

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

LOK SABHA
UNSTARRED QUESTION No. 733
TO BE ANSWERED ON THE 26th JULY, 2024

Pharmaceutical Waste Management

733 Shri Maddila Gurumoorthy:

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

- (a) whether the Government has taken/proposes to take any steps to ensure better pharmaceutical waste management, especially at the production level and if so, the details thereof;
- (b) whether the Government is aware that currently, only 38 percent of the pharma sector companies have been publishing sustainability reports in the country;
- (c) if so, whether the Government has any plan to mandate all pharma sector companies to publish similar reports, if so, the details thereof; and
- (d) whether the Government intends to mandate all major pharma manufacturing units to adopt sustainable practices like committing to reducing their carbon footprint, increasing water neutrality and reducing waste created during and after the manufacturing process, and if so, the details thereof?

ANSWER

**MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(MS. ANUPRIYA PATEL)**

(a): The Ministry of Environment, Forests and Climate Change (MoEF&CC) has notified effluent and emission discharge standards for pharmaceutical industry. The standards are implemented by State Pollution Control Boards (SPCBs) / Pollution Control Committees (PCCs) through consent mechanism i.e. notified standards are enforced by SPCBs/PCCs in the consent order issued under the Water Act or the Air Act or authorization under the Hazardous and Other Wastes (Management and Transboundary Movement) Rules.

Vide GSR 541(E) dated 6th August, 2021, the MoEF&CC notified standards for Bulk Drug and Formulation (Pharmaceutical) Industry in exercise of the powers conferred by Section 6 and 25 of the Environment (Protection) Act, 1986. These standards aim to regulate and mitigate the environmental impact caused by pharmaceutical manufacturing activities, ensuring compliance with environmental norms and promoting sustainable practices within the industry. This notification represents a significant step towards environmental protection and management in the pharmaceutical sector.

The Notification stipulates that:

(i) Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or Common Effluent Treatment Plants (CETP) catering to industries engaged in manufacturing of bulk drug formulations of pharmaceuticals, has been classified as Hazardous Waste as per the provisions of the

Hazardous Waste and Other Wastes (Management and Transboundary Movement) Rules, 2016 and shall be managed in environmentally sound manner in accordance with these rules.

(ii) SPCBs/PCCs shall prescribe additional relevant parameters as given in para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.

(iii) Expired or Discarded Medicines shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards provided in Schedule-II of the Bio-medical Waste Management Rules, 2016 (BMW Rules) by the health care facilities and common bio-medical waste treatment facility.

(iv) Date-expired products generated from production/formulation of drugs /pharmaceutical and health care is categorized as hazardous waste as category 28.5 of Schedule I of Hazardous & Other Wastes (Management and Trans-Boundary Movement) Rules, 2016 and the occupier / manufacturer is required to follow procedures for environmentally sound management and safe disposal as per responsibilities of the occupier stipulated under the rules.

(v) Guidelines on Monitoring Mechanism for Active Pharmaceutical Ingredient (API residue” has been prepared by Central Pollution Control Board (CPCB) and circulated to all SPCBs/ PCCs in compliance of Hon’ble NGT order of Principal Bench, New Delhi in the matter of Original Application No. 136/2020.

(vi) To reduce antibiotic residues from effluent sources, industry is adopting reduce, recycle and reuse of treated effluent to maximum extent or Zero Liquid Discharge (ZLD) to minimize risk of Pharmaceutical Compounds’ residues.

(b) to (c): The business responsibility and sustainability reporting by listed entities in terms of Securities and Exchange Board of India (SEBI) circular - SEBI/HO/CFD/CMD-2/P/CIR/2021/562, dated 10.05.2021 is mandatory for the top 1000 listed companies (by market capitalization).

(d): The manufacturing of bulk drugs and intermediates is listed at S.N. 5(f) of schedule of Environment Impact Assessment (EIA) Notification, 2006 and requires prior environmental clearance from Ministry of Environment, Forest and Climate Change or respective State Environment Impact Assessment Authority (SEIAA) based on proposals falling under category ‘A’ or ‘B’ in the schedule. While granting environmental clearance, Ministry of Environment, Forest and Climate Change stipulates the specific and general conditions as environmental safeguards. It is mandatory for Pharmaceutical industries to operate only after obtaining Consent to Operate from respective SPCBs/PCCs. It is mandatory for all the industries to have Effluent Treatment Plant and Air Pollution Control System and to comply with the prescribed effluent and emission discharge standards. Further, CPCB has directed all 17 categories of high pollution potential industries, Grossly Polluting Industries of Ganga basin and common waste treatment facilities to install Online Continuous Effluent/ Emission Monitoring Systems (OCEMS) for strengthening monitoring mechanism and effective compliance through self-regulatory mechanism and constant vigil on pollution levels. Real-time values of environmental pollutants of trade effluent and emissions generated through OCEMS are transmitted online to CPCB and concerned SPCB/PCC on 24x7 basis. Central software processes the data and in case of value of pollutant parameter exceeds prescribed environmental norms, an automatic SMS alert is generated and sent to industrial unit, SPCB and CPCB, so that corrective measures can be taken by the industry immediately and appropriate action can be taken by concerned SPCB/PCC/CPCB.
