# ANNEX 4.1 - UNRWA Product Information Questionnaire for Pharmaceutical Products approved by WHO/SRA/PIC.s/other UN Agencies

Please complete all the fields in the Questionnaire as required and attach the requested supporting documents.

**Part 1: MANUFACTURER/SUPPLIER CONTACT DETAILS**

Name of manufacturer:

Name of Supplier (if different from manufacturer):

Physical address of office (include Block number, line number etc.):

Physical address of manufacturing plant:

Postal address:

|  |  |
| --- | --- |
| City: | Country: |
| Telephone: | Fax: |
| E-mail: | Website: |

**Part 2: FINISHED PHARMACEUTICAL PRODUCT**

Please fill out one form separately for each pharmaceutical product

1. **IDENTIFICATION**

|  |  |  |  |
| --- | --- | --- | --- |
| Content | Active Pharmaceutical Ingredient | Amount in dosage form or amount per unit | \*Pharm. form and admin route(s) |
| Active Ingredient 1 |  |  |  |
| Active Ingredient 2 (if applicable) |  |  |  |

\*Pharmaceutical forms (Use all that apply from the selection below)

Inactive Ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. Contains Alcohol 10%):

Dosage form (tick whichever is applicable):

* **Tablets**
  + Uncoated
  + Sugar coated
  + Film coated
  + Enteric coated
* **Capsules**
* **Syrup/oral liquids**
* **Injection**
  + Microcrystalline Suspension
  + Oily Solution
  + Aqueous Solution
  + Powder for injection
* **Implants**

Route of administration (tick whichever is applicable):

⬜ Oral ⬜ I.M. ⬜ I.V. ⬜ S.C. ⬜ Other (Please specify)

A. Include sample of the Finished Pharmaceutical Product with the CoA of the sample.

B. Attach package insert if applicable and patient information leaflet (PIL). Kindly note that SRA or WHO PQT approval must be attached.

1. **PACKAGING**

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

(Fill the below if more than one type of packaging)

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

Description and composition of primary packaging materials:

Description and composition of secondary packaging materials:

1. **SHELF LIFE and STORAGE CONDITIONS**

Shelf life as it appears on the packaging:

Shelf life after primary package is opened:

Specific storage conditions for this product as they appear on the packaging and based on stability studies:

Temperature:

Light:

Humidity:

Other (Specify):

1. **REGULATORY STATUS**

Certificate of Pharmaceutical Product No.:

Valid until:

CPP issued by (Name of Agency):

Country:

C. Attach Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme-WHO Technical Report Series No. 863 (earlier version is not acceptable) or equivalent document. All questions on the certificate should be answered and all attachments included.

Tick and fill in all fields that apply:

|  |  |
| --- | --- |
| Product registered and currently marketed in the country of manufacture | |
| License no: | Valid until: |
| Issued by: Agency: | Country: |
| Product registered for marketing in the country of manufacture but not currently marketed: | |
| License no: | Valid until: |
| Issued by: Agency: | Country: |
| Product registered for export only | |
| License no: | Valid until: |
| Issued by: Agency: | Country: |

Product not registered in country of manufacture (please clarify):

D. Attach a list of countries where product is registered, including the specific product name and license number in each country.

E. Copy of registration certificate from Stringent Regulatory Authority OR Approval Letter from WHO Prequalification Team.

**Part 3: MANUFACTURER INFORMATION**

1. **GOOD MANUFACTURING PRACTICES (GMP)**

|  |  |
| --- | --- |
| WHO GMP certificate no: | Valid until: |
| Issued by: | Country: |

GMP inspections carried out by (tick all that apply):

WHO Prequalification Programme Date:       Outcome:

Stringent Regulatory Authority (SRA) Date:       Outcome:

PIC/s member country Date:       Outcome:

Any other UN agency/other

interagency partner organizations Date:       Outcome:

F. Copy of GMP certificate by WHO/SRA/PIC.s/UN agency

**Part 4: COMMITMENT AND AUTHORIZATION**

I (Full Name) , certify that:

The product offered is identical in all aspects (i.e. manufacturing, in-process controls, API specifications, in-process specifications, FPP specifications, manufacturing site, labelling, packaging etc.) to that registered and marketed

in       *(name of country) OR* WHO Pre-Qualified by the WHO Prequalification Team*.*

* I, the undersigned confirm that the company has no objection to the information contained herein being shared with UNRWA partner organizations

|  |  |  |
| --- | --- | --- |
| Signature: |  | Date: |
| Position: |  | Stamp here: |

**Annex: Checklist of attachments required**

Attachments or Annexes to the Questionnaire in Annex D1 should be in PDF format and should be well indexed to facilitate review. Examples of the indexing are as below.

Please ensure that all documents necessary to enable objective evaluation of your product are attached to your response to this EOI (this checklist may not be exhaustive):

Annex A. Sample of the Finished Pharmaceutical Product with the CoA of the sample.

Annex B. Package Insert if applicable and Patient Information Leaflet (PIL) with evidence of SRA or WHO Pre-Qualification Team approval

Annex C. Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme-WHO Technical Report Series No. 863.

Annex D. List of countries where product is registered, including the specific product name and license number in each country.

Annex E. Registration certificate from SRA[[1]](#footnote-1) or Approval Letter from WHO Pre-Qualification Team.

Annex F. Copy of GMP certificate by WHO/SRA1 /PIC.s/UN agency

1. The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority (SRA). For details on ICH, please look at [www.ich.org](http://www.ich.org) [↑](#footnote-ref-1)