

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 1988
TO BE ANSWERED ON 6th DECEMBER 2024

Supply of Medicines to Jan Aushadhi Kendras

**1988. Shri Rajesh Ranjan:
Dr. Amar Singh:**

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) the details of generic drug manufacturers supplying medicines to Jan Aushadhi Kendras, State-wise;
- (b) the total number of drug inspection officers in the country, State-wise;
- (c) whether the Government has taken note of the apprehensions raised that the proposed changes by the CDSCO could result in poor-quality drugs being sold in Jan Aushadhi outlets; and
- (d) if so, the steps taken/proposed to be taken by the Government to ensure proper quality control?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SMT. ANUPRIYA PATEL)**

(a): As on date, 206 pharmaceutical manufacturers are associated with Pharmaceuticals & Medical Devices Bureau of India (PMBI), the implementation agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) for supplies of medicines, surgical devices, nutraceuticals and ayurvedic products. List of these pharmaceutical manufacturers is enclosed as **Annexure**.

(b): The number of sanctioned posts of Drugs Inspector in CDSCO is 504 which include 419 posts of Drugs Inspector and 85 posts of Drugs Inspector (Medical device). State-wise information of Drug Inspection Officers is not maintained centrally.

(c): As informed by Ministry of Health & Family Welfare, there is no such proposal.

(d): For ensuring the quality of products, Pharmaceuticals & Medical Devices Bureau of India (PMBI) procures medicines only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers. Each batch of drug is tested at laboratories accredited by ‘National Accreditation Board for Testing and Calibration Laboratories’ (NABL). Only after passing the quality tests, the medicines are dispatched to Jan Aushadhi Kendras (JAKs).

Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken various measures to ensure quality, efficacy and safety of medicines manufactured in the country. The key measures are as stated below;

- i. In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) have conducted risk-based inspections of more than 400 premises. The firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality, complaints, criticality of the products etc. Based on findings of inspections, more than 300 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.
- ii. Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. As per the amendment, the revised Good Manufacturing Practices and Requirements shall come into force for manufacturers for implementation as under:

Category of manufacturers [Based on turnover (INR)]	Time line for implementation
Large manufacturers (Turnover > 250 crores)	Six months from the date of publication of these rules.
Small and Medium manufacturers (Turnover ≤ 250 crores)	Twelve months from the date of publication of these rules.

- iii. 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.
- iv. 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.
- v. 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.
- vi. 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.
- vii. States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.
- viii. 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.
- ix. 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.

- x. 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.
- xi. 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.
- xii. Central government is providing regular Residential, regional training and workshops to CDSCO, State Drug Regulatory Authorities on Good Manufacturing Practices. In the training Financial Year 2023-24 CDSCO has trained 22854 persons while in F.Y 2024-25 so far 13007 persons have been trained.
- xiii. Further, for strengthening the drug regulatory system in the country both at the Central and State level, the Government had approved Rs.1750 Crore. Out of this, Rs. 900 Crore was for strengthening the central drug regulatory structures and Rs. 850 Crore is for the Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS) which envisages to strengthen the laboratory infrastructure and up-gradation of existing State Drug Controller offices in States. So far under the SSDRS scheme, 17 New Drug Testing Labs have been constructed and 24 existing labs have been up-graded.

Annexure

Annexure referred to in reply to part (a) of the LOK SABHA UNSTARRED Q. No. 1988 for answer on 06.12.2024 raised by Shri Rajesh Ranjan and Dr. Amar Singh regarding Supply of Medicines to Jan Aushadhi Kendras

S. No.	Name of the Manufacturer	Category
1	Aculife Healthcare Pvt. Ltd.	Private
2	Admac Lifesciences	Private
3	Aegis Lifesciences Private Limited	Private
4	Affy Parenterals	Private
5	Agio Pharmaceuticals Ltd.	Private
6	Aishwarya Healthcare	Private
7	Ak Health Tech Private Limited	Private
8	Akums Drugs & Pharmaceuticals Limited (Plant-1)	Private
9	All Heavens Exim	Private
10	Amkay Products Pvt. Ltd.	Private
11	Andhra Pradesh Medtech Zone Limited	SPSU
12	Asoj Soft Caps Pvt. Ltd	Private
13	Bajaj Healthcare Limited	Private
14	Bal Pharma Ltd.	Private
15	Bdr Pharmaceuticals International Pvt. Ltd.	Private
16	Bharat Parentral Ltd	Private
17	Bharti Milk Foods Pvt Ltd	Private
18	Biocon Biologics Limited	Private
19	Biodeal Pharmaceuticals Limited	Private
20	Biogenix Inc Pvt. Ltd.	Private
21	Biological E Limited	Private
22	Brisk Surgical Cotton Limited	Private
23	Briyosis Soft Caps Private Limited	Private
24	Cadila Pharmaceuticals Ltd.	Private
25	Care Medical Devices Limited	Private
26	Centaur Pharmaceuticals Pvt. Ltd.	Private
27	Centurion Remedies Pvt. Ltd.	Private
28	Cian Healthcare Pvt. Ltd.	Private
29	Cipco Pharmaceuticals	Private
30	Cipla Limited	Private
31	Cmg Biotech Pvt. Ltd.	Private
32	Concept Pharmaceuticals Ltd	Private
33	Consern Pharma Ltd.	Private
34	Continental Milkose (India) Limited	Private
35	Coral Laboratories Ltd	Private
36	Crescenzia Wellness Private Limited	Private

37	Cupid Limited	Private
38	Daffodills Pharmaceuticals Ltd.	Private
39	Divine Laboratories Pvt Ltd	Private
40	Dynamic Techno Medicals Private Limited	Private
41	East African (India) Overseas	Private
42	Elnova Pharma	Private
43	Eris Lifesciences Limited	Private
44	Eskag Pharma Pvt.Ltd	Private
45	Essenzaa Nutrition Pvt. Ltd.	Private
46	Eucare Pharmaceuticals Pvt Ltd	Private
47	Fdc Limited	Private
48	Fertin India Private Limited	Private
49	Geno Pharmaceuticals Pvt Ltd	Private
50	Gentech Healthcare Pvt. Ltd.	Private
51	Globela Pharma Pvt. Ltd.	Private
52	Gls Pharma Ltd	Private
53	Gnosis Pharmaceuticals Pvt Ltd	Private
54	Hab Pharmaceuticals & Research Ltd.	Private
55	Halewood Laboratories Pvt. Ltd.	Private
56	Haseeb Pharmaceuticals Pvt. Ltd.	Private
57	Health Biotech Limited	Private
58	Healthium Medtech Limited	Private
59	Healthy Life Pharma Pvt. Ltd.	Private
60	Hetero Healthcare Limited	Private
61	Hi Care Gloves Pvt Ltd	Private
62	Hindustan Antibiotics Ltd	CPSU
63	Hindustan Laboratories Limited	Private
64	Imperial Medcare Private Limited	Private
65	Indian Medicines Pharmaceutical Corporation Limited	CPSU
66	Innova Captab Limited	Private
67	Innovative Linen Co. Pvt. Ltd.	Private
68	Integrated Laboratories Pvt. Ltd.	Private
69	Inventia Healthcare Limited	Private
70	Iscon Surgicals Ltd.	Private
71	J Duncan Healthcare Pvt Ltd	Private
72	Jajoo Surgicals Pvt. Ltd.	Private
73	K.A.Enterprises	Private
74	K.S. Surgical Pvt. Ltd.	Private
75	Kag Industries	Private
76	Karnataka Antibiotics And Pharmaceuticals Limited	CPSU
77	Kms Manufacturing Company	Private
78	Laborate Pharmaceuticals India Limited	Private
79	Lark Laboratories (India) Ltd.	Private

80	Legacy Remedies Pvt Ltd	Private
81	Logos Pharma	Private
82	Lokbeta Pharmaceuticals (I) Pvt Ltd	Private
83	Lupin Ltd.	Private
84	M D Hygiene Pvt. Ltd	Private
85	Maan Pharmaceuticals Ltd	Private
86	Macleods Pharmaceuticals Limited	Private
87	Macsur Pharmaa (India) Private Ltd	Private
88	Mahalaxmi Malt Products Pvt. Ltd.	Private
89	Malik Lifesciences Private Limited	Private
90	Mancare Laboratories Pvt. Ltd.	Private
91	Mankind Pharma Limited	Private
92	Marc Laboratories Limited	Private
93	Martin And Brown Biosciences Pvt. Ltd.	Private
94	Maruti Meditech Pvt Ltd	Private
95	Mascot Health Series Pvt. Ltd	Private
96	Matins Healthcare Pvt Ltd	Private
97	Maxtar Bio-Genics	Private
98	Med Manor Organics Pvt. Ltd.	Private
99	Medevis Rubplast India Private Ltd	Private
100	Medipol Pharmaceuticals India Pvt Ltd	Private
101	Mepromax Lifesciences Pvt Ltd	Private
102	Merril Pharma Pvt. Ltd.	Private
103	Mformillet Foods Private Limited	Private
104	Mgrm Medicare Pvt. Ltd.	Private
105	Micron Pharmaceuticals	Private
106	Micropure Parenterals Pvt Ltd	Private
107	Midas Care Pharmaceuticals Pvt. Ltd.	Private
108	Mj Biopharm Pvt Ltd	Private
109	Modern Laboratories	Private
110	Morepen Laboratories Limited	Private
111	Msn Laboratories Private Limited	Private
112	Multani Pharmaceuticals Ltd	Private
113	Nandani Medical Laboratories Pvt. Ltd.	Private
114	Nanz Medscience Pharma Pvt. Ltd.	Private
115	Naprod Life Sciences Pvt. Ltd	Private
116	Naulakha Industries	Private
117	Navkar Lifesciences	Private
118	Nem Laboratories Private Limited	Private
119	Nutrizo Advancis Healthcare Pvt Ltd	Private
120	Om Sai Pharma Pack	Private
121	Omega Pharma	Private
122	Optimus Pharma Pvt. Ltd.	Private

123	Overseas Health Care Pvt. Ltd.	Private
124	P. Bhogilal Pvt. Ltd.	Private
125	Paramount Surgimed Limited	Private
126	Penta Kraft	Private
127	Penta Latex Llp	Private
128	Perfect Surgicare Industries Private Limited	Private
129	Pharma Impex Laboratories Pvt. Ltd.	Private
130	Pharose Remedies Ltd.	Private
131	Polestar Power Industries	Private
132	Pontika Aerotech Ltd.	Private
133	Precise Chemipharma Pvt Ltd	Private
134	Preet Remedies Ltd.	Private
135	Proactive Health Inc	Private
136	Prochem Pharmaceuticals Pvt. Ltd.	Private
137	Pulse Pharma Pvt. Ltd.	Private
138	Pure & Cure Healthcare Pvt. Ltd.	Private
139	Ravenbhel Healthcare Pvt. Ltd.	Private
140	Ravian Life Science Pvt. Ltd.	Private
141	Regent Ajanta Biotech	Private
142	Reliance Formulation Pvt. Ltd.	Private
143	Relief Biotech Pvt. Ltd.	Private
144	Renown Pharmaceuticals Pvt. Ltd.	Private
145	Revat Laboratories Pvt. Ltd.	Private
146	Rhydburg Pharmaceuticals Limited	Private
147	Rivpra Formulation Pvt Ltd	Private
148	Rv Lifesciences Limited	Private
149	Saar Biotech Pvt. Ltd.	Private
150	Sai Parenterals Limited	Private
151	Saimirra Innopharm Pvt. Ltd.	Private
152	Saksham Life	Private
153	Salud Care (India) Limited	Private
154	Samarth Life Sciences Pvt. Ltd.	Private
155	Sance Laboratories Pvt. Ltd.	Private
156	Savi Health Science	Private
157	Sekhani Industries Private Limited	Private
158	Shamshree Lifesciences Limited	Private
159	Sharda Health Care Private Limited	Private
160	Shine Pharmaceuticals Ltd.	Private
161	Shivalik Remedies Private Limited	Private
162	Shourya Hygienes	Private
163	Shree Radhe Hygiene Products Pvt. Ltd.	Private
164	Signature Phytochemical Industries	Private
165	Smart Hygeia	Private

166	Smilax Healthcare Drug Company	Private
167	Spm Medicare Pvt Ltd	Private
168	Sterimed Medical Devices Pvt. Ltd.	Private
169	Sterimed Surgicals (India) Pvt. Ltd.	Private
170	Suncare Formulations Pvt Ltd	Private
171	Sunlife Sciences	Private
172	Suparshva Swabs (I) Limited	Private
173	Supermax Drugs & Pharmaceuticals Pvt. Ltd.	Private
174	Susheel Yarns Pvt. Ltd.	Private
175	Swear Healthcare Private Limited	Private
176	Swiss Garnier Life Sciences	Private
177	Swiss Garniers Biotech Private Limited	Private
178	Synmedic Laboratories	Private
179	Synokem Pharmaceuticals Limited	Private
180	Systochem Laboratories Ltd	Private
181	Tablets (India) Limited	Private
182	Themis Medicare Limited	Private
183	Theon Pharmaceuticals Limited	Private
184	Tirupati Medicare Ltd.	Private
185	Tmt Med Source	Private
186	Ultra Drugs Pvt. Ltd. (Unit-Ii)	Private
187	Unicure India Ltd.	Private
188	Unimarck Healthcare Ltd	Private
189	Universal Prophylactic Pvt. Ltd.	Private
190	Vaishali Hygiene Products	Private
191	Venus Remedies Limited	Private
192	Vidhyasha Pharmaceutical	Private
193	Vidit Healthcare	Private
194	Vivimed Labs Ltd.	Private
195	Wallace Pharmaceuticals Pvt Ltd	Private
196	Windlas Biotech Limited	Private
197	Wings Biotech Llp	Private
198	Wockhardt Limited	Private
199	Yacca Lifesciences Pvt. Ltd.	Private
200	Yacca Pharmaceuticals Pvt Ltd	Private
201	Zee Laboratories Ltd.	Private
202	Zenith Drugs Pvt. Ltd.	Private
203	Zeon Lifesciences Limited,	Private
204	Zest Pharma	Private
205	Zim Laboratories Limited	Private
206	Zydus Lifesciences Limited	Private
