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

LOK SABHA
UNSTARRED QUESTION NO. 1261
TO BE ANSWERED ON 22ND DECEMBER, 2017

TESTING OF DRUGS

1261. SHRI SHARAD TRIPATHI:
SHRI TAMRADHWAJ SAHU:

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

(a) whether the Government proposes to make stability test mandatory in pharmaceutical sector, if so, the details thereof;

(b) whether the Government is likely to issue any guideline to the companies to provide full information to the customers regarding the effectiveness of the drugs till their expiry date, if so, the details thereof;

(c) whether the Government has set up any monitoring mechanism to test the quality of medicines; and

(d) if so, the extant mechanism to test the quality of medicines being sold in the market?

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

(a): Yes. Ministry of Health & Family Welfare has published a draft notification for public comments vide GSR 429 (E) dated 02.05.2017.

(b): No.

(c) & (d): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments.

Drug Inspector is authorized under the said Act to draw samples of drugs from the market and other sources for their quality testing in accordance with the procedures prescribed in the Act and Rules and to institute prosecution in case of any violation of the provisions of the Act and Rules. State Licensing Authorities are also legally empowered to take action against violation of any condition of license issued by them.