**Annex 10. UNFPA Questionnaire for Pharmaceutical Products**

**WHO Prequalified/ERP/SRA approved**

**Please complete all the fields in the questionnaire as required and attach the requested support documents.**

1. **MANUFACTURER CONTACT DETAILS**

Name of manufacturer (s):

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

Postal address:

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

**Contract manufacturer:**

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

Postal address:

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

**SECTION 1: FINISHED DRUG 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%):

Brand/trade name (if any):

Dosage form:

* **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:

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

A. Include sample of the finished pharmaceutical product with the CoA of the sample.

(Labeling must be in English/French/Spanish)

B. Attach package insert if applicable and patient information leaflet (PIL).

(Must be in English/French/Spanish)

C. Attach release specifications and shelf-life (regulatory) specifications.

1. **PACKAGING**

Number of dosage units per unit packs:

Numbers of unit packs per secondary pack

(Multiples of unit packs):

Description and composition of primary

packaging materials:

Description and composition of secondary

packaging materials:

1. **STABILITY STUDIES, SHELF LIFE and STORAGE CONDITIONS**

☐ Ongoing (and/or long term) stability data of the product

D. Attach status report of any ongoing (and/or long term) stability studies

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):

☐ Product suitable for use in the following ICH Climatic Zones:

Zone I       Zone II

Zone III       Zone Iva

Zone IVb       Other (please specify):

E. Attach copy of the certificate of analysis for the 3 most recently released batches.

1. **REGULATORY STATUS**

Certificate of Pharmaceutical Product No.:       Valid until:

CPP issued by (Name of Agency):       Country:

WHO Prequalification Date:       WHO PQ number:

ERP opinion Date:       Valid until:

F. Attach CPP according to the WHO Certification Scheme-WHO Technical Report Series No. 863 (earlier version is not acceptable) or equivalent document. For WHO PQed products via the SRA route, the CPP should be from the reference SRA. **All questions on the certificate should be answered and all attachments included**.

G. When CPP is not available attach an official statement of licensing status.

H. WHO Prequalification letter

I. Full WHO Public Assessment report

J. ERP opinion if the medicine is not in the List of RH medicines eligible for WHO PQ

1. **LICENSING STATUS**

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):

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

L. Attach a copy of registration certificate from Stringent Regulatory Authority OR Approval Letter from WHO PQT

**SECTION 2: MANUFACTURER**

1. **GOOD MANUFACTURING PRACTICE (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:

☐ Other (please specify)       Date:       Outcome:

M. Copy of GMP certificate by SRA OR the most recent WHO Inspection Report.

**SECTION 2: Active Pharmaceutical ingredient**

**8) API DETAILS**

N. Attach API release specifications and shelf-life (regulatory) specifications.

**9) MANUFACTURER DETAILS**

Name of manufacturer (s):

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

Postal address:

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

**10) GOOD MANUFACTURING PRACTICE (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:

O. Copy of GMP certificate by SRA OR the most recent WHO Inspection Report for API manufacturer.

**COMMITMENT**

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, labeling, packaging etc.) to that registered and marketed

in       *(name of country) OR* WHO Prequalified by the WHO Prequalification Team*.*

| Signature: |  | Date: |
| --- | --- | --- |

| Position |  | Stamp here: |
| --- | --- | --- |

**DECLARATION BY APPLICANT**

P. Filled out declaration from applicant.

[*Company letterhead*]

**Declaration by an applicant**

I, the undersigned certify that all the information in this declaration and all accompanying documentation is correct and updated. I further certify that I have examined the following statements and I attest to their accuracy.

1. The holder of the national registration follows national requirements for handling adverse reaction on its products.
2. The holder of the national registration follows national requirements for handling batch recalls of its products.
3. The formula applied for is the exact formula as the one approved by Stringent Regulatory Authority (SRA), which is the reference National Regulatory Authority (NRA), WHO Prequalification or received positive opinion from ERP, whichever is applicable. The strength, specifications (API, excipients and FPP), etc. are the exact formula as the one approved by the SRA, which is the reference NRA, WHO Prequalification or received positive opinion from ERP, whichever is applicable.
4. The primary packaging is exact same in all aspects, including specifications, as the primary packaging approved for use in the same product as approved in the ICH member which is the reference NRA or WHO Prequalification whichever is applicable.
5. The secondary packaging is exact same in all aspects, including specifications, as the primary packaging approved for use in the same product as approved in the ICH member which is the reference NRA or WHO Prequalification whichever is applicable.
6. The information in the questionnaire/dossier submitted to UNFPA contains information which is the same as the information in the dossier which is approved in the ICH member which is the reference NRA or WHO Prequalification whichever is applicable.
7. Any amendments and variations, as defined in the current Variations guidelines as published in WHO Technical Series, or the reference NRA guidelines on variations; to the questionnaire/dossier approved by the ICH member or associate member will be communicated to UNFPA within 3 months of approval by the competent authority.
8. The package insert, summary of product characteristics, patient information leaflet submitted in the application are the same as those approved by the SRA which is the reference NRA, WHO Prequalification or received positive opinion from ERP whichever is applicable.
9. Where there are any differences in any aspect of the product including formula, manufacturing site of API, manufacturing site of FPP, specifications of primary packaging, specifications of secondary packaging, package insert, summary of product characteristics, patient information leaflet, I have stipulated these and the justification for the changes in a separate document and submitted to UNFPA.

Name: Signature:

Position in Company: Date:

**Annex: Checklist of attachments required**

Please ensure that all documents necessary to enable objective evaluation of your product are attached. This checklist may not be exhaustive.

☐ A. Sample of the finished pharmaceutical product offered together with COA of the sample.

**(Labeling must be in English/French/Spanish)**

☐ B. Package insert if applicable and patient information leaflet (PIL).

**(Must be in English/French/Spanish)**

☐ C. Attach release specifications and shelf-life (regulatory) specifications.

☐ D. Attach status report of any ongoing (and/or long term) stability studies.

☐ E. Copy of the certificate of analysis for the 3 most recently released batches.

☐ F. CPP according to the WHO Certification Scheme-WHO Technical Report Series No. 863 (earlier version is not acceptable) or equivalent document. For WHO PQed products via the SRA route, the CPP should be from the reference SRA. **All questions on the certificate should be answered and all attachments included.**

☐ G. When CPP is not available attach official statement of licensing status.

☐ H. WHO Prequalification letter

☐ I. Full WHO Public Assessment report

☐ J. ERP opinion if the medicine is not in the List of RH medicines eligible for WHO PQ

☐ K. List of countries where product is registered, including the specific product name, license number in each country and copies of registration certificate.

☐ L. Copy of registration certificate from Stringent Regulatory Authority OR Approval Letter from WHO PQT.

☐ M. Copy of GMP certificate by SRA OR the most recent WHO Inspection report.

☐ N. Attach API release specifications and shelf-life (regulatory) specifications.

☐ O. Copy of GMP certificate by SRA OR the most recent WHO Inspection Report for API manufacturer.

☐ P. Filled out declaration from applicant.

\* 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).



**CONFIRMATION FROM APPLICANT – to be returned at PO stage**



Supplier:

Address:

Product INN:

Dose:

Dosage:

FPP manufacturing address:

PO:

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, (full name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (position) in \_\_\_\_\_\_\_\_\_\_\_\_\_ (supplier company) hereby confirm that product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (INN and dose) shipped as part of PO number \_\_\_\_\_\_ (PO) is indeed the same as evaluated and approved by UNFPA in \_\_\_\_\_\_\_\_\_\_\_ (date), including FPP manufacturing site, API source, shelf life, storage conditions etc.

Date and place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature and stamp: \_\_\_\_\_\_\_\_\_\_\_\_

UNFPA review date: \_\_\_\_\_\_\_\_\_\_\_\_\_

# Commitment and authorization

## 1. Commitment

I, the undersigned, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ acting as responsible for the company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

certify that the information provided (above) is correct and true,

**☐** and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*country of origin*), including disease category type, intended use, intended population, specimen type, method and site of manufacture, sources of materials, quality control of the product and starting material, packaging, shelf-life and product information.

**☐** and I certify that the product offered is identical to that marketed in (name of country), except:

(e.g. state the stipulated exception)

If any changes occur to the information after the submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible.

Date: Signature:

## 2. Power of attorney

The manufacturer authorizes a distributor to submit the questionnaire.

Date: Signature:

Distributor (Signed by Distributor for Manufacturer under power of attorney) Please provide a copy of the power of attorney.