

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

(d) whether Government proposes to make any changes in the policy governing PCPIRs, if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS, (RAOINDERJIT SINGH): (a) and (b) Yes, Sir. The Government of India has approved setting up of 4 Petroleum, Chemical and Petrochemical Investment Regions (PCPIRs) in the States of Gujarat (Dahej), Andhra Pradesh (Visakhapatnam-Kakinada), Odisha (Paradeep) and Tamil Nadu (Cuddalore-Nagapattinam).

(c) Yes, Sir. These PCPIRs have so far attracted investments worth approximately ₹ 1.90 lakh crore and around 3.30 lakh persons have been employed in direct and indirect activities, as per monitoring mechanism in place at the State and Central Government levels. The PCPIRs also cover various Special Economic Zones (SEZs) which are contributing to the export basket of the country. Creation of infrastructure like roads, railways, airports, ports, water supply, power and effluent treatment etc. is a continuous process in the PCPIRs with a long gestation period.

(d) Review of policy is a dynamic process and undertaken from time to time on need basis and stakeholder consultations. Accordingly, this Department initiated an exercise to recommend broad policy for the petrochemical sector which includes recommendations regarding amendments to the existing PCPIR policy.

#### **Certification of fertilizers**

2610. SHRI TIRUCHI SIVA: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that the present system of certifying new fertilizers is time consuming;

(b) if so, whether Government plans to establish a Fertilizer Development and Regulating Authority to ensure efficient certification; and

(c) if not, the reasons therefor and the details of Government's plan to streamline the process of certification, quality checks, innovations, and fixing prices of fertilizers?

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (RAOINDERJIT SINGH): (a) No, Sir.

(b) Question does not arise.

(c) The details of Government's plan to streamline the process of certification, quality checks, innovations, and fixing prices of fertilizer process are as under:—