PHARMACEUTCIALS EXPORT PROMOTION COUNCIL OF INDIA
(Set up by Ministry of Commerce & Industry)

MARKET ACCESS INITIATIVE SCHEME (MAI) FOR PHARMA EXPORTERS & ROLE OF PHARMEXIL IN INDIAN PHARMA INDUSTRY

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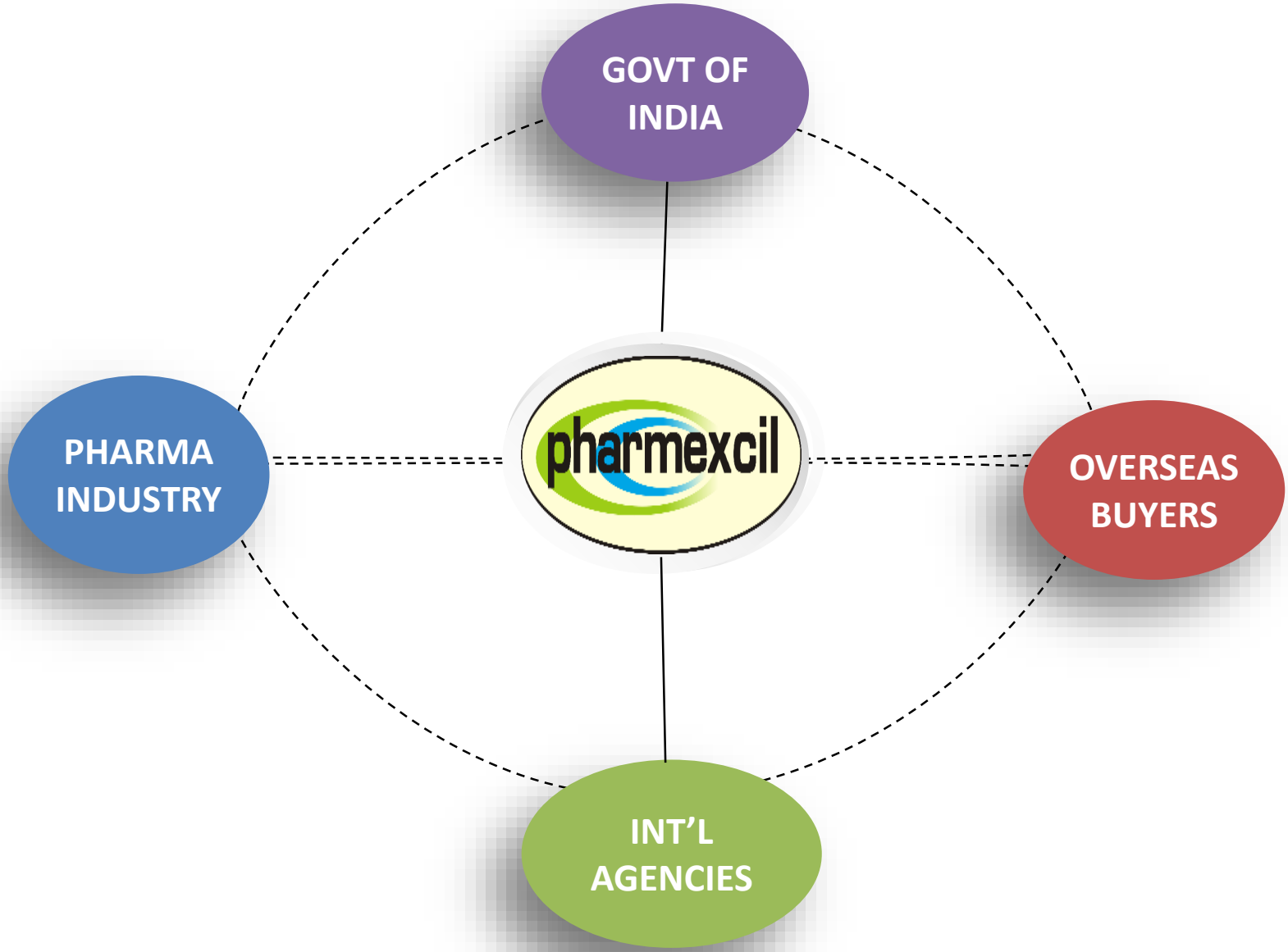
GOVT OF INDIA
PHARMA INDUSTRY
pharmexcil
OVERSEAS BUYERS
INT'L AGENCIES

Pharmaceuticals Export Promotion Council of India

(Set up Ministry of Commerce & Industry, Govt of India)

FACILITATOR

- Organises Export Promotional events and Trade delegations
- Industry's Voice - Represents issues with concerned Agencies

ADVISOR

- Make suggestions to Govt. of India & Regulators on policy issues relating to Pharma exports

EDUCATE

- Market / Regulatory reports of countries
- Importers / Distributors in overseas countries

Handholding Measures by Government of India

Ministry of Commerce & Industry → **MARKET ACCESS INITIATIVE SCHEME (MAI)**

Financial Assistance from
Govt. of India to PHARMEXCIL Members

Market Access Initiatives (MAI) Scheme is an Export Promotion Scheme envisaged to act as a **catalyst** to promote India's export on a sustained basis.

Under the Scheme the level of assistance for each eligible activity has been fixed.

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FOCUS OF THE SCHEME

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MARKET ACCESS INITIATIVE SCHEME (MAI)

Financial Assistance from Govt to PHARMEXCIL Members

50% Reimbursement of expenditure incurred on statutory compliances in the buyer country

a) Registration cost

b) Plant inspection cost

c) BA BE Studies

d) Patent Filing Charges etc

e) Quality Certifications for Natural Products

f) Implementation of Barcoding

g) Conduct of clinical Trials & Data validation

Max Rs. 2 Cr / Yr

Claim within 90 days

https://pharmexcil.com/relevent-members-forms

MAI SCHEME-2021

Eligibility Criteria

- **Member of Pharmexcil**
  Selecting the appropriate category of RCMC. (LSM/SSM/ME)

- **Filing in 90 days timeline**
  Select the correct country, financial year of claim, category.

- **Reimbursement under the Scheme will be limited to the exporters having f.o.b value of exports up to Rs. 100 Crore during the preceding financial year**.

- Reference dates for calculating the eligibility period

Reference Date Registration / Renewal

Reference Dates for Retention

MAI SCHEME-2021

- **Product Registration (PR):**
  - New Registration
  - Re-Registration/Renewal
  - Revision
  - Retention

  ✓For product registration FY of claim is considered based on the date of issue of product registration certificate.

  ✓ANDA : Action date (Approved ANDA's are eligible for claim)

  ✓ DMF : Complete assessment review date

  ✓WHO prequalification: Formulation & API's

For more details please visit

https://pharmexcil.com/docs/MAI/PR/0.PRRequirements.pdf

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MAI SCHEME-2021

- **List of documents required:**

➢ **Firm related:**

- Application Form
- Declaration by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR
- Affidavit by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR
- CA Certificate mentioning the Expenses
- Export Turn Over (FOB) & the Total Turn Over details of the company for the last three financial years duly attested by CA
- Power of Attorney if any

MAI SCHEME-2021

➢ Regulatory :

- Product Registration certificate/Grant of Patent Certificate/Plant Inspection or GMP approval Certificate/Quality certificate, etc. (duly verified by Pharmexcil Office).
- Valid manufacturing license reflecting and highlighting the name of claimed products for export purpose.
- Registration Guidelines, showing FEE structure

MAI SCHEME-2021

➢ Payment:

- Invoice issued by the Drug regulatory authority/Patent Issuing Authority
- Debit Note raised by Agent (if registered through agent)
- Payment of Fee Receipt paid to the Drug regulatory authority/Patent Issuing Authority
- Bank Transfer Remittance (Swift Copy) duly Attested by the Banker
- Outward remittance copy showing the RBI rate of exchange

MAI SCHEME-2021

- **Patent Filing (PA):**
  - ➢ Charges incurred towards obtaining

    New Patent approvals or Renewal of Patents abroad
  - ✓ FY of claim is considered based on the date of Grant of PATENT CERTIFICATE
  - ✓ Patent certificate should be duly verified by Pharmexcil Office
  - ✓ If the Patent is JOINTLY HELD, then Relevant Proof of document showing that the applicant has a Minimum of 75% Stake
  - ✓ INVOICE issued by Patent Issuing Authority
  - ✓ Payment of Fee RECEIPT paid to the Patent Issuing Authority
  - ✓ Patent and Attorney fee structure

    - For more details please visit
    - https://pharmexcil.com/docs/MAI/PT/0.PTRequirements.pdf

MAI SCHEME-2021

BE Studies Charges (BE):

- Charges incurred for carrying out the BE studies in India by the member companies that are submitted to the Drug Regulatory Authority for the registration of the Pharmaceutical product abroad.

- Expenses upto 50% of the costs subject to the ceiling of Rs. 2 Cr per annum for each exporter in case of companies whose investments in plants and machinery excluding land and building is less than Rs. 250 crores and 25% in respect of companies with investments in this category of assets over Rs. 250 crores would be considered for reimbursement on a case to case basis.

- Members can claim either product registration charges or BE study charges.

MAI SCHEME-2021

- NOC for BA/BE studies issued by DCGI
- BA/BE report indicating that the Pre-Clinical work is satisfactory
- BA/BE Study Protocol
- Invoices raised by the NABL laboratory for the clinical work

For more details please visit
https://pharmexcil.com/docs/MAI/BE/0.BERequirements.pdf

- **Eligibility criteria:**
- Export sale value of at least ten times the investment.
- Test to be conducted in laboratories approved by National Accreditation Board for testing and calibration Laboratories (NABL).

MAI SCHEME-2021

Plant Inspection Charges (PIC):

- The fee paid towards Inspecting Indian facilities/Manufacturing units by the Overseas Drug regulatory Authorities (DRA) of various countries.

- Previously fee paid towards visit of foreign regulators was reimbursed – MAI guidelines 2014. Not included in MAI guidelines 2018.

- Earlier 50% of the costs associated with travel and stay of visiting inspectors of foreign regulatory authorities subject to the ceiling of Rs. 75,000/- (Rs. 1,00,000/- in case of American Continent) was reimbursed upon receipt of approvals from such regulatory authorities.

MAI SCHEME-2021

- FY of claim is considered based on the date of issue of GMP approval certificate.
- Inspection Notice & Inspection report
- Inspection request letter
- First email communication between the Company and the Drug regulatory Agency towards Plant inspection.
- If application is submitted to the Drug Regulatory Authority in the form of hard copy, acknowledgement letter/acknowledgement receipt with concerned Regulatory Authority/Agency stamp is required.

For more details please visit
https://pharmexcil.com/docs/MAI/PIC/0.PICRequirements.pdf

MAI SCHEME-2021

- **Fees paid for Quality Certification required for Natural Products (Herbal, Ayush products, Dietary Supplement, Nutraceuticals)**

- Products
- Plant

- Halal, Kosher, NSF GMP (National Sanitation Foundation) NSF Safety & Certifications India etc.

  - For more details please visit
  - https://pharmexcil.com/docs/MAI/EQC/0.EQCRequirements.pdf

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MAI SCHEME-2021

- **Implementation of Barcoding**
- 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 one-time grant to defray actual expenditure limited to a maximum of Rs. 25 lakh per exporter).
- Product approval certificates or Good Manufacturing Practices (GMP) Certificate
- Registration details of applicants in iVEDA portal
- Chartered Engineers Certificate
- Color Photographs of the Plant and Machinery installed
- Cartons or Labels showing the barcoding on export consignments
- IQ (Installation Qualification), OQ (Operational Qualification) & PQ (Performance Qualification) documents of equipment
- **Details of export consignments (i.e., shipping bills -Reference date for calculation of timelines for initiation of application)**

For more deta
https://pharmexcil.com/docs/MAI/EIB/0.EIBRequi

MAI SCHEME-2021

- **Clinical Trails & Data Validation**

- DCGI approvals for Clinical trial Protocol & trail centers involved in conduct of studies *(Form CT-6 / NoC from DCGI)*along with Ethics Committee approvals

- Registration of Clinical trials in the central registry i.e Clinical Trails registry India (CTRI) and Clinical Trails registry abroad if study is conducted aboard

- Clinical Trials Report approved by the DCG(I)

- Agreement of Sponsor with the Clinical Trail Site & Analytical Laboratory for data validation

- REGISTRATION CERTIFICATES/ Market Authorization of product for which Clinical Trials conducted

REIMBURSEMENT OF AIRFARE FOR PARTICIPATION IN APPROVED INTERNATIONAL EVENTS

Maximum of Rs. 90,000 & (Rs. 1,50,000/- for Africa and American continents)

- **Permissible only to the regular director/ partner/proprietor or a regular officer of the company on senior managerial position.**
- **Claim forms to be submitted within 45 days of return to India.**
- **Eligible for members with exports < Rs 50 Cr FOB in the preceding financial year**
- **Members having Nil exports/start-up/new exporters : Exporter has been active in the domestic market and has at least annual turnover of Rs. 50.00 lakh in the preceding financial year**

REIMBURSEMENT FOR PARTICIPATION IN APPROVED INTERNATIONAL EVENTS DURING A YEAR

- **A maximum of three participations in a particular trade fair/exhibition would only be eligible for MAI assistance,**
- **In the case of exporters belonging to SC/ ST/ women and the exporters having F.O.B. Value of exports of or less than Rs.50 crore in a year, 5 participations in a particular event is allowed.**

Initiatives taken by PHARMEXCIL

- B2B meeting in India and abroad
- IP recognition : Ghana, Nepal, Afghanistan & Mauritius.
- WHO GMP Mutual Recognition

Pharmexcil Membership

Registration Cum Membership Certificate (RCMC)

Category	Membership Fee (INR)	Entrance Fee (INR)	GST (18%) (INR)	Total (INR)
Large Scale Manufacturer	36,000/-	18,000 /-	9,720 /-	63,720/-
Small Scale Manufacturer	10,000/-	5,000/-	2,700/-	17,700/-
Merchant Exporter	12,000/-	6,000/-	3,240/-	21,240/-

Note : Renewal Fee Every Financial Year (Membership Fee + GST)

The membership fee of Rs.1000/- for the exporters with ZERO turnover w.e.f 15/8/2019

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Any Questions?

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