

- (a): In recent past, no medicine has been removed from the National List of Essential Medicine (NLEM).
- (b): In view of reply at (a) above, the question does not arise.
- (c): The criteria adopted for addition/deletion of medicines is in the report of NLEM 2015 available on the website of *Central Drugs Standard Control Organization (CDSCO)* i.e. www.cdsc.gov.in.

The criteria for inclusion of a medicine is reproduced below from NLEM 2015:-

- (i) The medicine should be approved/licensed in India.
- (ii) The medicine should be useful in disease which is a public health problem in India.
- (iii) The medicine should have proven efficacy and safety profile based on valid scientific evidence.

- (iv) The medicine should be cost effective.
- (v) The medicine should be aligned with the current treatment guidelines for the disease.
- (vi) The medicine should be stable under the storage conditions in India.
- (vii) When more than one medicine are available from the same therapeutic class, preferably one prototype/ medically best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, cost-effectiveness.
- (viii) Price of total treatment to be considered and not the unit price of a medicine.
- (ix) Fixed Dose Combinations (FDCs) are generally not included unless the combination has unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.
- (x) The listing of medicine in NLEM is based according to the level of health care, i.e. Primary (P), Secondary (S) and Tertiary (T) because the treatment facilities, training, experience and availability of health care personnel differ at these levels.

The criteria for deletion of a medicine is reproduced below from NLEM 2015:

- (i) The medicine has been banned in India.
- (ii) There are reports of concerns on the safety profile of a medicine.
- (iii) A medicine with better efficacy or favorable safety profiles and better cost-effectiveness is now available.
- (iv) The disease burden for which a medicine is indicated is no longer a national health concern in India.
- (v) In case of antimicrobials, if the resistance pattern has rendered a medicine ineffective in Indian context.

(d): The Ministry of Health & Family Welfare notifies the National List of Essential Medicines (NLEM). All the medicines specified in the National List of Essential Medicines (NLEM) are included in the First Schedule of Drugs (Prices Control) Order, 2013 (DPCO, 2013) and brought under price control by National Pharmaceutical Pricing Authority (NPPA). The details of drugs under the list of Essential Medicines, as included in the National List of Essential Medicines (NLEM), 2015, are available on the website of *Central Drugs Standard Control Organization (CDSCO)* i.e. www.cdsc.gov.in/Notifications/Public-Notices.

(e): A Standing National Committee on Medicines (SNCM) has been constituted by Ministry of Health & Family Welfare in July, 2018 to review and revise the National list of Essential Medicines (NLEM) by way of additions and deletions in the existing NLEM in the context of contemporary knowledge of use of therapeutic products in health & hygiene of general public.
