GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 1789

TO BE ANSWERED ON THE 6th March, 2018

Sale of Unapproved Drugs

1789. SHRIMATI MAUSAM NOOR:

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

(a) whether the Government is aware of a study published in British Journal of Clinical Pharmacology stating that out of 118 different formulations of fixed dose combinations being sold in India between 2007 and 2012, over 64% were not approved by the Central Drugs Standard Control Organisation;
(b) if so, whether the Government has conducted a preliminary enquiry into the matter;
(c) if so, the details thereof along with the steps taken to address such anomalies through policy intervention and if not, the reasons therefor;
(d) whether the Government is also seized of the report that the rampant sale of unapproved antibiotics is triggering antimicrobial resistance in the country and puts its healthcare priorities at risk; and
(e) if so, the details of the action taken thereon?

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): Yes, Madam. A study was published in British Journal of Clinical Pharmacology dated 04.02.2018 regarding Centrally approved and unapproved antibiotic formulations sold in India.

(b) to (e): 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 Drugs Controller General of India (DCGI) 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 such unapproved FDCs including antibiotic combinations without due approval from DCG(I).

Further, as per the Action Taken report (ATR) on the Parliamentary Standing Committee report, DCGI 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 such 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 vide order No. X11035/53/2014-DQC dated: 16.09.2014 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). Prior to this, the Central Government had also prohibited 5 antibiotic FDCs.

However, 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.

With regard to the issue relating to antimicrobial resistances, it may be mentioned that Ministry of Health and Family Welfare and Central Drugs Standard Control Organisation (CDSCO) has taken various regulatory measures to curb the misuse of antibiotics. Details are as under:

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. Further in order to regulate the human consumption of antibiotics to restrict the over the counter availability of certain antibiotics, the Drug & Cosmetics Rules, 1945 have since been amended vide

Gazette Notification No GSR 588 (E) dated 30-08-2013 incorporating a new Schedule H1 under the Drugs & Cosmetics Rules containing 46 drugs which include antibiotic drugs, Anti TB drugs and certain habit forming drugs. The drugs falling under Schedule H1 are required to be sold in the country with the following conditions:

(a) the supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.

(b) The drug specified in Schedule H1 shall be labeled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and shall also be labeled with the following words in a box with a red border:

"SCHEDULE H1 DRUG-WARNING:

-It is dangerous to take this preparation except in accordance with the medical advice.

-Not to be sold by retail without the prescription of a Registered Medical Practitioner."

The Drugs and Cosmetics Rules were amended by the Ministry of Health and Family Welfare vide Gazette notification G.S.R. 28(E) dated 17.01.2012, 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.

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