GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 662
TO BE ANSWERED ON THE 13TH DECEMBER, 2022

Uniform Code of Pharmaceutical Marketing Practices (UCPMP)

662 Shri Mohammed Nadimul Haque:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether it is a fact that pharmaceutical companies are promoting specific drugs by incentivising doctors;
(b) the steps taken by Government to stop the over-use of such drugs which jeopardize the health of patients;
(c) the steps taken by Government to ensure mechanisms of transparency and accountability in the implementation of the Uniform Code of Pharmaceutical Marketing Practices;
(d) whether Government has taken any steps to prohibit the excessive flow of such irrational and high-priced drugs in the market; and
(e) if so, the details thereof and if not, the reasons therefor**?**

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI BHAGWANTH KHUBA)

(a) to (c): The Government has put in place a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for Pharmaceutical companies, which is in operation since 01.01.2015, to prevent unethical practices by the pharmaceutical companies. This code governs the conduct of pharmaceutical companies in their marketing practices, duly covering the various aspects such as medical representatives, textual and audio-visual promotional materials, samples, gifts, etc. Further, the code establishes relationship with healthcare professionals, wherein the provisions related to travel facilities, hospitality and cash or monetary grants to physicians or their families have been elaborated. The code also details the mode of operation of the code, responsibilities of the Pharmaceutical Associations in constituting the Ethics Committee for Pharmaceutical Marketing Practices (ECPMP) for handling the complaints and Apex Ethics Committee for Pharmaceutical Marketing Practices (AECPMP) for review, procedure of lodging a complaint, procedure of handling of complaints by the Pharmaceutical Associations and various penalty provisions.

The code has been adopted by the all the major associations of pharmaceutical companies and the Department on various instances has reviewed implementation of the code by the Pharmaceuticals associations. The complaints of violation of the voluntary UCPMP by pharma companies, as received by the Department, are forwarded to the concerned pharmaceutical associations for taking necessary action.

Besides UCPMP, there exists sufficient and enforceable legal regime to counter, control and dis-incentivize the unethical marketing practices such as "Indian Medical Council Professional Conduct, Etiquette and Ethics) Regulations, 2002" under the Indian Medical Council Act, 1956, provisions available under Income Tax Act, Drugs and Cosmetics Act, Prevention of Corruption Act, etc

(d) to (e): As per information received from Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare that the manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules 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. Under the said Rules, ***Fixed Dose Combinations (FDC) is a New Drug***. For the manufacture of any FDC falling under the definition of New Drug, permission is required from Central Drugs Standard Control Organisation (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority. Under the aforesaid Act, manufacture/sale/distribution of any banned drug is a punishable offence. State Licensing Authorities are empowered to take action in this regard.

Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government. Apart from issuing repeated statutory directions under Section 33P of the Drugs & Cosmetics Act, 1940 to the State Governments not to issue such licenses to FDCs falling under definition of new Drugs without approval of DCG(I), the Central Government constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such 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 also prohibited 5 FDCs vide notification dated 08.06.2017.

However, with respect to prohibition of the said 344 FDCs, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the Hon'ble High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Hon'ble Delhi High Court before the Hon'ble Supreme Court by way of filing Special Leave Petition (SLP). 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.

Accordingly, a Sub-Committee of DTAB was constituted which after providing hearing to all the petitioners/appellants, submitted its report to DTAB which was accepted by DTAB. Based on the recommendations of DTAB, the Central Government, vide notifications dated 07.09.2018, prohibited 328 FDCs for manufacture, sale or distribution. The Government also restricted 06 FDCs for manufacture, sale or distribution with certain conditions vide notifications issued on the same date. However, various firms/stakeholders have filed writ

petitions in various High Courts across the country including the Hon'ble Supreme Court against the said notifications dated 07.09.2018.

Earlier, in 2007, CDSCO had received complaints from consumer association regarding rationality of certain Fixed Dose Combinations (FDC) marketed in the country. As follow up action, CDSCO prepared a list of 294 FDCs and communicated to State Drugs Controllers vide letter dated 14.08.2007. A writ petition was filed in the Hon'ble High Court of Madras and the Hon'ble Court granted stay order. However, DTAB in its meeting held on 16.1.2008 constituted a sub-committee to examine these FDCs. The recommendation of the subcommittee was referred to Hon'ble Supreme Court. The Hon'ble Supreme Court in its judgment, dated 15.12.2017, accepted the recommendations of DTAB and ordered for disposal of these petitions. Accordingly, Central Government vide notifications S.O. 180(E) to S.O.259 (E), dated 11.01.2019, prohibited 80 FDCs for manufacture, sale or distribution.

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