GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 1729
TO BE ANSWERED ON THE 16th DECEMBER, 2022

Life Saving Drugs

†1729. SHRI MAHABALI SINGH:
SHRI KHAGEN MURMU:

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

(a) whether life saving drugs have been listed by the Government in the country and if so, the details thereof and if not, the reasons therefor;
(b) whether the Government has taken any specific steps to promote the production of life saving drugs in the country;
(c) whether the Government is dependent on other countries in respect of life saving drugs; and
(d) if so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI BHAGWANTH KHUBA)

(a): The Ministry of Health & Family Welfare publishes the National List of Essential Medicines (NLEM). Life-saving drugs are not specifically mentioned in the NLEM.

The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals, notifies the above list of essential medicines as the Schedule -I of the Drugs (Price Control) Order and fixes the ceiling price of these scheduled medicines. NPPA has fixed ceiling prices of 890 scheduled formulations under NLEM 2015. The formulations under Schedule-I are mentioned according to their therapeutic category.
Further, Ministry of Health & Family Welfare notified the National List of Essential Medicines (NLEM) 2022 on 13.09.2022. Accordingly, the Department of Pharmaceuticals (DoP) has notified Revised Schedule I of DPCO 2013 on the basis of NLEM 2022 vide SO No. 5249 (E) dated 11.11.2022.

(b) to (d): The Department of Pharmaceuticals implements three Production Linked Incentive (PLI) schemes

- Under PLI scheme for Bulk Drugs (Active Pharmaceutical Ingredients, Key Starting Materials and Drug Intermediates), domestic production of 41 identified bulk drugs used in the manufacture of *critical formulations* / medicines under different therapeutic categories is being promoted.
- PLI Scheme for Pharmaceuticals intends to encourage domestic production of high value drug formulations and bulk drugs.

- The Department also implements the scheme for promotion of three bulk drug parks in which crucial raw materials will be manufactured for subsequent use in drug formulations.
- Details of all these three schemes are available on the website of the Department of Pharmaceuticals i.e. http://pharmaceuticals.gov.in.

Further, as per information received from Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare, CDSCO regulates quality, safety, and efficacy of the drugs, medical devices and cosmetics under the provisions of Drugs & Cosmetic Act, 1940 & Rules, made there under. However, various regulatory measures have been taken to streamline the approval of ***new drugs including new anticancer drugs*** as under:

- New Drug and Clinical Trial Rules, 2019 have been notified vide G.S.R 227 (E) Dated 19/03/2019, which contain various provisions for improving transparency, accountability & predictability of approval process and also to promote research and development of new drugs leading to increased access to new drugs. The key provisions are as follows:
    - Disposal of clinical trial and new drug applications by way of approval or rejection or seeking further information within a period of 90 working days.
    - In case of application to conduct clinical trial of a new drug or investigational new drug as part of drug discovery, research and manufacture in India the application is to be disposed of within a period of 30 working days, in case of no communication from CDSCO, the application will be deemed to have been approved.
    - In case of application to conduct clinical trial of a new drug which is already approved outside India, the application is to be disposed of within a period of 90 working days.
    - Accelerated/ expedited approval process in certain situation like unmet need, orphan drugs for rare diseases etc.
    - Provisions for pre-submission and post-submission meetings of the applicants with CDSCO for formal discussion and decision about case specific regulatory pathway.
    - Provision for post-trial access of the investigational products for clinical trial participants in case there is no other alternative therapy available.

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