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

LOK SABHA
UNSTARRED QUESTION NO. 2622
TO BE ANSWERED ON 04TH AUGUST, 2023

PROMOTION OF GENERIC MEDICINES

2622: SHRI SUNIL BABURAO MENDHE:
SHRI GHANSHYAM SINGH LODHI:

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

(a) whether the Government has ensured that only generic medicines are made available in Government Civil Hospitals and Health Centres and if so, the details thereof;

(b) whether the Government has issued directives to the Government doctors to prescribe only generic medicines and not branded ones and if so, the details thereof;

(c) whether the Government is aware that most of the registered doctors are not prescribing generic medicines and if so, the details thereof;

(d) whether any case has been registered against such doctors who are not prescribing generic medicines and if so, the details thereof, State/UT-wise;

(e) whether there is a public perception that quality of generic medicines is substandard and if so, necessary steps taken in this regard including the steps taken to ensure the quality of such medicines;

(f) the number of generic medicines stores opened across the country during last three years, State/UTwise including Maharashtra and Uttar Pradesh;

(g) the total production, sale and export of generic medicines during the last three years; and

(h) the details of other steps the Government proposes to take to increase the availability and credibility of generic medicines?

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

(a) to (d): The Directorate General of Health Services has directed all Central Government hospitals to prescribe generic medicines only. Similar instructions also have been issued to 'prescribe drugs with generic name legibly' to all Central Government Health Scheme (CGHS) Doctors and Wellness Centres.

Moreover, Clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs. Further, the erstwhile Medical Council of India (MCI) had issued Circulars vide which all the Registered Medical Practitioners have been directed to comply with the aforesaid provisions.

The National Medical Commission Act, 2019, empowers the State Medical Councils/ Ethics and Medical Registration Board (EMRB) of the Commission to take disciplinary action against a doctor for violation of the provision of the aforesaid Regulations. When complaints are received against the violation of code of ethics for doctors, such complaints are referred by EMRB (previously by erstwhile MCI) to the concerned State Medical Councils where the doctors/medical practitioners are registered. States are advised to ensure prescription of generic drugs in public health facilities. Health being State subject, data of doctors not prescribing generic medicine is not maintained centrally.

(e): The safety, efficacy and quality of the medicines, whether branded or generic, imported or manufactured for sale, distribution in the country are required to comply to the same standard as specified in the Second Schedule of the Drugs and Cosmetics Act, 1940 and Rules. Isolated complaints regarding quality of drugs are received from time to time. As and when such complaints are received, the matter is referred to State Licensing Authorities (SLAs) for taking action as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945, as the SLAs are empowered to take action in case of any violation to the provisions of the said Act and Rules.

Central Drugs Standard Control Organization (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.

As per information received from Medical Stores Organization (MSO), all the batches of generic medicines procured by them for CGHS, para-military forces, state & central prisons, civil institutions etc, are sent to 02 National Accreditation Board for Testing and Calibration Laboratories (NABL) for quality check before they are supplied to the indenters.

(f): As informed by Department of Pharmaceuticals (DoP), under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), 3,838 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) have been opened across the country during the last three Financial Years, of which 216 Kendras have been opened in Maharashtra and 528 Kendras have been opened in Uttar Pradesh. State/UT-wise including Maharashtra and Uttar Pradesh is provided as **Annexure - I**.

(g): As per information provided by the National Pharmaceutical Pricing Authority, under DoP, the total sale of medicines by stockists/ dealers to retailers in the country is estimated as under:

Year	Sales Value (Rupees in Crore)
2019-2020	1,44,485.08
2020-2021	1,47,586.41
2021-2022	1,69,234.82
April 2022 - December 2022	1,40,865.31

(h): To increase the availability of generic medicines to the common man, sold through PMBJKs under PMBJP, till 30th June 2023, 9,512 PMBJKs have been opened across the country. Further, free drug initiatve of National Health Mission (NHM), support is provided for provision of essential generic drugs free of cost in public health facilities.

In order to increase availability of Generic Medicines in the Country, the Department of Pharmaceuticals and Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementing agency of scheme periodically requests State/UT Governments/ district administrations to create awareness about the scheme and provide rent free space for opening Janaushadhi Kendras in Community Health Centre (CHC)/ Primary Health Centre (PHC)/Government Hospitals. PMBI also spreads awareness about the scheme through advertisements in Print Media, Radio, TV & Cinema as well as Outdoor publicity like

Hoardings, Bus Queue Shelter branding, Bus branding, Auto wrapping, etc. In addition, public is educated about the benefits of Jan Aushadhi generic medicines and the scheme through various social media platforms regularly. Further, Jan Aushadhi Diwas is celebrated every year on 7th March for further dissemination and spreading awareness about the scheme. Workshops and seminars are being organized during various event celebrations such as Azadi Ka Amrit Mahotsav, National Unity Day week, etc. to educate the citizens about the Jan Aushadhi generic medicines.

CDSCO and Ministry of Health & Family Welfare has also taken various regulatory measures to ensure the credibility of generic medicines, as under:

(i). Directions have been issued to all the Principal/Health Secretaries of all States/UTs to instruct their respective Drug Licensing Authorities to grant/ renew licenses to manufacture for sale or for distribution of drugs in proper/generic names only,

(ii). Drugs and Cosmetics Rules, 1945 has been amended making it mandatory that the application for grant of license for a drug formulation containing single active ingredient shall be made only in proper name,

(iii). Amendments have been made in the Drugs and Cosmetics Rules, 1945 for 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 Drug 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.

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Annexure - I

State/UT- wise list of Pradhan Mantri Bhartiya Janaushadhi Kendras opened across the country during the last three financial years					
S No	State/UT	2020-21	2021-22	2022-23	Grand Total
1	Andaman & Nicobar	0	7	0	7
2	Andhra Pradesh	10	5	16	31
3	Arunachal Pradesh	0	0	1	1
4	Assam	11	15	23	49
5	Bihar	62	63	85	210
6	Chandigarh	1	0	2	3
7	Chhattisgarh	17	12	7	36
8	Delhi	157	81	14	252
9	Goa	1	1	1	3
10	Gujarat	76	44	17	137
11	Haryana	38	37	37	112
12	Himachal Pradesh	6	6	3	15
13	Jammu and Kashmir	5	38	95	138
14	Jharkhand	5	9	10	24
15	Karnataka	257	99	117	473
16	Kerala	229	247	19	495
17	Ladakh	0	0	0	0
18	Lakshwadeep*	0	0	0	0
19	Madhya Pradesh	46	26	38	110
20	**Maharashtra**	121	59	36	**216**
21	Manipur	1	3	3	7
22	Meghalaya	5	1	3	9
23	Mizoram	0	0	0	0
24	Nagaland	0	4	1	5
25	Odisha	74	88	55	217
26	Puducherry	0	3	1	4
27	Punjab	84	29	15	128
28	Rajasthan	16	29	16	61
29	Sikkim	1	0	1	2
30	Tamil Nadu	163	97	54	314
31	Telangana	26	22	19	67
32	The Dadra & Nagar Haveli and Daman & Diu	12	5	0	17
33	Tripura	0	0	1	1
34	**Uttar Pradesh**	194	135	199	**528**
35	Uttarakhand	24	15	7	46
36	West Bengal	36	37	47	120
Grand Total		1678	1217	943	3838

* Medicines are directly supplied to the administration of UT of Lakshwadeep