F. No. K- 11020/303/2018-E&MDA Government of India Ministry of Commerce & Industry Department of Commerce E&MDA Division

Udyog Bhavan, New Delhi Dated: 7th January, 2019

OFFICE MEMORANDUM

Subject: Minutes of the Meeting of the Empowered-Committee of MAI held on 07.12.2018 to consider the proposal to revise the MAI Guidelines.

The undersigned is directed to forward herewith minutes of the meeting of the Empowered Committee of MAI, held on 7th December, 2018, for information and necessary action.

(Rajeev Kumar) Under Secretary (E&MDA) 2306 1764

To

- 1. The Secretary, Ministry of External Affairs
- 2. The Secretary, Ministry of MSME
- 3. The CEO, Niti Aayog
- 4. Dr. Subash Chandra Pandey, SS&FA, DOC
- 5. Shri Alok Vardhan Chaturvedi DG, DGFT
- 6. The Director, IIFT
- 7. Shri Bhupinder Singh Bhalla, Joint Secretary, DoC.
- 8. Shri Santosh Kumar Sarangi, Joint Secretary, DoC
- 9. Shri Shyamal Misra, Joint Secretary, DoC.
- 10. Smt. Rupa Dutta, Economic Advisor, DoC.

Copy to:

- 1. Shri Paban K. Borthakur, Chairman, APEDA
- 2. Shri Ravi Uday Bhaskar, DG, Pharmexcil.
- 3. Shri Suranjan Gupta, ED. EEPC.
- 4. Shri S.G. Bharadi, ED, Chemexcil,

Copy to: PSO to CS / PS to JS(R)

DEPARTMENT OF COMMERCE E&MDA DIVISION

Minutes of the meeting of the Empowered Committee (EC) of MAI, held on 07.12.2018 to consider the proposal to revise MAI guidelines

The List of participants is at Annexure-I.

- 2. A brief presentation was made to the EC outlining the salient features of the MAI Scheme and the proposals received from the Export Promotion Councils to amend the provisions of MAI Scheme/ guidelines for 'enhancing the ceiling' and 'including new components' under statutory compliances.
- 3. The EC was apprised about the existing provisions under the MAI Scheme which provide for reimbursement of the following expenses incurred by Indian exporters to meet statutory compliances:
 - (i) registration of pharma, bio-tech, chemical/ agro-chem, agricultural/ animal/ marine and food products in buyer countries;
 - (ii) clinical trials/ data validation etc. for pharma, devices, medical consumables/ disposables;
 - (iii) Drug Master File (DMF) and Abbreviated New Drug Application (ANDA) filing;
 - (iv) bio-equivalence studies for pharma exports;
 - (v) patent filing for pharma products;
 - (vi) testing charges paid abroad for engineering products; and
 - (vii) regulatory requirement for services sector.
- 4. The EC was informed that reimbursement under the provisions of the MAI Scheme was limited to 50% of the expenses incurred, subject to a ceiling of Rs.50 lakh per exporter per year. The EC was also informed about the steep increase in the registration charges levied by the FDAs, while the ceiling of funding support under MAI has remained unchanged at Rs.50 lakh since 2007. Pharmexcil, Chemexcil and EEPC have submitted requests to increase this ceiling to Rs.2 crore per annum per exporter. They have also proposed to include the following additional components for reimbursement under the MAI Scheme: (i) plant inspection charge, (ii) expenses incurred on bar coding of export consignments for pharma products, (iii) fees paid for quality certification for natural products, (iv) data generation charges, letter of access

cost for chemicals/ agro-chemicals/ cosmetics sector, and (v) expenses incurred on testing in India for export of engineering products.

- 5. The EC was apprised that the instant proposal for amending the MAI guidelines has been supported by EP (Pharma), EP (CAP) and EP (Engg) Divisions.
- 6. JS (E&MDA) apprised the EC about the concern raised by NITI Aayog regarding approval of the present guidelines of MAI by the EFC. It was clarified to the representative of NITI Aayog that the existing guidelines of the MAI Scheme were appraised and approved by EFC in November, 2017 and were issued on 16th February, 2018 after obtaining approval of the competent authority. It was also clarified that as per para 5 and para 4.2 (12) of the MAI Scheme, 2018, the EC was competent to approve revision of MAI guidelines.
- 7. The representatives of Ministry of MSME and MEA supported the proposal under consideration for revising the MAI guidelines.
- 8. The EC was informed about the estimates of annual financial outlays projected by Pharmexcil (Rs.110 crore), EEPC (Rs.75 crore), APEDA (Rs.50 crore) and Chemexcil (Rs.65 crore). However, the actual expenditure incurred on statutory compliances had been rather low (Pharmexcil: Rs.22.01 crore, EEPC: Rs.0.19 crore and Chemexcil: Rs.0.02 crore) in 2018-19. JS (E&MDA) informed that the actual outlays under the revised MAI guidelines will be kept within the limits prescribed under the extant instructions of Department of Expenditure, Ministry of Finance with regard to the outlay approved by the EFC for the period 2017-2020.
- 9. After detailed discussions, the EC approved the following proposals:
 - (a) Revision in the para 6.1 of Part-III of Guidelines for funding under MAI as under:

Existing : "Ceiling: Rs.50 lakh per annum

per exporter

Sharing: 50%: 50%"

To be replaced with : "Ceiling: Rs.2 crore per annum

per exporter

Sharing: 50%: 50%"

- (b) Revision of para 4.2 (8) of the Market Access Initiative Scheme, 2018 by including the following additional components within the overall limit of assistance per exporter as at (a) above:
 - (i) Plant Inspection Charges for the Pharmaceutical products;
 - (ii) Charges incurred by small scale exporters [below the f.o.b value of exports of Rs.30 crore] on bar-coding of export consignments [this would be a one-time grant to defray actual expenditure limited to a maximum of Rs.25 lakh per exporter);
 - (iii) Fees paid for Quality Certification required for Natural Products (Herbal, Ayush products, Dietary Supplement, Nutraceuticals);
 - (iv) Cosmetics products would also be eligible for reimbursement of registration charges;
 - (v) Data generation/ letter of access cost, including study cost, data purchase cost, research on existing data, data evaluation cost, consultancy cost, study monitoring cost, etc. for chemicals/ agrochemicals/ cosmetics products; and
 - (vi) Testing charges in respect of testing done in India for export of engineering products.
- (c) The financial outlays involved in the proposal would be kept within the limit prescribed under the extant instructions of Ministry of Finance (Department of Expenditure) with regard to the Schemes appraised by the EFC for the period 2017-2020.
- (d) The above revision in the Scheme would be effective from the date specified by Department of Commerce in this regard.

LIST OF PARTICIPANTS

- 1. Dr. Anup Wadhawan, Commerce Secretary In chair
- 2. Dr. Subhash Chandra Pandey, SS & FA, Department of Commerce
- 3. Shri Rajneesh, Joint Secretary (E&MDA), Department of Commerce
- 4. Shri Shyamal Misra, Joint Secretary [EP (Pharma), EP (CAP)], Department of Commerce
- 5. Ms. Rupa Dutta, Economic Advisor, Department of Commerce
- 6. Shri Vijay Kumar, Addl. DGFT
- 7. Shri Prakash Nevatia, Director (E&MDA), Department of Commerce
- 8. Shri N. Ramesh, Director (EP: Agri), Department of Commerce
- 9. Ms. Priya Nair, Director, Ministry of External Affairs
- 10. Ms. Mandeep Kaur, Jt. Development Comm., M/o MSME
- 11. Ms. Padma Gánesh, DS (Engg.), Department of Commerce
- 12. Shri U. K. Gupta, Dy. Adviser, NITI Aayog
- 13. Shri Rajeev Kumar, US (E&MDA), Department of Commerce
- 14. Dr. Areej A. Siddiqui, Asstt. Prof., IIFT
- 15. Dr. Dileep Wakankar, Chairman, REACH, Chemexcil
- 16. Shri S. G. Bharadi, ED, Chemexcil
- 17. Dr. J. P. Tiwari, RD, Chemexcil
- 18. Shri Ravi Uday Bhaskar, DG, Pharmexcil
- 19. Dr. Abhay Sinha, Sr. Dir., Pharmexcil
- 20. Shri S. S. Nayyar, GM, APEDA
- 21. Shri Gurvinder Singh, Dir., EEPC India
- 22. Ms. Pallavi Saha, Sr. DD, EEPC India
