

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

**LOK SABHA  
UNSTARRED QUESTION NO. †971  
TO BE ANSWERED ON 08<sup>TH</sup> DECEMBER, 2023**

**QUALITY OF MEDICINAL PRODUCTS**

**†971: SHRI RAMESH CHANDER KAUSHIK:**

**SHRI SUNIL KUMAR PINTU:**

**SHRIMATI NAVNEET RAVI RANA:**

**SHRIMATI RAMA DEVI:**

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

- (a) the details regarding the registered cases of spurious medicinal products along with the number of cases where punishment has been given State/UT-wise;
- (b) whether the Government has taken/proposes to take steps to strengthen the basic infrastructure in Maharashtra under Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) and if so, the details thereof;
- (c) whether the Government has taken steps to maintain the quality standard of the medicinal products since 2019, if so, the details thereof; and
- (d) the expenditure incurred on the scheme during the last three years and the current year, State/UTs/district-wise?

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

(a): Isolated complaints regarding spurious drugs are received. As and when such complaints are received, based on merit, the matter is taken up by CDSCO in coordination with State/UT's Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and Rules 1945.

As per information received from State/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 each of the last three years (from 2020-2023) is enclosed as Annexure-I.

(b): Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) aims at correcting regional imbalances in the availability of affordable tertiary healthcare services and to augment facilities for quality medical education in the country. The Scheme has two components, namely, (i) Setting up of All India Institute of Medical Sciences (AIIMS); and (ii) Up-gradation of existing Government Medical Colleges/Institutions (GMCIs). The setting up of AIIMS contains Medical College, Nursing College, Hospital, Trauma Centre, Emergency, Blood Bank, ICU, Diagnostic & Pathology, Research etc. Up-gradation of GMCIs under PMSSY broadly involves construction of Super Specialty Block (SSB) and/or Trauma Care Centre / or other facilities and/or procurement of medical equipment. In Maharashtra, one AIIMS at Nagpur has been established and 6 projects have been taken up for the up-gradation of Gmci under PMSSY. The details of these projects are as under:

S. No.	Name of GMCs	Phase	Approved outlay (Rs. In Cr)			Central fund released (Rs. Cr)	Status
			Central Share	State/ Institute Share	Total		
1	Grant Medical College & Sir JJ Group of Hospitals, Mumbai	I	100.00	20.00	120.00	93.87	Completed
2	Government Medical College, Nagpur	II	125.00	25.00	150.00	120.25	
3	Govt. Medical College, Aurangabad	III	120	30	150	102.93	
4	Govt. Medical College, Latur		120	30	150	101.15	
5	Govt. Medical College, Akola		120	30	150	98.01	
6	Shri Vasantrao Naik Govt. Medical College, Yavatmal		120	30	150	103.09	
7	AIIMS, Nagpur					1235.04 (Fund release as on date)	

(c): CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines in the country. Details of such measures taken since 2019 are as under.

- i. On 17-11-2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.
- ii. On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and

tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

- iii. On 06.11.2019, the Drugs and Cosmetics Rules, 1945 were amended vide G.S.R 828 (E) making it mandatory that, in case the applicant intends to market the drug under a brand name or trade name the applicant shall furnish an undertaking in Form 51 to the licensing authority that such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.
- iv. On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.
- v. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 492 till January 2022. Further, 220 posts have been created on 16-06-2022 and 219 posts have been created on dated 13.07.2022.
- vi. Central regulator 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.

(d): Details of funds released under Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) for All India Institute of Medical Sciences (AIIMS); and Government Medical Colleges/Institutions (GMCI) during the last three years and current year is annexed at Annexure- II.

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## Annexure-I

As per information received from various States/U.Ts Drugs Controllers, Number of drug samples tested and enforcement action taken, number of drug samples reported Not of Standard Quality/spurious/adulterated and enforcement action taken by the States/UTs Drugs Controller during last three years is as below:

Year (1 <sup>st</sup> April of preceding year to 31 <sup>st</sup> 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	No. of persons arrested
2020-21	84,874	2652	263	236	164
2021-22	88,844	2545	379	592	450
2022-23	*89729	2921	422	642	262

\*Except from State of Rajasthan

**Annexure II**

Statement refer to in reply to Part (d) of Lok Sabha Unstarred Question no. †971 dated  
08.12.2023

S. No.	Government Medical College/Institutions	Funds released during last 3 years (Amount in Rs.)		
		(2020-21)	(2021-22)	(2022-23)
1	Government Medical College, Anantapur	0.00	8030028.74	3000552.98
2	Siddhartha Medical College, Vijaywada	281565.50	2548906.19	1140719.73
3	Kakatiya Medical College, Warangal, Telangana	30069099.00	998209.39	16036240.73
4	Rajiv Gandhi Institute of Medical Science, Adilabad, Telangana	31658675.00	3628769.65	1907787.62
5	Gauhati Medical College, Guwahati, Assam	3427418.39	3593059.05	1295033.38
6	Assam Medical College, Dibrugarh	4197169.22	1637042.22	1651381.07
7	Sri Krishna Medical College, Muzaffarpur, Bihar	199828769.60	26339.71	0.00
8	Govt. Medical College, Darbhanga, Bihar	27515076.64	162618845.41	82492392.67
9	Goa Medical College, Goa	12800000.00	0.00	0.00
10	P.D.U Government Medical College, Rajkot, Gujarat	167013868.00	2003804.85	24459517.47
11	Indira Gandhi Medical College, Shimla, H.P	879100.00	0.00	106116390.92
12	Patliputra Medical College, Dhanbad	80080154.00	170734.07	19563.79
13	Vijaynagar Institute of Medical Science, Bellary, Karnataka	45914425.00	1909701.62	1286425.11
14	Karnataka Institute of Medical Science, Hubli, Karnataka	29386668.00	1845549.31	64431888.07
15	Kozhikode Medical College, Kozhikode, Kerala	146675984.78	576670.09	2223421.27
16	T.D Medical College, Alappuzha, Kerala	140240277.00	36163.49	1055809.62
17	Netaji Subhash Chandra Bose Medical College, Jabalpur	1535526.09	2898925.35	563277.84
18	Shyam Shah Medical College, Rewa	520113.24	4018697.29	1097659.88

S. No.	Government Medical College/Institutions	Funds released during last 3 years (Amount in Rs.)		
		(2020-21)	(2021-22)	(2022-23)
19	Gajra Raje Medical College, Gwalior	409598.02	3179710.65	801177.04
20	Government Medical College, Latur	423539.56	1972790.38	1035418.20
21	Govt. Medical College, Akola	60164002.00	233726.39	1361304.11
22	Shri Vasantnaik Govt. Medical College, Yavatmal	175291.00	486286.99	588067.32
23	Government Medical College, Aurangabad	573155.68	2091900.30	247976.24
24	MKCG Medical College, Berhampur	4634991.76	1825746.28	2046009.69
25	VSS Medical College, Burla	30265224.90	397539.67	9522948.33
26	Government Medical College, Patiala	1873519.21	2155021.99	52836233.66
27	Sardar Patel Medical College, Bikaner	726445.08	1504397.19	37739260.84
28	Government Medical College, Kota	309795.22	2978185.28	10921288.70
29	Rabindra Nath Tagore Medical College, Udaipur	7950428.77	2714474.04	1091000.91
30	Thanjavur Medical College, Thanjavur (Tamil Nadu)	64866652.00	2554977.63	300037.55
31	Tirunelveli Medical College, Tirunelveli (Tamil Nadu)	44500000.00	2719299.85	175147.23
32	Agartala Government Medical College, Tripura	120412988.00	76200829.35	975684.53
33	Maharani Laxmi Bai Medical College, Jhansi	1062051.07	2901082.86	430413.94
34	Motilal Nehru Medical College, Allahabad	290104.48	2430526.02	294633.63
35	Government Medical College, Gorakhpur	233260.00	2109776.89	589802.69
36	LLRM Medical College, Meerut	416824.00	1580933.12	576018.95
37	North Bengal Medical College, Siliguri, Darjeeling	1415776.30	2161331.89	121990.82
38	BS Medical College, Bankura	31344468.00	484919.84	1148897.24
39	Government Medical College, Malda	760851.00	1581242.36	877398.20

S. No.	Government Medical College/Institutions	Funds released during last 3 years (Amount in Rs.)		
		(2020-21)	(2021-22)	(2022-23)
40	Government Medical College, Bilaspur	19852559	267900000	0
41	Government Medical College, Jagdalpur	2509048		0
42	Government Medical College, Patna	211119177	0	0
43	Government Medical College, Bhagalpur	306609345	0	0
44	Government Medical College, Gaya	300045848	0	0
45	Government Medical College, Agra	281495964	2908848	5482575
46	Government Medical College, Kanpur	90071556	7657487	10965150
47	Government Medical College, Indore	68921000	809800	0
48	Government Medical College, Bhavnagar	59156000	2311821	0
49	Government Medical College, Jaipur	72952284	9741907	22913700
50	Government Medical College, Cuttack	2268000	0	0
51	Government Medical College, Surat	0	0	0
52	University College of Medical Sciences - Guru Teg Bahadur Hospital, Delhi			0
53	Institute of Medical Sciences, Banaras Hindu University, Varanasi	0		0
54	Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum	0		0
55	RIO IMS BHU Varanasi	125454000		0
56	Indira Gandhi Institute of Medical Sciences, Patna	0	180770000	0

Sr.No.	All India Institute of Medical Sciences (AIIMS)	Fund Released Funds released during last 3 years for new AIIMS (Rs. in Crores)			
		(2020-21)	(2021-22)	(2022-23)	(2023-24)
1	AIIMS, Mangalagiri, Andhra Pradesh	261.10	258.17	181.95	7.05
2	AIIMS, Nagpur, Maharashtra	231.77	219.11	65.35	0.00
3	AIIMS, Kalyani, West Bengal	274.02	331.73	44.62	8.13
4	AIIMS, Gorakhpur, U.P	127.13	96.36	41.08	8.67
5	AIIMS, Bathinda, Punjab	202.02	47.57	110.46	0.00
6	AIIMS, Guwahati, Assam	166.32	179.94	213.90	77.82
7	AIIMS, Bilaspur, Chhattisgarh	378.78	444.02	121.06	1.06
8	AIIMS, Deoghar, Jharkhand	206.63	350.70	189.88	25.91
9	AIIMS, Jammu	322.35	305.00	398.45	410.24
10	AIIMS, Kashmir	211.16	130.00	290.00	250.00
11	AIIMS, Madurai, Tamil Nadu	4.23	-		6.02
12	AIIMS, Rajkot, Gujarat	161.86	128.96	380.52	155.03
13	AIIMS, Bibinagar, Telangana	6.77	5.42	350.63	144.97
14	AIIMS, Manethi, Haryana	0.00	0.00	5.00	6.03
15	AIIMS, Darbhanga, Bihar	0.00	0.00	0.00	0.00