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

LOK SABHA
UNSTARRED QUESTION NO. 2451
TO BE ANSWERED ON 9TH MARCH, 2018

ANTI-MICROBIAL RESISTANCE

2451. SHRI KAMAL NATH:

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

(a) whether multinational companies continue to produce and sell unregulated antibiotics in the country;

(b) if so, the details thereof and whether a UK based research has revealed that antibiotics pills in the Indian market are not yet regulated;

(c) if so, the reaction of the Government thereto;

(d) whether the problem of antimicrobial resistance in the country is worsening day by day; and

(e) if so, the steps taken or proposed to be taken by the Government to address the matter in an effective way?

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

(a) to (c): A study was published in British Journal of Clinical Pharmacology dated 04.02.2018 regarding Centrally approved and unapproved antibiotic formulations sold in India.

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 of such unapproved FDCs including antibiotic combinations without due approval from DCG (I).

DCG (I) vide letter dated 15.01.2013 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 vide this Ministry's Order dated 16.09.2014 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 are 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 15.12.2017 has directed that an analysis be made in greater depth and these cases (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.

(d) & (e): Manufacture, sale and distribution of drugs including antibiotics in the country are 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.

Following measures have 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.