GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2423
TO BE ANSWERED ON THE 2nd January, 2018

Tweaking of Drugs Formulations

2423. SHRIMATI K. MARAGATHAM:

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

(a) whether the pharmaceutical companies often launch new drugs after tweaking drug formulations by combining them with other medicines to circumvent price control and if so, the details thereof;
(b) whether it is also true that the pricing authority has found most of these medicines to be Fixed Dose Combinations (FDCs) and raised doubts on whether they had been approved by the Drug Controller General of India (DCGI) and if so, the details thereof;
(c) whether the DGCI has said that the practice was illegal and not in conformity with the law and would have disastrous consequences; and
(d) if so, the details thereof and the corrective steps being taken in this regard?

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): Pharmaceutical companies also launch their products as a 'new drug' as defined in the Drug (Prices Control) Order, 2013.
(b): The Office of Drug Controller General of India (DCGI) has informed that the combination of two or more drugs for the first time in the country is considered as "New Drugs" under the Drugs & Cosmetics Rules, 1945. Application for approval of such New drugs, when received by Central Drugs Standard Control Organization (CDSCO) are examined in consultation with Subject Expert Committees (SEC) and decisions are taken based on the recommendations of SEC and fulfillment of requirements as per the said Rules.
(c) & (d): As per the Action Taken Report (ATR) on the Parliamentary Standing Committee report, DCG (I) vide letter dated: 15.01.2013 requested all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of FDCs licensed to manufacture for sale in the country without due approval from office of DCG(I) before CDSCO within a period of 18 months, failing which such FDCs will 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 and Family Welfare has constituted an Expert Committee under the chairmanship of Prof. C. K. Kokate. On the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government prohibited the manufacture for sale, sale and distribution for human use of 344 drug fixed dose combination vide gazette notification no. S.O 705(E) to 1048(E) dated 10.03.2016. However, various stakeholders filed various writ petitions in different High Court across the country and the said notification was quashed by Hon'ble High Court of Delhi vide its order dated 01.12.2016. Further, the Union of India challenged the order of Delhi High Court before the Supreme Court by way of SLP. Recently on 14.12.2017, Supreme Court bench has issued Order that these FDCs should be sent to Drugs Technical Advisory Board (DTAB) constituted under Section 5 of the Drugs and Cosmetics Act, so that it can examine each of these FDCs and send a report to the Central Government.

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