PRODUCT REGISTRATION (PR)

List of Documents to be enclosed with MAI Application

1. **Annexure - I** duly completed & authenticated by CEO/CHAIRMAN/MD (click here)
2. **Product Registration Certificates "Original + Copy" (Registration Certificate SHOULD BE on the Name of the Applicant as MARKET AUTHORIZATION HOLDER / MANUFACTURER)**
    a. Originals Certificates need to be Verified/Attested by PHARMEXCIL Office (Hyderabad/Mumbai)
    b. All the Primary/Previous Registration Certificates/Renewal/Retention Copies need to be Verified/Attested
        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, Reference Numbers and if required then Login and Password of the company for Verification.
        ii. Now-a-days, some counties were issuing online Renewal/Retention Certificates, then all the OLD Physical Certificates which were issued (long time back) need to be Verified/Attested by PHARMEXCIL Office
    c. 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
    d. After Verification, the Originals will be returned back immediately
3. Copies of **Invoices & Receipts** raised by Drug Registration Authorities as Proof of Payment
4. Bank Transfer Remittance (**SWIFT** copy) showing the Customer Name, Beneficiary Name & Payment details
    a. Attestation/Round Seal by the Banker is MANDATORY on the Bank Transfer Remittance (Swift Copy)
5. Foreign outward remittance to known the exchange rate as on payment date
6. In case of cash payment, the Payment Invoice Number of each product against which the payment was made should be reflected on Cash Receipt
7. Self-Attested Translation Copies in English wherever necessary:
    a. Registration Certificates
    b. Invoice
    c. Receipts
8. **Valid Manufacturing Drug Licenses** (Form 25/28) and Renewal License (Form 26) reflecting and highlighting the name of claiming products for export purpose.
9. Copy of the Product Registration **Guidelines of FDA**, showing the details of Registration Fee to be paid for the subject product, procedure of product registrations etc.
10. A Brief report on Pharma Market of the Product Registered Country
11. **Specimen Labels** or cartons of claiming products
12. **Export Turnover (FOB) & Total Turnover** details of the Company for the last Three Financial Years duly attested by CA (click here)
13. CA Certificate mentioning the **Product Expenses** (click here)
14. **Affidavit** (click here)
15. **Export Values of Products** (for which MAI benefit has been availed) from the Date of Registration to till Last Financial Year (click here)
16. Processing Fee of 5% will be charged on sanction of the amount

Note:

- **Financial year of the claim**, is considered basing on the **DATE OF ISSUE OF REGISTRATION CERTIFICATE** (Financial year period : **1st April** to **31st March**)
    - Applications FY 2018-19 from 01-Apr-2018 onwards Government has issued Revised Guidelines and all the Claims to be filed within 90 days from the date of Registration. Claims received after this date will not be considered
- Products **Registered in different Countries** need to be submitted in **different Applications**
- Products **pertaining to different Financial Years** to be submitted in **different Applications**

Contd...

ANNEXURE I

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

Ref No . Date:

1.	Name of the firm with full address	IEC No.
2.	EH/TH Certificate Whether SSI/Non-SSI/Trader	No. & Date: Valid Up to
3.	FOB Value of exports during last financial year	Rs. In Crores:
4.	Particulars of products registered by the Company	Name of the Product: Category: Pharma/Biotech/Agro-chem Place: 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 Amount paid in US$ 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: 1.Name of the product (Pharma/Biotechnologyical/agro-chemical) 2. The country of registration 3. Date of receipt of reimbursement 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 licence issued by State Drugs Controller/Licensing Authority (in India) for the subject product	

Contd…

On Companies 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: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Countersigned by CEO/CHAIRMAN/MD of the Company:

Signature: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Designation: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Office seal: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Place: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Contd…

Affidavit to be submitted on Rs.50/- 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/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 of the CEO/CHAIRMAN/MD/Proprietor of the company:

Signature: _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _

Designation: _ _ _ _ _ _ _ _ _ _ _ _ _ _

Office seal: _ _ _ _ _ _ _ _ _ _ _ _ _ _

Place: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Contd…

On CA Letter Head

CERTIFICATE

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 product names in individual cells)	Amount in	
		USD/EUROS	RUPEES
1			
2			
3			
4			
5			

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 WHOMSOEVER IT MAY CONCERN

This is to certify that the company **M/s…… (Company Name)** having its registered office **(Address)……**, has the **Export Turnover (FOB)** & the **Total Turnover** for the last three financial years as mentioned below:

S.No.	Financial Year	Amount in Crores	
		FOB value of Export	Total Turnover
1			
2			
3			

Signature & Stamp/Seal of the Signatory:

Signature: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Membership No.:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Full Address: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name and address of the Institution where registered.

Place: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Contd…

On Companies Letter Head

EXPORT VALUES OF PRODUCTS (for which MAI benefit has been availed) from the Date of Registration to till Last Financial Year

Name of the Company: _

Sl.No	Country	Name of the Product	Export Values (INR/lacs)		
			FY 20_ _- _ _	FY 20_ _- _ _	FY 20_ _- _ _
1					
2					
3					
4					
5					

Note: If information is NIL indicate the same.
Country wise details not necessary, give total export value only.
In case of difference please inform us.