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

LOK SABHA
UNSTARRED QUESTION NO.1544
TO BE ANSWERED ON 4TH MARCH, 2016

ROLLING OUT DIAGNOSTIC MACHINES

1544. SHRI KALIKESH N. SINGH DEO:
DR. VIRENDRA KUMAR:
SHRI PARBHUBHAI NAGARBHAI VASAVA:

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

(a) whether the Government proposes to roll out diagnostic machines that are capable of conducting a highly sensitive molecular diagnostic test for Tuberculosis, if so, the details thereof and timeline for rolling out these machines;

(b) the measures taken by the Government to ensure availability of adequate finances, storage and stocks of cartridges to keep the machines functioning;

(c) whether the foreign companies selling medical devices in India which are banned in their parent countries, if so, details thereof;

(d) whether the companies imparting medical devices sell these devices without MRP; and

(e) the steps taken/being taken by the Government to curb this practice?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) & (b): Diagnosis of Drug Resistant TB is undertaken through quality assured drug susceptibility testing at 64 culture & drug susceptibility testing laboratories, of which 51 laboratories are equipped with rapid molecular test namely Line Probe Assay (LPA). Cartridge Based Nucleic Acid Amplification (CBNAAT) Test Machines are installed at 121 sites for early detection of Rifampicin resistance among TB cases. In addition, Govt. of India has procured 300 CB NAAT machines for conducting a highly sensitive molecular diagnostic test for Tuberculosis in 300 districts across country. These 300 machines are ordered along with cartridges.

(c): Presently, 15 categories of notified Medical Devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder. The CDSCO has not received any information/report that foreign companies are selling Medical Devices in India which are banned in their parent countries.

(d) & (e): Manufacturer/importer/marketing companies of Medical Devices, notified as "Drugs" are required to submit the information of prices in Form- V for monitoring of price movement under the Drug Price Control Order, 2013. As provided in the said order, no manufacturer/ importer/ marketing companies are allowed to increase the Maximum Retail Price of such non-scheduled drugs more than ten percent of MRP during the preceding twelve months.