GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 518
TO BE ANSWERED ON THE 6th February, 2018

WHO Report on Medical Products

518. SHRI B. SENGUTTUVAN:
Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the report of WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS) 2013-17 has found that just about 2% of the medical products manufactured in South-East Asia, including India, were either spurious or substandard as against 21% in the Americas and as against the global figure of 10.5%;
(b) whether the report has also indicated that globally there was clear evidence that about 38 to 90% of the most important antimalarial medicine, artemisinin, available in the market are either substandard or falsified;
(c) whether the Government has taken steps to ensure that the medicines dispensed by the online pharmacies in India are up to the standard and genuine and if so, the details thereof; and
(d) whether the Government would issue instructions to the pharmaceutical and pharmacological sectors to use bar codes in their products so as to eliminate circulation of the spurious imitation products and if so, the details thereof ?

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): Director-General, WHO Geneva has launched two documents concerning substandard and falsified medical products, at the Graduate Institute, Geneva:
(i) a study on the public health and socioeconomic impact of substandard and falsified medical products ; and
(ii) WHO global surveillance and monitoring system for substandard and falsified medical products
They include estimations on the observed failure rates of sampled medicines in quality surveys carried out during 2007-2016, involving over 48,000 samples from 88 Member States. The aggregate observed failure rates in low and middle income countries are estimated at 10.5%. As per the Report of WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS) 2013-17, “there is clear evidence that resistance to the most important antimalarial medicine, artemisinin, first appeared in a part of the world where at one point between 38 and 90% of the artemisinin medicines on the market were substandard or falsified.”
(c): 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. Licensees are required to comply with all the conditions of such licenses. The State Licensing Authorities are empowered to take action in case of any violation of above requirements.
(d): Ministry of Health & Family Welfare has issued a draft notification vide GSR 449(E) dated 03-06- 2015 to amend the Drugs and Cosmetics Rules 1945 to make barcoding mandatory for drugs. However, a large number of comments were received raising difficulties to be faced by the industry, if the barcoding is made mandatory and the draft notification could not be finalized.

xxxxx