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

LOK SABHA
UNSTARRED QUESTION NO. 4552
TO BE ANSWERED ON 20TH MARCH, 2020

BANNED/UNAPPROVED DRUGS

4552. SHRI K. NAVASKANI:
SHRI BALUBHAU ALIAS SURESH
NARAYAN DHANORKAR:

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

(a) whether the Government proposes to put in place a comprehensive mechanism to stop manufacturing and marketing of banned/unapproved drugs across the country;

(b) if so, the details thereof;

(c) whether certain cases of manufacturing and marketing of banned/unapproved drugs have been reported in the country;

(d) if so, the details thereof indicating the number of such cases reported during each of the last three years and the current year, State/UT-wise; and

(e) the action taken against the offenders during the said period, State/UT-wise?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (e): 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, for manufacture of any 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 in this regard, 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 had also prohibited 5 FDCs vide notification dated 08.06.2017.

However, with respect to 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 High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Delhi High Court before the 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 as there was no therapeutic justification for these FDCs and they could involve risk to human beings. 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.

Further, based on the recommendations of DTAB, the Central Government vide notifications dated 11.01.2019 prohibited 80 FDCs for manufacture, sale or distribution as there was no therapeutic justification for these FDCs and they could involve risk to human beings. These 80 FDCs were part of the list of 294 FDCs identified in year 2007, which were earlier sub-judice in Hon'ble High Court of Madras.