National Medicines Regulatory Authority, Sri Lanka

NMRA
NATIONAL MEDICINES REGULATORY AUTHORITY

Application for Approval of an Overseas Manufacturer of Medicines

Part A: Details of the Authorized Importer (Local Agent)-

1. Name of the Company:
2. Address and contact details of the company:
3. a) Registered office- Address:
   Telephone:
   Facsimile:
   Email:

   b) Operations office- Address:
   Telephone:
   Facsimile:
   Email:

   c) Ware house- Address:
   Telephone:
   Facsimile:
   Email:

4. Are you already a licensed market authorization holder in Sri Lanka? Yes/No
   (If yes, copy of the current wholesale license to be attached)

5. Mode of business e.g. individually owned, partnership, corporation etc.:
   (Copy of business registration by registrar of companies including addendums indicating details of directors and nature of business to be attached)

6. Details of the management and relevant staff:
   Names of the Board of Directors:
   1.
   2.
   3.

   Responsible officers (With qualifications, experience and responsibilities):

   1. Technical [including person(s) in-charge of Regulatory Affairs]:

Name	Designation	Qualifications	Experience (years)

b) Administrative:

Name	Designation	Qualifications	Experience (years)

7. Have you been appointed as the sole agent of the manufacturer in Sri Lanka or as agent for a specific product range? *(Letter of appointment issued by the manufacturer and copy of the agreement to be attached)*
8. Details of the pharmacist who is responsible for importing:
   - Name:
   - Designation:
   - SLMC Registration No:
   - Telephone:
   - Email:
9. Give details of premises, equipment and facilities for the handling, storage and distribution of pharmaceuticals which may be imported under his license, and necessary to avoid deterioration of such pharmaceuticals.
10. Details of the person who is responsible for Pharmacovigilance:
    - Name:
    - Designation:
    - SLMC Registration No:
    - Telephone:
    - Email:
11. Proposed post marketing surveillance plan:
    (Standard operating procedure (SOP) shall be attached)
12. Recall procedure of the company:
    (SOP shall be attached)
13. Declaration by the applicant:
    (An authorized person of the local agent should sign the declaration for which the format is given in annexure II)

Part B-Business information on manufacturing company

1. Name of the Company:
2. Address:
   - Head Office:
   - Manufacturing Plant:

   Indicate whether there are any other manufacturing plants at different locations:

   (Information on each manufacturing sites should be submitted in separate applications, and will be evaluated and registered separately)
3. Nearest Airport:
4. Telephone:
5. Fax:
6. Email:
7. Web site:
8. Contact person:

- Telephone:
- Email:

9. Year of Establishment:

10. Nature of the Company: *Individually owned / Partnership/ Corporation*
11. Names and Addresses of international pharmaceutical companies with whom there is collaboration or joint ventures, (if any):
12. Indicate whether the company is the actual manufacturer, contract manufacturer, manufacturing on a loan license. *(Copies of agreements to be submitted)*
13. Drug Manufacturing License Number issued by the Central Drug Authority:
    (*A copy of that certificate to be to be submitted)*
14. Capital., Value of Authorized capital / Paid up capital/Reserves –
15. Total sales turnover in the previous three years -each year separately. Split between export and domestic sale.

Year	Domestic	Export

(Proof documents for export & domestic sales should be enclosed)

[Also three drug registration certificates issued by the Drug Regulatory Authority in your own country as a proof of domestic sales]

16. Types/Categories of products manufactured at the site: *(please tick where appropriate)*

Sterile products Yes ☐ No ☐ Non-sterile products Yes ☐ No ☐

	Products with Special requirements (if any)	√
1.	Vaccines	☐
2.	Biotechnological products	☐
3.	Plasma products	☐
4.	Beta lactam Antibiotics (please specify – e.g. penicillin)	☐
5.	Other highly sensitizing antibiotics	☐
6.	Cytotoxic	☐
7.	Sex hormones	☐
8.	Radiopharmaceuticals	☐
	Other <Please specify>	☐
		☐
		☐

17. Names of finished pharmaceuticals products actually manufactured at the site and which are available for export and/or intended to submit for registration in Sri Lanka. *(To attach the list, in non-proprietary names)*
18. Indicate if the products manufactured at the site are not marketed in your own country. *(If yes, give reasons)*
19. List pharmaceuticals and /or raw materials manufactured by other companies and marketed by you. Please give names of these companies, against items (if applicable).
20. List pharmaceutical products and /or raw materials manufactured by you and marketed by other companies. (if applicable)
21. List GMP inspections of the facilities carried out within last five years by the local Authority and if any, International Agencies.
22. List of Countries to which your drugs are presently exported and the names of the drugs exported to each country. *(At least three copies of drug registration certificates from three deferent countries for three deferent years and three Certificates of a Pharmaceutical Product (CPPs) issued according to W.H.O Certification Scheme, by the Drug Regulatory Authority of the country of origin to be enclosed).*

Explanatory notes:

1. A loan license - which a Licensing Authority may issue to an applicant who does not have his own arrangements for manufacture but intends to avail him-self of the manufacturing facilities owned by a licensee".
2. Contract manufacturer - a manufacturer who performs some aspect of manufacturing on behalf of the original manufacturer. This definition is included in the ICH and WHO Guidelines for GMP.

Annexure I

Mandatory documents to be submitted along with the application:

- Site master file (SMF) - relevant to the facility as per the guideline and, authenticated by the head of quality assurance should be enclosed in the application dossier.
- Declaration by the applicant as per the format given in annexure II
- Letter of authorization and copy of the agreement between the manufacturer and the authorized importer
- Letter by responsible person of the manufacturer, certifying that the content submitted are true and accurate (see annexure III for the format)
- Copy of business registration of the authorized importer by registrar of companies including articles
- Copy of valid wholesale license of the authorized importer by NMRA.
- Certifications by Chamber of Commerce – Justifications should be submitted, if unable to submit.
- Copy of valid GMP certificate indicating the product range
- Copy of valid manufacturing licence for the site indicating details of qualified persons and scope.
- Minimum of three CPPs issued to three different products.
- Certificates of registration issued by three different authorities other than the country of origin.
- A list of products intended to be registered and marketed in Sri Lanka.
- A list of market complaints and recalls in the last three years including one investigation report for one of the complaints classified as high risk to public health. (or declaration)
- Details of any regulatory actions in the past three years such as warning letters and product alerts , or equivalent regulatory action issued by any competent authority to which the site provides or has applied to provide the product. (or declaration)
- An undertaking by the manufacturer that it is agreeable to an onsite GMP inspection if and when required.

<u>Documents required to consider exemption from an onsite GMP inspection</u>

- A notarized copy of the last inspection report by the competent authority of the country of origin.
- A notarized copy of the full inspection report(s) for inspections performed by a reference NRA or WHO within last five years.
- CAPA and proof of CAPA implementation related to the last inspection report observations/deficiencies or any warning letters or equivalent regulatory actions (production line specific).
- The most recent product quality review (PQR) report(s) for each dosage form relevant to products intended to be registered, covering all required subsections and trend results.
- The batch manufacturing record(s) of a product for each dosage form relevant to products intended to be registered and manufactured in the past 6 to 12 months.
- Process validation report of a product for each dosage form relevant to products intended to be registered.
- Validation Master Plan.
- Aseptic processing and filling validation reports if the products intended include sterile products which are not terminally sterilized.
- List of reprocessed or reworked product batches in last two years.

N.B: If certificates and/or licenses are not in English, translation copies to be certified by the Sri Lankan Embassy of the issuing country)

Annexure II

To be typed on company's original letterhead

Declaration by the Applicant

Date: .....

Chief Executive Officer
National Medicines Regulatory Authority
No. 120, Norris Canal Road
Colombo 10
Sri Lanka

Declaration of the Authorized Person

I, ...(full name of the authorized person)....., the undersigned, hereby declare that all the information submitted with this application is true and correct and certify that all documents uploaded in support of this application are accurate and most recent as per to date.

I agree to provide any further information and documents requested by the National Medicines Regulatory Authority, which is required for processing of this application and, facilitate any requests by the National Medicines Regulatory Authority for inspection of premises and/or records.

I further declare that I take full responsibility for all consequences, which might arise from false or erroneous information submitted in the application and that I will cooperate with any official of the National Medicines Regulatory Authority for any such investigations relevant to the application.

If this application is approved, I agree to comply with all applicable laws, regulations and guidelines that are relevant.

.....
Signature of the Authorized Person

Company's/Authorized person's
Official rubber stamp

Name of the Authorized Person:
Designation of the Authorized Person:

Annexure III

CERTIFICATION BY THE MANUFACTURER

I, the undersigned (full name of the person responsible) .....
.....hereby declare that all the information given above is true, and I take the full responsibility for all consequences, which might arise from false or erroneous information. If required, I will cooperate with any official of the National Medicines Regulatory Authority of Sri Lanka and avail for inspection of the manufacturing facilities and records.

We hereby certify that the information given with this application is true and that the company concerned fulfils the requirements of the local regulation concerning the manufacturing of pharmaceuticals.

.....

Signature of the responsible person of the manufacturer

Name:

Designation:

Date:

Annexure- IV

Certification by the Chamber of Commerce or Similar Organization.

(To be filled by authorized officer of above-mentioned organization)

1. Name of Company: . .....

2. Address :

   Head Office: .....

   Manufacturing Plant: .....

3. Membership details on manufacturing plant on your organization.

   Membership No-
   Issued date-

4. Details on total sales turnover in the previous three years of the manufacturing plant.

Year	Domestic	Export

We hereby certify that the information given is true and that the company concerned fulfills the requirements of the local regulation concerning the manufacturing of pharmaceuticals.

Name of the Authorized Officer:

Contact Details:

Signature/Date: