

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

**LOK SABHA
UNSTARRED QUESTION NO. 2539
TO BE ANSWERED ON 04TH AUGUST, 2023**

CONTAMINATED MEDICINE/SYRUP

**†2539: SHRIMATI RAMA DEVI:
SHRIMATI NAVNEET RAVI RANA:
MS. LOCKET CHATTERJEE:
DR. SANJAY JAISWAL:
SHRIMATI GEETA KORA:
SHRI TIRATH SINGH RAWAT:
SHRI RAMESH CHANDER KAUSHIK:
SHRI AJAY KUMAR MANDAL:
SHRI JUGAL KISHORE SHARMA:**

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

- (a) whether the Government has conducted any survey to assess the spread of spurious, substandard and contaminated medicines in the Indian Market and if so, the details thereof;
- (b) whether the Government has formulated any policy for the regulation of spurious, substandard and contaminated medicines in the Pharmaceutical Industry of the country and if so, the details thereof and if not, the reasons therefor;
- (c) the action taken/proposed to be taken by the Government to deal with the issue of spurious medicines in the country;
- (d) the details of the various health schemes being implemented in Maharashtra by the Government, district-wise;
- (e) the funds allocated, released and utilized during the year 2021-22 and 2022-23 for the said purpose, scheme-wise and district-wise; and
- (f) the details of the Central schemes being implemented to improve the basic facilities in the hospitals of Maharashtra during the years 2021-22 and 2022-23, district-wise?

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

- (a): A National Drug Survey was conducted in the year 2014-16 to assess the extent of Not of Standard Quality (NSQ)/Spurious drugs. Out of a total of 47,012 drug samples drawn

from both Government and private sources, the estimated percentage of NSQ and spurious drugs from Retail outlets was 3% and 0.023% respectively, while that from Government sources was 10.02% and 0.059% respectively.

(b) & (c): The manufacture, sale and distribution of drugs are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules there under. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by the respective State Governments and SLAs are empowered to take the action in case of violation of any condition of licenses.

CDSCO and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the quality of medicines in the country:-

- (i). The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.
- (ii). States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.
- (iii). The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.
- (iv). To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.
- (v). The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.
- (vi). The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.
- (vii). CDSCO coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

Isolated complaints regarding spurious drugs are received in Central Drugs Standard Control Organisation (CDSCO). As and when such complaints are received, based on merit, the matter is taken up by the CDSCO in coordination with State/UT Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945. As per information received from various States/UT's Drugs Controllers, number of drug samples tested, number of drug samples reported spurious/adulterated, sub-standard drugs and action taken against the offenders during last three years i.e. 2019-2022 is as below.

Year (1 st April of preceding year to 31 st March of following year)	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs
2019-20	81,329	2497	199	421
2020-21	84,874	2652	263	236
2021-22	88,844	2545	379	592

(d) to (f): The Ministry of Health and Family Welfare supplements the efforts of all States/UTs in healthcare sector through various Central Schemes. Few of the major Schemes implemented in the State of Maharashtra are National Health Mission (NHM), Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM) and Emergency COVID Response Package (ECRP-I & ECRP-II), National AIDS and STD Control Programme (NACP), Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), etc. Under the National Health Mission (NHM), Government of India provides financial and technical support to States/UTs to strengthen their health care systems for provision of equitable, affordable healthcare to all its citizens based on requirements posed by the States in their Programme Implementation Plans (PIPs).

NHM support is provided for provision of a range of free services related to maternal health, child health, adolescent health, family planning, universal immunisation programme, and for major diseases such as Tuberculosis, vector borne diseases like Malaria, Dengue and Kala Azar, Leprosy etc.

Other major initiatives supported under NHM include Janani Shishu Suraksha Karyakram (JSSK), Rashtriya Bal Swasthya Karyakram (RBSK), implementation of Free Drugs and Free Diagnostics Service Initiatives, Mobile Medical Units (MMUs), Ambulance Services & Teleconsultation services, PM National Dialysis Programme and implementation of National Quality Assurance Framework in all public health facilities. The funds under the NHM framework are released State-wise and not district-wise. The details of Central funds released and Expenditure under the major Schemes in the State of Maharashtra is provided in “**Annexure-I**”

The Ministry of Health & Family Welfare is implementing a Centrally Sponsored Scheme (CSS) namely (i) Establishment of new Medical Colleges attached with existing district/referral hospitals, (ii) Up-gradation of existing state Government/Central Government medical colleges to increase MBBS seats in the country, (iii) Strengthening and up-gradation of State Government Medical colleges for starting new PG disciplines and increasing PG seats. The above schemes are dealt in collaboration with State/UT Governments. Details of the Scheme with respect to the State Government of Maharashtra is provided below:

- (i). Under Phase-I of 'Establishment of new medical colleges attached with existing district/referral hospitals', one medical college at Gondia was approved. An amount of Rs.113.40 Crore has been released to the State Government. The college has become functional.
- (ii). Under Phase-III of 'Establishment of new medical colleges attached with existing district/referral hospitals', One medical college at Nandurbar was approved. An amount of Rs.150 Crore has been released to the State Government. The college has become functional.
- (iii). Under the Centrally Sponsored Scheme for Strengthening and up-gradation of Government Medical Colleges for Increase of PG seats, 11 medical colleges were approved for increasing a total of 692 seats. An amount of Rs. 233.39 Crore has been released so far as Central Share in this scheme.
- (iv). Under the Scheme for upgradation of existing State Government/Central Government medical colleges to increase MBBS seats in the country, an amount of Rs.72 Crore has been released to the State Government till date. A total of 100 seats have been increased.
- (v). Under PM Swasthya Suraksha Yojana (PMSSY), one (1) All India Institute of Medical Sciences has already been established in Nagpur. Further, under another component of the scheme, six (6) existing Government Medical Colleges in Maharashtra have been upgraded in the State of Maharashtra.
- (vi). During the 15th Finance Commission period, Health grants amounting to Rs. 1,330.72 crore and Rs. 1,204.33 crore for the Financial year 2021-22 and 2022-23 respectively, has been approved for the State of Maharashtra.

“Public Health and Hospital” is a State subject and the primary responsibility of ensuring availability of healthcare facilities lies with respective State/UT Governments including Maharashtra.

Annexure-I

(I) Central Releases and Expenditure to the State of Maharashtra under National Health Mission (NHM)

Financial Year	Amount (Rupees in Crore)	Expenditure (Rupees in Crore)
2021-22	1,769.67	4,227.31
2022-23	2,187.13	4,501.75

Note:

- (i) The above releases relate to Central Government Grants and do not include State Share Contribution.
- (ii) Expenditure includes expenditure against Central Release, State release & unspent balances at the beginning of the year. Expenditure are as per Financial Management Reports submitted by States/UTs and are provisional.

(II) Central Releases to the State of Maharashtra under Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM)

Financial Year	Amount (Rupees in Crore)
2021-22	17.45
2022-23	4.07

Note:

- (i) The above releases relate to Central Government Grants and do not include State Share Contribution.
- (ii) The State of Maharashtra has reported Nil expenditure during the FY 2021-22 and FY 2022-23.

(III) Central Releases under Emergency COVID Response Package (ECRP-I & ECRP-II) to the State of Maharashtra

Scheme	Amount (Rupees in Crore)
ECRP-I	1248.08
ECRP-II	820.77

Note:

- (i) Release of funds under ECRP Phase-I is 100% Centrally Funded.
- (ii) Release of funds under ECRP Phase-II is as per the approved Centre-State funding under NHM per the approved Centre-State funding under NHM.