

procurement issue, unpredictability in drug pricing, difference in stand taken by NPPA and Department of Pharmaceutical, etc.; and

(b) if so, the reasons therefor along with details thereof?

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH MANDAVIYA): (a) and (b) Yes, Sir. Pharma Industry has brought to the notice of the Government that due to closure of the manufacturing plants in China on issue of increasing pollution and environment concerns, the industry is facing inconsistent hike in the price of Raw Material [Active Pharmaceutical Ingredients (API) and Intermediates] imported from China for manufacture of formulations in India to meet the demand of domestic market and also affecting the availability of Raw Material (API and Intermediate). The Government is closely monitoring the situation.

Further, National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling/retail prices of drugs under the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) and any person aggrieved by any notification issued or order made under paragraphs 4, 5 and 6 of this Order, may apply to the Government for a review of the notification or Order within a period of thirty days of the date of publication of the notification in the Official Gazette or the receipt of the order by him. The Department of Pharmaceuticals (DoP) examines the review applications filed by the companies and directs NPPA to remove any discrepancy, if found in price fixation as per DPCO, 2013. NPPA implements the Review order given by Department of Pharmaceuticals.

Overhauling drug pricing policy and dismantling NPPA

2602. SHRI PARIMAL NATHWANI: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether Government is considering a proposal to overhaul the drug pricing policy and ease regulatory framework to facilitate smooth business environment for pharmaceutical companies;

(b) if so, the details and objectives thereof;

(c) whether Government has decided to dismantle the National Pharmaceutical Pricing Authority (NPPA) and if so, the details thereof and the reasons therefor; and

(d) whether Government has established any other agency for issuing licences and approval of new drugs and if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH MANDAVIYA): (a) and (b) There is no proposal at present to overhaul the drug pricing policy. However, minor changes are made in the Drugs (Prices Control) Order, 2013 from time to time to facilitate a smooth business environment and in the larger public interest. As regards regulatory framework, the licenses for manufacturing, sale and distribution of drugs under the provisions of Drugs and Cosmetics Act and Rules thereunder are issued by Licensing Authority appointed by State Governments. However, for new drug, the permission/approval is required to be obtained from Central Drugs Standard Control Organisation (CDSCO) under Ministry of Health and Family Welfare, before obtaining manufacturing license from the State Licensing Authority. In order to streamline the regulatory process and to improve the efficiency and transparency in CDSCO, various measures have been taken like perpetuity of drug manufacturing/sale license, increasing the validity of World Health Organisation- Good Manufacturing Practices Certificate of Pharmaceutical Product (WHO GMP COPP) certificate from 2 years to 3 years, delegation of power to the State Licensing Authorities regarding issuance of NOC (No Objection Certificate) for export purpose. Further, e-governance in the form of 'SUGAM' for online submission and permission of various applications for grant of licenses/approvals.

(c) No, Sir.

(d) No Sir, approval of new drugs is granted by CDSCO and manufacturing licenses are granted by State Licensing Authorities.

**Pradhan Mantri Bhartiya Janaushadhi Kendras in
Himachal Pradesh**

2603. SHRIMATI VIPLOVE THAKUR: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the details of Pradhan Mantri Bhartiya Janaushadhi Kendras functioning in the country, location-wise;

(b) whether the Government proposes to open new Janaushadhi Kendras in the Himachal Pradesh under the said scheme;

(c) if so, the number of such Kendras proposed to be opened in Himachal Pradesh, location-wise; and

(d) the efforts made to set up the said Kendras at the earliest?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH MANDAVIYA): (a) As on 31.12.2018, 4677