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

LOK SABHA
UNSTARRED QUESTION NO. 2951
TO BE ANSWERED ON 3rd AUGUST, 2018

RESTRUCTURING OF NATIONAL LIST OF ESSENTIAL MEDICINES

2951. SHRI TEJ PRATAP SINGH YADAV:
SHRI K. ASHOK KUMAR:
SHRIMATI ANJU BALA:

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

(a) whether the Government has decided to restructure National List of Essential Medicines (NLEM) which may include medical devices, disposables and consumables and if so, the details thereof;

(b) the perceived benefit therefrom;

(c) whether many unapproved drugs continue to be available in the market and if so, the details thereof and Government's reaction thereto including the measures taken to monitor compliance and enforce law regarding the same; and

(d) whether the Ministry has proposed changes to the Drugs and Cosmetics Rule 1945, requiring pharma companies to disclose information about their operation, products etc. and if so, the details thereof ?

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

(a) & (b): Ministry of Health & Family Welfare vide order dated 03.07.2018 has constituted Standing National Committee on Medicines (SNCM) to review and revise the National List of Essential Medicines (NLEM). Amongst other things, the committee will also suggest inclusion of Medical Devices, Medical Disposables, Medical Consumables and other products used for Health & Hygiene of general public in NLEM. A robust and dynamic NLEM will aid the Government's efforts in addressing the healthcare needs of the people.

(c): 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 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 Petitions (SLPs). 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, DTAB has examined these FDCs.

(d): The Government has published draft Rules vide Gazette notification No. 629(E), dated 11.07.2018 inviting public/stakeholders' comments to amend the Drugs & Cosmetics Rules, 1945 providing that the licensed manufacturers of drugs shall register with SUGAM portal of Central Drugs Standard Control Oganisation (CDSCO) and upload information as per the format provided in the portal pertaining to the licenses granted for manufacture for sale or distribution of drugs which shall be updated from time to time.