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

RAJYA SABHA
UNSTARRED QUESTION NO. 1410
TO BE ANSWERED ON 01ST AUGUST, 2023

REGULATORY CHALLENGES OF INDIAN DRUGS

1410: SHRI MOHAMMED NADIMUL HAQUE:

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

(a) whether Government has taken cognizance of the fact that Drugs and Cosmetics Act, 1940 does not cover many aspects such as clinical trials, bioequivalence studies, good manufacturing practices and is outdated and inadequate to deal with the complexities and challenges of the modern pharma market;
(b) if so, the plan of Government to cover aspects such as clinical trials, bioequivalence studies and good manufacturing practices;
(c) if not, the reasons therefor; and
(d) the steps taken by Government to ensure transparency and accountability in Central Drugs Standard Control Organization?

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

(a) to (c): The clinical trials, bioequivalence studies, good manufacturing practices are covered under the New Drugs and Clinical Trial Rules, 2019 and various Schedules of the Drugs and Cosmetics Act, 1940 which regulates import, manufacture, distribution and sale of Drugs and Cosmetics. Also, amendment of Drugs & Cosmetics Rules carried out for incorporating new provisions in accordance with the changing requirements to deal with the complexities and challenges of the modern pharma market.

(d): Various measures have been taken to ensure transparency and accountability in Central Drugs Standard Control Organisation (CDSCO) like online submission, processing and tracking of various applications, prescribing timelines for applications, evaluation of

applications of clinical trials; New Drugs and Investigational New Drug (IND) including r-DNA derived products and vaccines; new medical devices in consultation with Subject Experts Committees/IND committee.

Further, CDSCO regularly uploads various guidance documents / FAQs and details of drugs declared as spurious/substandard/adulterated/misbranded by Central Drug Testing Laboratories on its website (www.cdsco.nic.in). A Public Relation Office is also in place in CDSCO for resolving the issues of stakeholders.

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