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

LOK SABHA
STARRED QUESTION NO. 346
TO BE ANSWERED ON THE 19TH MARCH, 2021
FIXED DOSE COMBINATIONS

***346. SHRI RAVNEET SINGH BITTU:**

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

(a) whether the Government is aware that several unscientific combinations of drugs have flooded the markets as Fixed Dose Combinations (FDCs) and if so, the details thereof;

(b) whether a lax regulatory framework has led to this situation in the country and if so, the reaction of the Government thereto;

(c) whether the National Pharmaceutical Pricing Authority (NPPA) has raised some concerns on drug cocktails and has flagged the issue to the Indian Council of Medical Research (ICMR) and if so, the details thereof;

(d) the details of FDC drugs banned during the last three years;

(e) whether the Government has taken any measures to fix the prices of new drugs which were FDC medicines or drug cocktails; and

(f) if so, the details thereof and if not, the reasons therefor?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)

(a) to (f) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.346* FOR 19TH MARCH, 2021

(a) to (d): 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 Does Combinations is a new Drugs. For the manufacture of any FDC falling under the definition of New Drug, permission is required from Central Drugs Standard Control Organsiation (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority.

Under the afore-said 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) falling under the purview of Rule 122E of the Drugs & Cosmetics Rules, 1945 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 recommendations 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.

National Pharmaceutical Pricing Authority (NPPA), under the Ministry of Chemical & Fertilizers, flagged the following to Indian Council of Medical Research (ICMR), New Delhi. The detail is as below:

‘‘*The Authority noted that the retail price applications of new drugs mainly consist of Fixed Dose Combinations (FDCs) of two or more drugs. The Authority deliberated upon the matter in detail and expressed its concern that approval of these FDCs may compromise the rationale in the usage of the drugs and may lead to over medication. The Authority also apprehended that fixation of retail price of these FDCs may lead to a higher price being fixed than the sum of the price of their individual components resulting in profiteering by the companies. The Authority is of the view that guidelines in the usage of these FDCs needs to be looked into. Accordingly, the Authority requested that matter may be highlighted to Indian Council of Medical research (ICMR), New Delhi."*

(e) & (f): NPPA which is mandated with the task of dealing with pricing issues of drugs fixes the retail price of only those new drugs which have been approved/No Objection Certificate (NOC) issued by CDSCO. Further, NPPA has extended retail price to 1495 FDCs under DPCO 2013.

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