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

RAJYA SABHA
UNSTARRED QUESTION NO. 2316
TO BE ANSWERED ON 16TH March, 2021

SALE OF GENERIC DRUGS IN THE COUNTRY

2316 **SHRI HARNATH SINGH YADAV:**

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

(a) the numbers of public and private centres for the sale of generic drugs across the country, State-wise;

(b) whether the efficacy of allopathic and generic drugs is same, in general, if so, the reasons for the high price of drugs provided at allopathic drug centres and low price of generic drugs;

(c) whether the Ministry is aware of the fact that the doctors of public and private sectors discourage patients from using generic drugs; and

(d) if so, whether Government has any action plan for bringing more and more generic drugs in trend?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a): 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' (PMBJP) was launched by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India under which quality generic medicines are sold across the country through dedicated outlets Pradhan Mantri Bharitya Janaushadhi Kendra (PMBJK). As on 10.03.2021, 7507 PMBJKs has been opened across the country. State-wise details are annexed at **Annexure**.

(b): There is no definition of generic or branded medicines under the Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder. However, generic medicines are generally those which contain same amount of same active ingredient(s) in same dosage form and are intended to be administered by the same route of administration as that of branded medicine. Further, drugs manufactured in the country, irrespective of whether they are generic or branded, are required to comply with the same standards as prescribed in the Drugs and Cosmetics Act, 1940 and Rules, 1945 made thereunder for their quality. As such they are expected to have similar effects.

The price of an unbranded generic version of a medicine is generally lower than the price of a corresponding branded medicine because in case of generic version, the pharmaceutical company does not spend money on promotion of its brand. The sale of a generic version is incentivized by a pharmaceutical company by keeping a high trade margin for wholesalers and retailers

(c) & (d): The Government has not received any such report.

However, 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 drug. Further, the erstwhile Medical Council of India had issued Circular dated 21.04.2017 vide which all the Registered Medical Practitioners (RMPs) have been directed to comply with the aforesaid provisions. The MCI or the appropriate State Medical Councils have been empowered to take disciplinary action against a doctor for violation of the provision of the aforesaid Regulations. As and when complaints are received against the violation of code of ethics for doctors, such complaints are referred by MCI to the concerned State Medical Councils where the doctors/medical practitioners are registered. Further, even Tele-Medicine Guidelines 2020; notified on 22nd May, 2020, do direct all the RMPs to use Generic Names of the drugs in capital letters on the prescription format as appended with the document.

Further, the Ministry of Health & Family Welfare has taken various regulatory measures to promote and ensure the quality of generic medicines. These include instructions to Licensing Authorities to grant/ renew licenses to manufacture for sale or for distribution of drugs in proper/generic names only, amendment in the Drugs and Cosmetics Rules, 1945 for making it mandatory to grant license for a drug formulation containing single active ingredient in proper name only, and inclusion of provision in the Rules, 1945 for submission of the result of bioequivalence study alongwith application for grant of manufacturing license in the case of certain drugs and also provision for joint inspection of manufacturing establishment by the Drugs Inspectors of Central Government and State Government.

Sl. No.	Name of the State/UT	Number
1	Andaman & Nicobar	1
2	Andhra Pradesh	178
3	Arunachal Pradesh	28
4	Assam	77
5	Bihar	222
6	Chandigarh	7
7	Chhattisgarh	229
8	Delhi	291
9	Goa	9
10	Gujarat	508
11	Haryana	200
12	Himachal Pradesh	58
13	Jammu And Kashmir	90
14	Jharkhand	70
15	Karnataka	868
16	Kerala	744
17	Ladakh	3
18	Lakshadweep*	0
19	Madhya Pradesh	216
20	Maharashtra	566
21	Manipur	32
22	Meghalaya	14
23	Mizoram	22
24	Nagaland	15
25	Odisha	267
26	Puducherry	16
27	Punjab	275
28	Rajasthan	114
29	Sikkim	3
30	Tamil Nadu	773
31	Telangana	141
32	The Dadra And Nagar Haveli And Daman And Diu	31
33	Tripura	24
34	Uttar Pradesh	1058
35	Uttarakhand	201
36	West Bengal	156
	Grand Total	7507
*Medicines are directly supplied to the administration of UT of Lakshwadeep		