GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 391
TO BE ANSWERED ON THE 05th February, 2019

Display of Generic Medicines

391. SHRI G. HARI:

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

(a) whether it is true that chemists across the country have been asked to display generic medicines in a dedicated rack in their shops;
(b) if so, the details thereof;
(c) whether several manufacturers of generic drugs did not meet this quality standards; and
(d) if so, the details thereof and the corrective steps taken by the Government in this regard?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a): Yes, Madam.

(b): On 12.06.2018, Drugs Controller General (I) has requested all the State Drugs Controllers to direct all the outlets licensed to sell drugs by retail under their jurisdiction to provide a separate shelf/rack reserved exclusively for stocking of generic medicines in the licensed premises separated from other medicines, which shall be visible to the consumers. Also, in order to make generic medicines more accessible, the Department of Pharmaceuticals on 21.02.2018 has requested all the States/Union Territories to explore and enforce the proposal of keeping a separate shelf/rack for generic medicines in every pharmacy in the country.

(c) & (d): Manufacturing, sale and distribution of Drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection. License for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. Drug manufactured in the country, irrespective of whether branded or generic, are required to comply with the same standards as prescribed in the Drugs and Cosmetics Act, 1940 and Rules made thereunder for their quality. The State Licensing Authorities are empowered to take action against violations of any of the above requirements.

As per the information received from Central Drugs Standard Control Organization (CDSCO), the details of drugs samples declared not of standard quality and spurious/ adulterated, received from various State/U.T. Drugs Controllers for the last three years are as follows:

Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	% of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	% of drugs samples declared spurious/ adulterated
2015-16	74586	3703	4.96	234	0.31
2016-17	76721	2780	3.6	123	0.16
2017-18	82599	2783	3.36	236	0.28

Such information received from various Zonal/Sub-zonal offices of CDSCO are as under:

Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	% of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	% of drugs samples declared spurious/ adulterated
2015-16	2897	115	3.96	5	0.17
2016-17	5207	146	2.80	Nil	0.0
2017-18	7088	381	5.37	2	0.028

CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of generic medicines in the country. Details are as under:

1. 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.
2. The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.
3. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.
4. The inspectorate staffs have been instructed to keep a vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

5. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 510 in 2018.
6. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened to expedite testing of drug samples in the country.
7. On 3.4.2017, in order 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 licence of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.
8. On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) 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. The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.
9. On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.
10. The Government has approved a proposal for strengthening the drug regulatory system in the country, both at the level of Central and the State Governments at a total expenditure of Rs.1750 crores. Out of this, Rs. 900 crore is for strengthening the central drug regulatory structures and Rs.850 crore is for strengthening the drug regulatory system in the States. During the years 2016-17 and 17-18, Rs. 128.39 crore has been released under the Central component whereas Rs. 87.90 crore has been allocated during 2018-19 under this component. Under the State component, Rs. 81.36 crore has been released during 2016-17 and 17-18 whereas Rs. 206 crore has been allocated during 2018-19 under this component.

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