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

LOK SABHA
STARRED QUESTION NO. 361
TO BE ANSWERED ON THE 13TH DECEMBER, 2019
FUNCTIONING OF CDSCO

***361. SHRI SUNIL KUMAR MONDAL:**

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

(a) whether the Government has reviewed the functioning of Central Drugs Standard Control Organisation (CDSCO);

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

(c) whether any complaint has been registered regarding the death of any person due to use of spurious/counterfeit medicine during the last five years and the current year; and

(d) if so, the details thereof along with the action taken on such complaints?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)

(a) to (d): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 361* FOR 13TH DECEMBER, 2019

(a) & (b) The Government of India is continuously involved in monitoring/review of the functioning of Central Drugs Standard Control Organisation (CDSCO) to strengthen the Drugs regulatory system.

Earlier in 2011 and 2012, Department Related Parliamentary Standing Committee on Health and Family Welfare reviewed the functioning of CDSCO in respect of various aspects such as mandate and structure of CDSCO, role of the State drug regulatory authority, capacity building of CDSCO and Central & State Drug Testing Laboratories, New Drugs and Clinical Trial approval, banning of drugs, issue of granting licence of Fixed Dose Combinations without approval of Drugs Controller General (India) [DCG(I)], issues regarding similar brand names, post marketing surveillance, spurious/sub-standard drugs, advertisement of prescription drugs in media, etc.

Further, during the last five years, based on regular review of CDSCO and its functioning, a number of measures has been taken to address these issues which include strengthening of infrastructure and manpower of CDSCO; framing of Medical Devices Rules, 2017; New Drugs and Clinical Trials Rules, 2019; online submission and processing of various applications under SUGAM portal; 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; amendments in Drugs and Cosmetics Rules including prohibition of advertisement of Schedule H, H 1 & X drugs and provision to address issues related to similar brands etc.

(c): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provisions of the Act and Rules.

As per information received from State/UT Drugs Controllers, no complaint has been registered regarding death of any person due to use of spurious/counterfeit medicine during the last five years and the current year.

(d): Does not arise.

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