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

LOK SABHA UNSTARRED QUESTION NO. 3122 TO BE ANSWERED ON 13TH DECEMBER, 2024

QUALITY AND EFFECTIVENESS OF CGHS MEDICINES

3122. SHRI LUMBA RAM:

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

- (a) whether Central Drug Standards Control Organisation and any other reputed or Government institution check the standards of Allopathy, Homoeopathy, Ayurvedic and Unani medicines being supplied to the beneficiaries of the CGHS Wellness Centres;
- (b) if so, the details of the sub standard medicines found during the last three years with their manufacturers along with the measures being taken to improve the quality and effectiveness of the medicines being supplied through CGHS Wellness Centres; and
- (c) if not, the reasons therefor?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI PRATAPRAO JADHAV)

(a) to (c) Central Drug Standard Control Organisation (CDSCO), other reputed institutes and NABL accredited Labs, check the standards of Allopathic medicines, through the system of sample collection and subsequent lab testing.

In Homeopathy, the Homoeopathic Medical Store Depot (HMSD) ensures quality by sourcing medicines from CGHS-approved firms with lab reports from accredited labs. The Homoeopathic Medicine Inspection Team verifies compliance with Homoeopathic Pharmacopeia of India (HPI) standards. Batches failing to meet standards undergo further testing, ensuring only approved medicines are accepted.

In Ayurveda, the manufacturers supplying Ayurvedic medicines to the CGHS Ayurvedic Medical Store Depot (AMSD) are WHO-GMP/COPP or QCI certified. Each batch is tested at government-approved NABL accredited laboratories to ensure quality.

In Unani, CGHS procures GMP-certified Unani medicines and ensures quality by obtaining in-house analytical reports and quality analysis from government-approved or NABL accredited labs. These reports test for identity, purity, quality, and strength as per the Unani Pharmacopeia.

The list of substandard medicines found during last three years is annexed at **Annexure**. Government has taken following measures to improve quality and effectiveness of the medicines being supplied through CGHS Wellness Centers:

- (i) Effective grievance system within CGHS, allowing patients to raise issues related to medicines, with prompt action taken to address and resolve their concerns.
- (ii) Medical Store Organization (MSO), a central procuring agency, ensures the procurement of safe, high-quality products by mitigating risks like substandard or counterfeit goods. It involves inspections at key stages like pre-dispatch, receipt, and post-installation and are conducted by qualified personnel to verify compliance with contract specifications. Findings are documented in Inspection Reports, which are used for record-keeping and payment authorization.
- (iii) Details of quality assurance of Jan Aushadhi medicines are as under:
 - (a) Pharmaceuticals & Medical Devices Bureau of India (PMBI) investigates product complaints and reviews control samples.
 - (b) Random sampling from Jan Aushadhi Kendras and warehouses is conducted, with retesting in NABL labs.
 - (c) Corrective and preventive actions (CAPA) are taken as necessary.
 - (d) PMBI has started a comparative study between branded and Jan Aushadhi generic products.
 - (e) Not of Standard Quality (NSQ) rate for open market medicines is 3.70%, while PMBI products maintain a rate of 0.34%.
- (iv) High value restricted medicines are procured on case-to-case basis from rate contracted manufacturers who have in-house lab testing facility for products, DCGI approval and Good Manufacturing Practices (GMP) certificate, etc.

List of substandard medicines found during last three years

S.No.	Medicine Name	Batch No.	Source of	Manufacturer
			Procurement	
1	Ramipril 5 mg	RMFT901	GMSD	Unicure India Ltd
2	Methylcobalmin 500 mcg	MBT904	GMSD	Unicure India Ltd
3	Omeprazole 20 mg Cap	GM20126	GMSD	SKYMAP
				PHARMACEUTICAL
4	Enalpril 2.5 mg Tab	GB21079	GMSD	ORTIN
5	Tab Lorazpam 1MG	TLRZ-013	GMSD	Medipol Pharma India
6	Ranitidine 150 mg	NSTX 11	GMSD	HAL
7	Sertaline 50 mg	GM20105	GMSD	SKYMAP PHARMA
8	Tab Ascorbic Acid 500mg	VATZ02	GMSD	HAL
9	Acebrophylline 100 mg	PF8AA04	GMSD	Pure& cure health
10	Tab Fenofibrate 160 mg	MG22007	GMSD	LABORATOIRES
				GRIFFON
11	Tacrolimus cream 0.03%	HT0203	GMSD	MED MANOR
				ORGANICS
12	Tab Divalpoex Sod. 500 mg	PF8A019	GMSD	Pure & Cure
13	Tab L Methyl Folate 7.5 mg	PF8CY03	GMSD	Pure & Cure
14	Sy.Paracetamol	HVEZ01	GMSD	HAL
15	Gabapentin 300 mg	22SIGTB467	GMSD	Unicure India Ltd
16	Olmesartan 40 mg	GT221831	GMSD	THEON PHARMA
17	Folic Acid 5 mg	T112005	GMSD	ANG LIFESCIENCE
18	Rosuvastatin +Vit.D3	22SIGTA576	GMSD	SYNOKEM PHARMA
	10+1000 IU			
19	Bromelain+Rutoside+Trypsin	PF8CC12	GMSD	Pure & Cure
	180+200+96			
20	Cetirizine Syp.	L042301	GMSD	Bengal Chemicals
		L042302		Pharmaceuticals Ltd
21	Diacerein 50mg (G02023)	DCT1102	GMSD	Unicure India Ltd
22	Losartan 25MG (G12047)	3803821	GMSD	KAPL
23	Amlodipine And Perindopril	K2102200	GMSD	INTAS
	5mg + 4mg (G12169)			
24	Ranitidine 150 mg	0403423	GMSD	KAPL
25	Clopidogrel 75 mg	T2405299	GMSD	Ribpra Formulation
26	Ethamsylate 500 mg	ELT1104	GMSD	Unicure India Ltd
27	Fexofenadine 120 mg	MP9AA2303	GMSD	Maxtar Boigenics
28	Hydroxychloroquine	HCQ09E24	GMSD	Bajaj Healthcare Ltd
	Sulphate 200 mg			
29	Methylcoblamin 500 mcg	MBT904	GMSD	Unicure India Ltd