

**GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY
DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE**

LOK SABHA

**UNSTARRED QUESTION NO. 3635.
TO BE ANSWERED ON WEDNESDAY, THE 17TH MARCH, 2021.**

EASE OF DOING BUSINESS

3635. SHRI NAMA NAGESWARA RAO:

Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state:

वाणिज्य एवं उद्योग मंत्री

- (a) whether the Government has taken any steps to improve ease of doing business in pharma sector;
- (b) if so, the details thereof; and
- (c) if not, the reasons therefor?

ANSWER

वाणिज्य एवं उद्योग मंत्रालय में राज्य मंत्री (श्री सोम प्रकाश)

**THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE & INDUSTRY
(SHRI SOM PARKASH)**

- (a) & (b):** Yes, Sir. Department for Promotion of Industry and Internal Trade (DPIIT), in coordination with Central Ministries/Departments, States and Union Territories (UTs), has spearheaded various reforms to improve business regulatory environment in the country across all the sectors including the pharmaceuticals sector. As a result of the initiatives undertaken, India ranks 63rd in the World Bank's annual Doing Business Report (DBR), 2020 as against 77th rank in DBR, 2019, registering a jump of 14 ranks.

As a part of State Reforms Action Plan (SRAP), DPIIT has recommended States/UTs to design and implement an online single window system for submission, processing and issuance of applications for grant of Retail Drug License, Wholesale Drug License, Drug Manufacturing License. The SRAP also recommends States/UTs to eliminate the requirement of renewal and allow for auto-renewal in case of drug licenses.

During the last five years, Ministry of Health and Family Welfare and Central Drugs Standard Control Organization (CDSCO) have taken various measures for streamlining regulatory system and ease of doing business in the country such as notification of Medical Devices Rules, 2017, New Drugs and Clinical Trials Rules, 2019, online submission

and processing of various applications under SUGAM portal, for evaluation of applications of Clinical Trials, New Drugs and Investigational New Drugs (IND) including r-DNA derived products and vaccines, new medical devices, etc., notification of Cosmetics Rules, 2020, increasing the validity of World Health Organizations' (WHO) Certificate of Pharmaceutical Product (COPP) under the WHO Good Manufacturing Practice (GMP) Certification Scheme from 2 years to 3 years, waiver of No Objection Certificate (NOC) for export purpose for the export consignments to any country, delegation of power to all States'/UTs' Drug Controllers for issuance of NOC with respect to unapproved /banned drugs for export purpose only, etc.

M/o Environment, Forest and Climate Change (MoEFCC), vide Notification S.O. 1223(E) dated 27th March, 2020 and vide Notification S.O. 3636(E). dated 15th October, 2020 has decided that all proposals for projects or activities in respect of Active Pharmaceutical Ingredients (API) received up to 30th March, 2021, shall be appraised, as Category 'B2' projects. MoEFCC, vide Office Memorandum dated 28th January, 2021, has categorized 'API and Intermediates' as single category instead of individual products, in order to provide flexibility to the Industry to change the raw materials mix and/or product mix within the sanctioned pollution load. MoEFCC, vide Notification S.O.980(E) dated 2nd March, 2021, has decided that any increase in production capacity in respect of processing or production or manufacturing sectors (listed against item numbers 2,3, 4 and 5 in the Schedule to this notification) with or without any change in (i) raw material-mix or (ii) product-mix or (iii) quantities within products or (iv) number of products including new products falling in the same category or (v) configuration of the plant or process or operations in existing area or in areas contiguous to the existing area (for which prior environmental clearance has been granted) shall be exempt from the requirement of Prior Environmental Clearance provided that there is no increase in pollution load. Expert Appraisal Committee (EAC) meetings are conducted by MoEFCC fortnightly for expeditious appraisal of environmental clearance proposals.

Department of Pharmaceuticals has constituted a Committee on 6th January, 2021 for suggesting ways for reducing the compliance burden faced by the Industry.

(c): Does not arise.
