No. K-53013(21)/2/2022-EP-ENGG-DoC Government of India Ministry of Commerce and Industry Department of Commerce

Dated: 21st, September 2022 Udyog Bhawan, New Delhi

OFFICE MEMORANDUM

Subject: Setting up of an Export Promotion Council for Medical Devices, under the aegis of D/o Pharmaceuticals, Government of India

Based on the detailed deliberations in the meetings held by Department of Commerce(DoC), Ministry of Commerce and Industry, Government of India(GoI), with regard to creation of an Export Promotion Council for Medical Devices and the suggestions/responses received from the stakeholders in the Medical Devices sector, approval of DoC, GoI is hereby conveyed to the setting up of an Export Promotion Council for Medical Devices as under:

- i. A separate EPC for medical devices sector may be created under the administrative control of Department of Pharmaceuticals, Government of India, being the nodal Department for the medical devices sector. [The creation of the EPC for medical devices is approved by DoC with one time waiver of the condition in the guidelines on the subject, stipulating creation of an Export Promotion Forum initially, before its upgradation as EPC.]
- ii. The EPC shall be established with Headquarters in YEIDA, Greater Noida, Uttar Pradesh and regional offices in Andhra Pradesh (in AMTZ, Visakhapatnam) and Telangana (in Hyderabad).
- iii. For setting up of the headquarters of the Council, YEIDA to provide, among other things, initial funding support of ₹ 3 crore, free office space (of approx. 5000 sqft area) at the upcoming Medical Devices Park Common Facility Centre (CFC), Greater Noida, and required secretarial staff to run the Council. Till the completion of construction of CFC, YEIDA shall provide suitable office space in their current office building. Kalam Institute of Health Technology at AMTZ to provide two technical scientific resources on free of cost basis for the technical work of the Council.
- iv. The Regional Office at AMTZ, Visakhapatnam (Andhra Pradesh) shall be set up in a period of one year, i.e., by the end of 2023 and the Regional Office at Hyderabad (Telangana) shall be set up in a period of three years, i.e., by 2025. The AMTZ and Telangana government shall facilitate establishment of regional offices in Vishakhapatnam and Hyderabad respectively by providing,

inter alia, suitable office space (free of cost), manpower (free of cost), and

appropriate funding.

v. The administration and management of the council shall be through a Committee of Administration (CoA) as per the extant guidelines of the Department of Commerce. The CoA shall have elected and nominated members (without voting rights). The nominated members shall be from Department of Pharmaceuticals, Department of Commerce, Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Health and Family Welfare, Central Drugs Standard Control Organization (CDSCO), and CEOs/ MDs of major medical device clusters/ parks especially from where regional offices will be established viz. MD, AMTZ; CEO, Hyderabad Pharma City; etc.

vi. The Chairman and Vice Chairman of the Council shall be elected from members who are manufacturers or processors of medical devices. Other members, including from merchant exporters, shall not be eligible to become Chairman and Vice Chairman of the council. However, they will be eligible for

other positions in the CoA.

vii. While the headquarters in YEIDA will currently serve the requirements of member exporters PAN India, once the ROs are functional, the states would be distributed among the 3 offices (HQ and Two ROs). It has been provisionally agreed that while the RO in Vishakhapatnam will have jurisdiction over the states of Andhra Pradesh, Orissa, Tamil Nadu and Chhattisgarh, the RO in Hyderabad will have jurisdiction over the states of Telangana, Karnataka, Kerala, and Maharashtra. However, a final decision regarding the jurisdiction of the ROs will be taken by the Committee of Administration (CoA) after the operationalisation of the Council with headquarters at Greater Noida. If required, the CoA will decide to set up separate regional/sub-regional offices in other states based on the requests from members and feasibility.

viii. The entire range of medical devices goods and services could be broadly qualified into sub-groups called panels, such as disposables, consumables, orthopaedic implants, IVD Equipments & Reagents and surgical instruments. Further, to coordinate the activities of the Council in a more focused manner, there could also be panels like Policy advocacy, technology upgradation and

transfer and start-ups.

ix. The proposed council shall, inter alia, help exporters in promoting their products in international markets, through various promotional activities including organising / participating in international trade fairs, buyer-seller meets, RBSM in India, etc., in line with the foreign trade policy (FTP) of India. The Council may also organize awareness programs for dissemination of information regarding assistance available for the MSME exporters under various government schemes.

- x. EEPC India to provide all assistance and guidance to the newly set up medical devices export promotion council in discharge of its function for a period of 5 years.
- xi. Department of Pharmaceuticals shall ensure that the Export Promotion Council for Medical Devices follows the guidelines and instructions issued from time to time by the Department of Commerce to the EPCs and also the provisions contained in the Foreign Trade Policy pertaining to the EPCs, and is fully compliant with the rules, including conduct of elections, within a period of one year.
- 2. This is issued with the approval of Hon'ble Commerce and Industry Minister.

(Meena Pillai)

Deputy Secretary to the Government of India

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Department of Pharmaceuticals (Ms. S. Aparna, Secretary)
Shastri Bhawan, New Delhi

Copy to:

- (i) E&MDA Division, DoC, New Delhi
- (ii) Dr. Arun Vir Singh CEO, YEIDA;
- (iii) Dr. Jitendra Sharma, MD, AMTZ
- (iv) Shri Shakthi Nagppan, Director (Lifesciences and Pharma), Chief Executive Officer, Hyderabad Pharma City Ltd, Government of Telangana
- (v) Shri Rajiv Nath, Forum Coordinator, AIMED
- (vi) Dr. Satheesh Kumar, ADMI
- (vii) Shri Suranjan Gupta, ED, EEPC India