GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA UNSTARRED QUESTION No. 1140 TO BE ANSWERED ON 8TH DECEMBER, 2023

Assistance under AMD CF Scheme

1140. DR. KRISHNA PAL SINGH YADAV:

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DR. SHRIKANT EKNATH SHINDE:

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

- (a) whether the Government has set up any mechanism to identify and select the medical device clusters that will be eligible for assistance under the Assistance for Medical Devices Clusters for Common Facilities (AMD-CF) scheme and if so, the details thereof, State/UT-wise particularly in UP, Madhya Pradesh and Maharashtra;
- (b) whether the Government has established any specific criteria or requirements for clusters to qualify for the said scheme and if so, the details thereof;
- (c) whether the Government has undertaken/ proposes to take any measures to monitor the utilization of funds and the overall impact of such scheme and if so, the details thereof; and
- (d) whether the Government has taken/proposes to take measures to prevent the migration of manufacturing units from existing natural clusters to planned clusters in Medical Devices parks, which could disrupt the ecosystem and competitiveness of the industry and if so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI BHAGWANTH KHUBA)

- (a): The Department conducted a Study "Survey of Medical Devices Clusters" to identify the Medical Device Clusters in India. Details for Uttar Pradesh, Maharashtra and Madhya Pradesh are given as **Annexure.**
- (b): There are two sub-schemes under the Scheme "Assistance to Medical Device Clusters for Common Facilities (AMD-CF)" i.e. "Assistance for Common Facilities (ACF)" and "Assistance for Testing Facilities (ATF). Criteria for qualifying under these sub-schemes are as follows:-

Under the sub-scheme "Assistance for Common Facilities (ACF)" Medical Devices manufacturing units in a cluster shall form a Special Purpose Vehicle (SPV) to execute the project. There shall be a minimum of 5 Medical Device manufacturing units as members of SPV. If a cluster is promoted by the State Government, such Project Implementing Agency shall be a legal entity under the Indian law with oversight of the State Government and an

Executive Committee shall be set up for implementation of the project. The SPV or the Executive Committee will have representatives from Cluster Members, financial institutions, State/Central Government and R&D organization. Individual manufacturing unit cannot hold more than 40% in the SPV. Medical Devices enterprises shall hold at least 51% equity of the SPV. The combined net worth of members of SPV shall be equivalent to total grant amount applied for and each SPV member must have a net worth of at least 1.5 times of their proposed equity contribution. The SPV members shall be legally independent entities without any related-party relationship with each other as described under Accounting Standard (AS) 18 of the Companies (Accounting Standard) Rules, 2006.

Under the sub-scheme "Assistance for Testing Facilities (ATF)" any National or State level Government or Private institutions interested to establish or strengthen testing facilities for testing of Class A, B, C and D medical devices including in-vitro diagnostic medical devices under MDR, 2017 are eligible. Such legal entity under the Indian law will open a separate account for the funds to be utilized for the projects assisted under the sub-scheme.

- (c): The Department set up a Scheme Steering Committee under the Chairmanship of Secretary, Department of Pharmaceuticals with Drug Controller General of India as a Member and representatives from Ministry of Micro, Small & Medium Enterprises, Ministry of Electronics and Information Technology, Department for Promotion of Industry and Internal Trade, as Members for consideration and approval of the applications received under the "Assistance to Medical Device Clusters for Common Facilities Scheme (AMD-CF) and also for monitoring the utilization of funds under the Scheme.
- (d): The Scheme AMD-CF aims to strengthen the existing and new Medical Device Clusters by providing financial assistance for creation of Common Infrastructure Facilities which would help in boosting the domestic manufacturing capacity, improving the quality of clusters and sustainable growth of the Medical Device Sector.

Annexure

Sl. No.	State	Medical Device Clusters	Location of the Cluster
1.	Uttar Pradesh	Agra	UPSIDC, Sikandra, Agra,
2.		Noida	GautamBuddha
3.		Sahibabad	Ghaziabad Sahibabad, Ghaziabad
4.		Kanpur	Kakadeo, Kanpur
5.		Lucknow	Hazratganj, Lucknow
6.		Meerut	Shastri Nagar, Meerut
7.	Maharashtra	Ambarnath, Pune	MIDC Anandnagar, Ambernath, Pune
8.		Satpur, Nashik	Malegaon Sinnar MIDC, Nashik
9.		Sinnar, Nashik	Malegaon Sinnar MIDC, Nashik
10.		Bhiwandi	Kalyan-Bhiwandi Road, Bhiwandi

No Medical Device Cluster is identified in the State Madhya Pradesh
