GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 5795
TO BE ANSWERED ON THE 3rd April, 2018

Unregulated Antibiotics

5795. SHRI B. SENGUTTUVAN:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government is aware of the fact that MNCs continue to produce and sell unregulated antibiotics which result in the problem of antimicrobial resistance and if so, the details thereof;
(b) whether out of the 118 Fixed Dose Combination Antibiotics sold in India between 2007 and 2012, 64 per cent were not approved by the Central Drugs Standard Control Organisation (CDSCO) and if so, the details thereof;
(c) whether the country has one of the highest rate of antibiotic consumption and antimicrobial resistance and if so, the details thereof; and
(d) the proactive steps likely to be taken by the Government to curb the production and sale of antibiotics not approved by the CDSCO?

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) & (d): As per Rule 122E 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 office of Drug Controller General of 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 SLAs were granting licenses of unapproved FDCs including antibiotic combinations without due approval from DCG(I).

DCG(I) vide letter dated 15.01.2013 had requested all State/UT Drugs Controllers to ask the concerned manufacturers in their State to prove the safety and efficacy of such FDCs as mentioned above before the office of DCG (I) within a period of 18 months, failing which FDCs would be considered for being prohibited for manufacture and marketing in the country. To examine the applications received in response to the direction of the DCG(I), Ministry of Health & Family Welfare constituted an Expert Committee under the Chairmanship of Prof. C. K. Kokate 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 has also prohibited 5 FDCs vide notification dated 08.06.2017. Out of these 349 (344+5) FDCs prohibited, there were 46 FDCs of antibiotics (44 FDCs prohibited on 10.03.2016 and 02 FDCs prohibited on 08.06.2017).

With respect to above said 344 FDCs which includes 44 FDCs of antibiotics, various stakeholders filed writ petitions in different High Courts across the country and the said notification was quashed by Hon'ble High Court of Delhi vide its order dated 01.12.2016. Subsequently, the Union of India had challenged the order of Delhi High Court before the Supreme Court by way of SLP. Further, about 20 cases including 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country were also transferred to Hon'ble Supreme Court. Hon'ble Supreme Court vide its order 15.12.2017 has directed that to have an analysis made in greater depth, 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.

Accordingly, in the 78th meeting of DTAB held on 12.02.2018, a sub-committee is constituted to examine the banned FDCs.

The Central Government had also prohibited 5 antibiotic FDCs during from 1983 to 2001, which are still under prohibition.

Further, Ministry of Health and Family welfare and CDSCO have taken various regulatory measures to curb the misuse of antibiotics. Details are as under:-

(i) 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.

(ii) The Drugs and Cosmetics Rules were amended by the Ministry of Health and Family Welfare to make a provision that the container of a medicine for treatment of food producing animals shall be labelled with the withdrawal period of the drug for the species on which it is intended to be used.

(c): No such data regarding rate of antibiotic consumption and antimicrobial resistance is maintained by the Department.

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