(b) The government has fixed the ceiling prices of the 856 scheduled formulations upto 31.12.2018 resulting in the reduction in the prices as follows:–

Statement showing reduction in ceiling prices of scheduled formulations with respect to maximum price under NELM 2015 as on 31.12.2018

% reduction with respect to Maximum Price	No. of scheduled formulations
0<= 5%	237
5<=10%	135
10<=15%	98
15<=20%	99
20<=25%	93
25<=30%	65
30<=35%	46
35<=40%	24
Above 40%	59
Total formulations in NLEM 2015	856

(c) The National List of Essential Medicines (NLEM) is a list of essential drugs prepared by the Ministry of Health and Family Welfare. There is no such case as doctors not prescribing medicine from NLEM as essential medicines are those medicines that satisfy the priority healthcare needs of the population.

(d) and (e) There is no such direction of the Hon'ble Supreme Court to stick to cost-based pricing formula.

Sale of unapproved Fixed Dose Combinations

2608. SHRI SAMIR ORAON:
SHRI MAHESH PODDAR:

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

(a) whether it is a fact that sale of unapproved Fixed Dose Combinations (FDCs) in the Indian markets has been rampant and unchecked, if so, the details thereof;

(b) whether the Government has banned any FDCs for being unsafe to the public, if so, the details thereof; and

(c) the steps taken by the Government to ensure effective and robust post-marketing surveillance programmes of manufacturers of FDCs?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH MANDAVIYA): (a) and (b) Concerns have been raised from time to time regarding grant of manufacturing license of new drugs including FDCs falling under definition of Rule 122E of Drugs and Cosmetic Rules by some of the State Licensing Authorities without approval from CDSCO.

Ministry of Health and Family Welfare had issued repeated statutory direction under Section 33P to the State Governments to instruct their respective drugs licensing authorities to refrain from granting licenses for manufacture of new drugs and FDCs covered under the definition of the terms 'new drug' without due approval of the Drugs Controller General (India). The last such direction was issued *vide* Letter No. X.11035/201/2018-DR dated 13.04.2018. As decided, CDSCO *vide* Letter No. 4-01/2013-DC (Misc. 13-PSC) dated 15.01.2013 requested all State/UT Drug Controller to ask the concerned manufacturers in their State to prove the safety and efficacy of such FDCs as mentioned above before the office of DCG (I) within a period of 18 months, falling which such FDCs will be considered for being prohibition for manufacture and marketing in the country.

In reply to CDSCO letter dated 15.01.2013, CDSCO received approx. 6320 applications from the manufacturers for proving the safety and efficacy, which were examined by the Expert Committee constituted by Ministry of Health and Family Welfare *vide* Order No. X11035/53/2014-DFQC dated 16.09.2014 under the Chairmanship of Prof. C. Kokate, VC, KLE University, Belgaum.

After detailed examination, the Committee submitted its report to the Ministry of Health and Family Welfare. For FDCs which are considered as Irrational by the Committee have been categorised under category 'a', and 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 petition in different High Court across the country and the said notifications were quashed by Hon'ble High Court of Delhi *vide* its order dated 01.12.2016.

Further, in pursuance of the action taken note on the 59th PSC report, based on the examination by the Subject Expert Committee constituted by the Central Government, the Central Government had prohibited 5 more FDCs *vide* Gazette Notifications S.O. Nos.1851(E) to 1855 (E) dated 08.06.2017 for the manufacture for

sale, sale and distribution for human use. Subsequently, the Central Government had challenged the order of Delhi High Court before the Supreme Court dated 01.12.2016 by way of SLP. The Hon'ble Supreme Court of India after a series of hearings in its Judgement dated 15.12.2017 pertaining to the issue of FDCs has directed DTAB and/or a Sub-Committee formed by DTAB for the purpose, to have a relook into these cases. Accordingly, as per the judgement of Supreme Court, the agenda with respect to 344 FDCs+05 FDCs were deliberated in DTAB meeting held on 12.02.2018 and a Sub-Committee of DTAB was constituted for this purpose.

After a series of meetings and providing hearing to all the petitioners/appellants the Sub-Committee of DTAB submitted its report which was accepted by the DTAB.

Based on the DTAB recommendation, the Central Government *vide* Gazette Notifications S.O. number 4379 (E) to S.O. number 4706(E) dated 07.09.2018 prohibited 328 FDCs for manufacture, sale or distribution. Further the Central Government *vide* Gazette Notifications S.O. number from 4707(E) to 4712 (E) dated 07.09.2018 restricted 06 FDCs for manufacture, sale or distribution with certain conditions. However, various firms/stakeholder have filed the writ petitions in various High Courts across the country including the Hon'ble Supreme Court against the said Gazette Notification dated 07.09.2018.

(c) Government *vide* GSR No. 287(E) dated 08.03.2016 has amended the Drugs and Cosmetics Rule 1945, providing that the applicant of new drug shall have a Pharmacovigilance system in place for collection, processing and forwarding the report to the licensing authority for information on Adverse Drug Reactions (ADRs) emerging from the use of the new drugs manufactured or marketed by the applicant in the country. Further, as per Good Manufacturing Practices prescribed in Schedule M of the Drugs and Cosmetics Rule 1945, reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority.

Assessment of the achievements of PCPIRs

2609. SHRI NARAYAN LAL PANCHARIYA: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether Government has set up Petroleum, Chemical and Petrochemical Investment Regions (PCPIRs):

(b) if so, the details thereof;

(c) whether Government has made an assessment of the achievements of PCPIRs and if so, the details thereof, if not, the reasons therefor; and