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

RAJYA SABHA
UNSTARRED QUESTION NO. 4135
TO BE ANSWERED ON 3RD APRIL, 2018

SALE OF UNAPPROVED ANTIBIOTICS

4135. SHRI RIPUN BORA:

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

(a) whether it is a fact that more than 64 per cent of antibiotics are sold in the country without the approval of Central Drugs Standard Control Organisation (CDSCO);

(b) if so, whether Government has received any survey report in this regard;

(c) whether it is also a fact that India rates as the highest consumer of antibiotics with more than unapproved 3300 brand names with different 118 types of formulations of Fixed Dose Combination; and

(d) if so, the action plan of Government to restrict the usage of unapproved drugs in the country?

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

(a) to (d): No drug can be sold in the country without due approval and valid license of the concerned licensing authority as stipulated in the Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder.

As per the said Act and the Rules, manufacture, sale and distribution of drugs including antibiotics in the country are regulated 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.

As per Rule 122 E of Drugs & Cosmetics Rules 1945, the combination of two or more drugs i.e. Fixed Dose Combination (FDC) combined for the first time fall under the definition of New Drug and therefore permission from the Drugs Controller General (India) [DCG(I)] is required before these are licensed by State Licensing Authorities (SLAs) for manufacture for sale in the country. However it was observed that some SLAs were granting licenses for some such FDCs, including antibiotic combinations, without due approval from DCG (I).

DCG (I) had requested all States/UTs Drugs Controllers to ask the concerned manufacturers in their State to prove the safety and efficacy of such FDCs within a period of 18 months, failing which such FDCs would be considered for being prohibited for manufacture and marketing in the country. An Expert Committee under the chairmanship of Prof. C.K. Kokate was constituted to examine such applications and also for examining the safety and efficacy of these FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, the Central Government prohibited 344 FDCs vide notification dated 10.03.2016. Further the Central Government had also prohibited 5 FDCs vide notification dated 08.06.2017. Out of these 349 (344+5) FDCs prohibited, 46 FDCs were antibiotics (44 FDCs prohibited on 10.03.2016 and 02 FDCs prohibited on 08.06.2017).

It is pertinent to mention that the Central Government had also prohibited 5 antibiotic FDCs during the period from 1983 to 2001, which is still in force.

However, with respect to the said 344 FDCs including 44 FDCs of antibiotics, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Delhi High Court before the Supreme Court by way of filing Special Leave Petitions (SLPs). Further, about 20 cases against 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country, were also transferred to Supreme Court. Hon'ble Supreme Court vide its order dated 15.12.2017 directed that an analysis be made in greater depth and these cases of (344+5) FDCs should go to the Drugs Technical Advisory Board (DTAB) and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases.

Thus, Government has taken measures to prohibit manufacture and marketing of various FDCs as above, which have been found irrational.

Following measures have also been taken by the Ministry to curb the misuse of antibiotics:

- Antibiotics are included in Schedule H and H1 of the Drugs and Cosmetics Rules, 1945 and are required to be sold by retail only under the prescription of a Registered Medical Practitioner.

- A new Schedule H1 under the Drugs & Cosmetics Rules, 1945 containing 46 drugs which include antibiotic drugs, Anti TB drugs and certain habit forming drugs has been notified. The drugs falling under Schedule H1 are required to be sold in the country with certain strict conditions.