GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3252
TO BE ANSWERED ON THE 1st January, 2019

Quality tests of Medicines

3252. SHRI ANTO ANTONY:

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

(a) whether any mechanism exists to test the quality of medicines supplied through the hospitals run by the Government;
(b) if so, the details thereof;
(c) whether the Government has taken note of the fact that the medicines supplied through the hospitals run by it are of low quality;
(d) if so, the steps taken/being taken by the Government in this regard;
(e) whether the Government has received any complaint on the aforesaid matter; and
(f) if so, the details thereof and the response of the Government thereto?

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) & (b): There is no specific mechanism under the provisions of Drugs and Cosmetics Rules to test the quality of medicines supplied through the hospitals run by the Government. There may be such mechanism under procurement policy to test the quality of medicines supplied through the hospitals run by the Government. For all the medicines procured in Central Government Hospitals, the lab report/ quality certificate (Form-39) of all the drugs is taken to ensure the quality of medicine.

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. One of the condition of the license is that licensee shall either in his own lab or in any other laboratory approved by the Licensing Authority test each batch of the raw material used by him for the manufacture of products and also each batch of the final product and shall maintain records showing the particulars in respect of such tests. All drugs manufactured in the country are required to comply with the same standards

prescribed under the said Act and Rules. The State Licensing Authorities are empowered to take action in case of any violation of above requirements.

(c) & (d): A nation-wide survey (2014-16) was conducted to assess the extent of Not of Standard Quality (NSQ)/Spurious drugs. Out of a total 47012 drug samples drawn from both Governments and private sources, the percentage of 'Not of standard quality' drugs was 3.16 and that of spurious/adulterated drugs was 0.0245. Out of the total samples, the number of samples drawn from Government sources was 8369 and the percentage of 'Not of standard quality' and spurious/adulterated drugs was 10.02 and 0.0597 respectively. The test Reports of the drug samples declared as Not of Standard Quality (NSQ) were forwarded to the concerned State Licensing Authorities with a request to take appropriate action and also to take legal samples of same batch of drugs for testing.

(e) & (f): Isolated complaints regarding suspected quality of medicines have been received. As and when such complaints are received, based on the merit, the matter is taken up by CDSCO/ in coordination with State Licensing Authority for action as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945.

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