GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO.†3957
TO BE ANSWERED ON 24TH MARCH, 2023

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

†3957: SHRI RAMDAS C. TADAS:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the new rules for registration of all patented pharmaceutical products including new drugs being marketed in the country have been framed by the Government in coordination with Central Drugs Standard Control Organization;
(b) if so, the mechanism established by the Government for proper enforcement/compliance of the above said provisions/rules in the country;
(c) whether the information regarding incomplete data reported by pharmaceutical companies/importers and registration/marketing of new medicines imported in contravention of the rules have been received;
(d) if so, the details thereof and the action taken/ proposed to be taken by the Government thereon;
(e) whether some multi-national pharma companies have warned the Indian Generic Pharma manufacturers to stop the supply of medicines made for treatment of various chronic diseases; and
(f) if so, the measures taken/proposed to be taken by the Government in this regard?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (f): Regulatory requirements and guidelines for permission to Import and / or Manufacture of new drugs for marketing are specified in the New Drugs and Clinical Trials Rules, 2019.

For grant of permission to Import and/or Manufacture of new drugs for marketing, the applicant is required to submit various information including Chemical and pharmaceutical information's, preclinical & clinical data of safety and efficacy, Regulatory status in other countries etc. depending on category and nature of the new drug as per the provisions of New Drugs and Clinical Trials Rules, 2019.

Such applications for introduction of new drugs first time in the country are examined in consultation with Subject Expert Committees (SEC) of CDSCO and decisions for approval or otherwise are taken considering the recommendations of the Committees.

As communicated by Central Drugs Standard Control Organisation (CDSCO), there is no information that multi-national pharma companies have warned Indian Generic Pharma manufacturers to stop the supply of medicines made for treatment of various chronic diseases.

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