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:
  o 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.
  o 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.
  o 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.
  o Accelerated/ expedited approval process in certain situation like unmet need, orphan drugs for rare diseases etc.
  o Provisions for pre-submission and post-submission meetings of the applicants with CDSCO for formal discussion and decision about case specific regulatory pathway.
  o 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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