## Product Registration (PR)

### List of Documents to be enclosed with MAI Application

1. **Product Registration Reimbursement Application form. Annexure-I** duly completed & authenticated by CEO/CHAIRMAN/MD / PARTNER/PROPRIETOR /Authorized Person.(click here- refer page no: 2)
2. **Declaration -** On the letter head of the Company, duly completed & authenticated by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR (click here- refer page no: 3)
3. **Affidavit -** Completed & authenticated by CEO/CHAIRMAN/MD/ PARTNER/PROPRIETOR (click here- refer page no: 4) Note: Declaration and Affidavit should be signed by the same person.

3a. If Declaration and Affidavit both were signed by other than CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR, Power of Attorney (or) Board Resolution in the name of signed person.

4. CA Certificate mentioning the **Product Expenses** (With Exchange rate) (click here- refer page no: 5)
5. FOB Value of Exports for the preceding Financial Year. (click here- refer page no: 6)
6. **Product Registration Certificates "Original+Copy"(Registration Certificate SHOULD BE on the Name of the Applicant as MARKETAUTHORIZATION HOLDER / MANUFACTURER)**
   a. Original Certificates need to be Verified/Attested by PHARMEXCIL Office (Hyderabad/Mumbai/Delhi).
   I. As in some cases where the Original Product Registration certificates were not issued by the Particular Regulatory Authority then, we will verify those certificates through on-line providing us the Online Links to verify in Official website of drug regulatory authority, and Login credentials, if required (Login id and Password of the company for Verification).
   II. Now-a-days, some countries were issuing online Renewal/Retention Certificates, then all the Invoice and Receipt copies which were issued in original need to be Verified/Attested by PHARMEXCIL Office.
   b. If the product is re-registered, then the details of previous registration along with date of registration and its validity period and a copy of the registration certificate.
   c. After Verification, the Originals will be returned back immediately.
7. **Self-Attested Translation Copies** in English wherever necessary (when documents are in foreign language):
   a. Registration Certificates.
   b. Previous registration certificate.
   c. Invoice.
   d. Receipt.
   e. Registration guidelines reflecting and highlighting the registration fee structure.
8. Copies of **Invoices & Receipts** raised by Drug Regulatory Authorities as Proof of Payment.
9. **Debit Note** raised by Agent (if registered through agent), payment is made by the agent.
10. Bank Transfer Remittance (**SWIFT** copy) showing the Customer Name, Beneficiary Name & Purpose of Payment details a. Attestation/Round Seal by the Banker is MANDATORY on the Bank Transfer Remittance (Swift Copy) with Employee code.
11. **Foreign Outward Remittance** to known the exchange rate as on payment date.
12. In case of **Cash Payment**, the Payment Invoice Number of each product along with product name against which the payment was made should be reflected on Cash Receipt.
13. **Valid Manufacturing Drug Licenses** (Form 25/28) and Renewal License (Form 26) reflecting and highlighting the name of claiming products for export purpose.
14. **Manufacturing Agreement** (if manufacturing is done through Third Party- enclosing Annexure with name of the claimed products).
15. Copy of the Product Registration **Guidelines of FDA**, showing/reflecting the details of Registration Fee to be paid for the Subject product, procedure of product registrations etc.
16. Applicant name should be clear from DGFT DEL STATUS (Denied Entity List).

Note:

- Financial year of the claim, is considered basing on the DATE OF ISSUE OF PRODUCT REGISTRATION CERTIFICATE (Financial year period: 1st April to 31st March).
- Products Registered in different Countries need to be submitted in different Applications.
- Products pertaining to different Financial Years to be submitted in different Applications.
- For all the MAI claims filed by Exporters to Pharmexcil from 26th June 2023, the following two provisions would apply:
  - 90 days' timeline for submission of MAI claims by Exporter to Pharmexcil
  - Limitation of reimbursement to the exporters having f.o.b value of exports up to Rs. 100 crore during the preceding financial year.
- In case of unaudited F.O.B Values of Exports ( April- September) - applicants have to submit the Chartered Accountant Certificate w.r.t FOB value of Exports during the preceding FY along with GST returns filed during the preceding year.
- Application will be accepted only if the company submit all the mandatory documents and confirm the application on-line.
- Processing fee of 5% will be charged on sanction of the amount.

ANNEXURE I

**FORM FOR CLAIMING REIMBURSEMENT OF REGISTRATION CHARGES PAID FOR REGISTRATION ABROAD OF PHARMACEUTICAL/ BIOTECHNOLOGICAL/ AGRO CHEMICAL PRODUCTS**

Date:

| | | |
|---|---|---|
| 1. | Name of the firm with full address | IEC No. |
| 2. | EH/TH Certificate<br><br>Whether SSI/Non-SSI/Trader | No. & Date:<br>Valid Up to: |
| 3. | FOB Value of exports for the preceding financial year | Rs. In Crores: |
| 4. | Particulars of products registered by the Company | Name of the Product:<br>Category: Pharma/Biotech/Agro-chem<br><br>Place:<br><br>Country: |
| 5. | Particulars of certificate procured from Ministry of Health/ Agricultural etc. of Foreign Country along with receipt for payment of registration fee | Date of letter/certificate<br><br>Amount paid in US($)/Euro(€)/ Foreign currency and Indian (Rs.) |
| 6. | Whether certificate from Indian mission concerned certifying the amount paid towards registration charges is enclosed | |
| 7. | Details of registration fees claimed in past:<br><br>1. Name of the product (Pharma/Biotechnological/agro- chemical)<br><br>2. The country of registration<br><br>3. Date of receipt of reimbursement<br><br>4. Amount received | |
| 8. | Details of claims of reimbursement for the year | |
| 9. | Enclose copy of registration certificate issued by foreign agency (if the certificate is in a language other than English, enclose attested translated copy) | |
| 10. | Enclose copy of manufacturing license issued by State Drugs Controller/Licensing Authority (in India) for the subject product | |

**On Company Letter head**

**DECLARATION**

I solemnly declare that the particulars given in the above statement are correct. I bound myself and the company accountable and responsible for any incorrect information given in the above statement and shall immediately refund amount received on the basis of wrong information provided in the above statement.

Signature: _____

Name: _____

Designation: _____

Office Seal: _____

Counter signed by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR of the Company:

Signature: _____

Name : _____

Designation: _____

Office seal: _____

Place: _____

Date: _____

Contd…

**Affidavit to be submitted on Rs.50/- or Rs.100/- Non-Judicial Stamp Paper**

**AFFIDAVIT**

I,…… S/o …… Aged about..... Years Resident of

… ..... do here by affirm on oath as under.

That I am CEO/CHAIRMAN/Managing Director/Partner/Proprietor of M/s.....on whose behalf an application is made for claiming reimbursement of Registration charges paid for Registration Abroad of Pharmaceutical /Biotechnological Products to the Department of Commerce, Ministry of Commerce and Industry, Government of India, New Delhi Under MAI Scheme.

I, solemnly declare that the particulars given in the above application are correct. I bound myself and the company accountable and responsible for any information given in the application. If any of the information and documents found false by any agency, we are responsible for any action initiated by the Government under any law and we will also refund that amount as per govt. rules, immediately.

Signature by CEO/CHAIRMAN/MD/PARTNER/PROPRIETOR of the Company:

Signature: _____

Name: _____

Designation: _____

Office seal: _____

Place: _____

Date: _____

Contd…

**On CA Letter Head**

This is to certify that we have verified the records of M/s..... **Company Name & Address** and found that they incurred US$/EUROS… ..... as per following details:

| S.NO | Particulars of expenses (each products names in individual cells) | Amounts in | | |
|---|---|---|---|---|
| | | USD/EURO | Exchange rate | Rupees |
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |
| 5. | | | | |
| 6. | | | | |

Signature & Stamp/Seal of the Signatory:

Signature: _____

Name: _____

Membership No.: _____

Full Address: _____

Name and address of the Institution where registered.

Place: _____

Date: _____

Contd…

**On CA Letter Head**

**TO WHOM SO EVER IT MAY CONCERN**

This is to certify that the company **M/s……(Company Name)** having its Registered office **(Address)……**, has the **Export Turnover (FOB values of exports)** for the proceeding financial year as mentioned below:

| S.No. | Financial Year | Amount in Crores (Only) (Audited or Unaudited) |
|---|---|---|
| 1 | | |

Signature & Stamp/Seal of the Signatory:

Signature: _____

Name: _____

Membership No.: _____

Full Address: _____

Name and address of the Institution where registered.

Place: _____

Date: _____

Note :- (Please mention whether the FOB values of exports are audited or unaudited –it's mandatory)

Date:

# SELF DECLARATION

## TO WHOM SOEVER IT MAY CONCERN

We, M/s……(Company name)……, hereby confirm that the following MAI Claim application ( Application No. … .....) was submitted to Pharmexcil towards reimbursement of Product Registration Charges.

The following product was submitted/filled/initiated to the Drug Regulatory Authority of …… Submission/Filing details are as given in the trailing table.

| Product Name | Product Registration number | Category: Registration/Re-Registration/Renewal/Retention | Date of submission/initiation of application to Drug Regulatory Authority towards particular category. |
|---|---|---|---|
| | | | |
| | | | |

We confirm that the application towards particular product registration/re-registration/renewal/retention was Submitted to Drug Regulatory Authority of the country of .....on or after 07.01.2019.

Yours sincerely,

(Authorize person signature)

Designation:

**ON Company letter head**

**To Whom So Ever It May Concern**

We M/s……(Company name ) hereby providing the following details towards payment for the claimed products.

| S.NO | Product Name | Invoice. No. | Invoice Date | Receipt No | Receipt Date | Debit Note No. | Debit Note date | Bank statement Date | TT reference Number | Amount in Foreign currency |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | | |
| 2 | | | | | | | | | | |
| 3 | | | | | | | | | | |

**And also mention the Purpose of payment:**

Yours sincerely,

(Authorize person signature)

Designation: