United Nations Nations Unies

Economic Commission for Africa (ECA)
Ethiopia

REQUEST FOR EXPRESSION OF INTEREST (EOI)

This notice is placed on behalf of UNECA. United Nations Procurement Division (UNPD) cannot provide any warranty, expressed or implied, as to the accuracy, reliability or completeness of contents of furnished information; and is unable to answer any enquiries regarding this EOI. You are therefore requested to direct all your queries to Economic Commission for Africa (ECA) using the fax number or e-mail address provided below.

Title of the EOI:
Invitation for Pre-qualification of Essential Health Products Manufacturers for the AfCFTA-anchored Pharma Initiative's Pooled Product Evaluation by the United Nations Economic Commission for Africa

Date of this EOI: 10 June 2020

Closing Date for Receipt of EOI: 10 July 2020

EOI Number: EOIUNECA17541

Address EOI response by fax or e-mail to the Attention of: Rahel Tarekegne

Fax Number:

E-mail Address: shiferaw3@un.org

UNSPSC Code: 51000000

DESCRIPTION OF REQUIREMENTS

To maximize the opportunities arising from African Continental Free Trade Area (AfCFTA), African Medicines Agency (AMA) and to realize the objectives of the Pharmaceutical Manufacturing Plan for Africa, the United Nations Economic Commission for Africa (ECA) in collaboration with the African Union Commission (AUC), the African Union Development Agency (AUDA-NEPAD), WHO, UNAIDS and other relevant UN agencies, is commissioning an AfCFTA-anchored pharmaceutical project in selected African countries (Seychelles, Madagascar, Comoros, Mauritius, Djibouti, Eritrea, Rwanda anchored by Ethiopia, Kenya, Sudan, and IGAD with a specific aim to bring ideas into action through successful operationalization of the AfCFTA.

The AfCFTA-anchored Pharma initiative has a three-pronged approach; localized production; pooled procurement and a harmonized regulatory and quality framework focusing on maternal and child health care (MCH) products to address persistent challenges in MCH burden, unmet needs and access to reproductive health products across the region but also to the necessity and efficacy of investment in initiatives that address women's health as a key component of inclusive and sustainable economic development.

This invitation is one of the several recommended regional harmonization efforts envisioned by the Head of States of the African Union (AU) for "A prosperous Africa based on inclusive growth and sustainable development". In as much as sustainable development depends on health workers, the health of the society depends on the supply of quality-assured and affordable medicines.

It is against this background and in line with the objectives specifically to advocate from the policy angle for pooled procurement and local production essential medicines that ECA would like to invite supplier(s) of

MCH product(s) to realize Africa's vision in line with the AfCFTA agenda to fulfill the unmet needs of pilot member countries by increasing access to affordable and reliable supply of quality assured medicines

SPECIFIC REQUIREMENTS / INFORMATION (IF ANY)

Objective of the project, list of medical products, deliverables, Eligibility criteria, Submission Requirements and instructions are avialable in the attached TOR. Kindly follow strictly the submission requirements and provide all the required documentations. Failure to do so may result in exclusion from further consideration.

NOTE

Information on tendering for the UN Procurement System is **available free of charge** at the following address: https://www.ungm.org/Public/Notice

Only the United Nations Global Marketplace (UNGM) has been authorised to collect a nominal fee from vendors that wish to receive automatically Procurement Notices or Requests for Expression Of Interest. Vendors interested in this Tender Alert Service are invited to subscribe on http://www.ungm.org

Vendors interested in participating in the planned solicitation process should complete/submit the Vendor Response Form of this EOI either electronically (through the link available on the next page) or send it via fax or e-mail to Economic Commission for Africa (ECA) (UNECA) before the closing date set forth above.

VENDOR RESPONSE FORM

TO: Rahel Tarekegne **EOI Number:** EOIUNECA17541

Email: shiferaw3@un.org

FAX:

FROM:

SUBJECT: Invitation for Pre-qualification of Essential Health Products Manufacturers for the AfCFTA-anchored Pharma Initiative's Pooled Product Evaluation by the United Nations Economic Commission for Africa

NOTICE
• Companies can only participate in solicitations of the UN Secretariat after completing their registration (free of charge) at the United Nations Global Marketplace (www.ungm.org).
• As you express interest in the planned solicitation by submitting this response form, please verify that your company is registered under its **full legal** name on the United Nations Global Marketplace (www.ungm.org) and that your application has been submitted to the UN Secretariat.
• We strongly recommend all companies to register at least at **Level 1** under the United Nations Secretariat prior to participating in any solicitations.

PLEASE NOTE: You can express your interest to this REOI by filling out this form manually or electronically (recommended) at:
https://www.un.org/Depts/ptd/node/add/interest-expressed?EOI=EOIUNECA17541

*To be completed by the Vendor (**All fields marked with an '*' are mandatory**)*

COMPANY INFORMATION	
UNGM Vendor ID Number*:	
Legal Company Name (Not trade name or DBA name) ***:**	
Company Contact *:	
Address *:	
City *:	**State:**
Postal Code * :	
Country *:	
Phone Number *:	
Fax Number *:	
Email Address *:	
Company Website:	

We declare that our company fully meets the prerequisites A, B, C, D, E and F, for eligibility to register with the United Nations as outlined in the paragraph 1 of the EOI INSTRUCTIONS page.

Signature :_____ Date:_____

Name and Title :_____

EOI INSTRUCTIONS

1) Registering as a Vendor with the United Nations

Vendors interested in fulfilling the requirement described above must be registered at the UN Global Marketplace (**www.ungm.org**) with the UN Secretariat in order to be eligible to participate in any solicitation. Information on the registration process can be found at **https://www.un.org/Depts/ptd/vendors**.

Prerequisites for Eligibility
In order to be eligible for UN registration, you must declare that:

A. Your company (as well as any parent, subsidiary or affiliate companies) is not listed in, or associated with a company or individual listed in:

   I. the Compendium of United Nations Security Council Sanctions Lists (**https://www.un.org/sc/suborg/en/sanctions/un-sc-consolidated-list**), or

   II. the IIC Oil for Food List website or, if listed on either, this has been disclosed to the United Nations Procurement Division in writing.

B. Your company (as well as any parent, subsidiary or affiliate companies) is not currently removed or suspended by the United Nations or any other UN organisation (including the World Bank);

C. Your company (as well as any parent, subsidiary of affiliate companies) is not under formal investigation, nor have been sanctioned within the preceding three (3) years, by any national authority of a United Nations Member State for engaging or having engaged in proscribed practices, including but not limited to: corruption, fraud, coercion, collusion, obstruction, or any other unethical practice;

D. Your company has not declared bankruptcy, are not involved in bankruptcy or receivership proceedings, and there is no judgment or pending legal action against your company that could impair your company's operations in the foreseeable future;

E. Your company does not employ, or anticipate employing, any person(s) who is, or has been a UN staff member within the last year, if said UN staff member has or had prior professional dealings with the Vendor in his/her capacity as UN staff member within the last three years of service with the UN (in accordance with UN post-employment restrictions published in ST/SGB/2006/15.

F. Your company undertakes not to engage in proscribed practices (including but not limited to: corruption, fraud, coercion, collusion, obstruction, or any other unethical practice), with the UN or any other party, and to conduct business in a manner that averts any financial, operational, reputational or other undue risk to the UN.

For Registered Vendors: Vendors already registered at the UN Global Marketplace with the UN Secretariat must ensure that the information and documentation (e.g. financial statements, address, contact name, etc.) provided in connection with their registration are up to date in UNGM. Please verify and ensure that your company is registered under its full legal name.

For Vendors Interested in Registration: Vendors not yet registered should apply for registration on the United Nations Global Marketplace (**http://www.ungm.org**); information on the registration process can be found at **https://www.un.org/Depts/ptd/vendors**. Vendors must complete the registration process prior to the closing date of the REOI. Vendors who have not completed the UNGM registration process with the UN Secretariat before the closing date of the REOI are not considered eligible to participate in solicitations of the UN Secretariat. We strongly recommend all companies to register at least at Level 1 under the UN Secretariat prior to participating in any solicitations.

IMPORTANT NOTICE: Any false, incomplete or defective vendor registration may result in the rejection of the application or cancellation of an already existing registration.

2) EOI Process

Vendors interested in participating in the planned solicitation process should forward their expression of interest (EOI) to Economic Commission for Africa (ECA) (UNECA) by the closing date set forth in this EOI. *Due to the high volume of communications UNECA is not in a position to issue confirmation of receipt of EOIs.*

Please note that no further details of the planned solicitation can be made available to the vendors prior to issuance of the solicitation documents.

This EOI is issued subject to the conditions contained in the EOI introductory page available at **https://www.un.org/Depts/ptd/eoi**.

United Nations
Economic Commission for Africa

Terms of Reference (TOR)

Invitation to Manufacturers of Essential Health Products to Submit an Expression of Interest (EOI) For the AfCFTA-anchored Pharma Initiative's Pooled Product Evaluation by the United Nations Economic Commission for Africa

1. Background

To maximize the opportunities arising from African Continental Free Trade Area (AfCFTA), African Medicines Agency (AMA) and to realize the objectives of the Pharmaceutical Manufacturing Plan for Africa, the United Nations Economic Commission for Africa (ECA) in collaboration with the African Union Commission (AUC), the African Union Development Agency (AUDA-NEPAD), WHO, UNAIDS and other relevant UN agencies, is commissioning an AfCFTA-anchored pharmaceutical project in select African countries (Seychelles, Madagascar, Comoros, Mauritius, Djibouti, Eritrea, Rwanda anchored by Ethiopia, Kenya, Sudan, and IGAD with a specific aim to ***bring ideas into action*** through successful operationalization of the AfCFTA. The AfCFTA-anchored Pharma pilot project leverages on the establishment of the AMA and AfCFTA which brings on board a market of 1.3 Billion people, a gross domestic product (GDP) of $2.5 trillion, across 55 member states of the Africa Union (AU). The Agreement is expected to make a significant contribution to Africa's ongoing efforts to materialize the aspirations and goals contained in Agenda 2063 and the 2030 Agenda for Sustainable Development Goals.

The AfCFTA-anchored Pharma initiative has a three-pronged approach; localized production; pooled procurement and a harmonized regulatory and quality framework focusing on maternal and child health care (MCH) products to address persistent challenges in MCH burden, unmet needs and access to reproductive health products across the region but also to the necessity and efficacy of investment in initiatives that address women's health as a key component of inclusive and sustainable economic development. The emphasis on pharmaceuticals is driven by inadequate access to medicines for many infectious and Non-Communicable Diseases (NCDs) across Africa as well as the undue strain on both the public and consumer budget. Medicines consume a large proportion of African nation's healthcare budget. One of the reasons is related to issues of inefficient pharmaceutical procurement models, as well as long lead times for international orders, high transport and distribution costs, poor logistic and storage capacity, limited public finances, and gaps in global and local production of medicines, among others. These in turn lead to slow progress towards SDGs. Also, the current supply of medicines to Africans does not meet demand. Africa manufactures "less than 2 percent of the medicines it consumes" while it imports about 70 percent of its needs from outside the continent at an annual cost of $14.5 billion.

This invitation is one of the several recommended regional harmonization efforts envisioned by the Head of States of the African Union (AU) for "A prosperous Africa based on inclusive growth and sustainable development". In as much as sustainable development depends on health workers, the health of the society depends on the supply of quality-assured and affordable medicines.

To realize the aspirations of the Africa we want without leaving no one behind, one of such strategic approaches is to bring the African nations to work together in the assessment of medicines quality assurance. In principle, products are eligible to be funded through AfCFTA-anchored Pharma pilot procurement resources if,

- prequalified by WHO prequalification program, **OR**
- approved for marketing authorization within Stringent Regulatory Authority region which is also referred to as WHO and/or ICH recognized member countries, **OR**
- approved and marketed within regional harmonization communities, for example, Intergovernmental Authority on Development (IGAD), East African Community (EAC), South African Development Community (SADC), Economic Community of West African States (ECOWAS) **OR**
- approved and marketed within SIDS **OR**
- reviewed and listed by GDF and/or other procurement agencies participating in WHO ERP program, **AND**
- accepted, reviewed, and permitted for use by an independent technical review panel (TRP) organized by ECA as described under item number 4 and 5 below.

2. Overall objectives of the project

ECA is facilitating the AfCFTA- anchored pharmaceutical project to convene relevant stakeholders across the public and private sector to pilot selected strategies for improving access to maternal and child health essential medicines and commodities across selected geographic areas in Africa and then scale up in other regions across the continent. Given the pivotal role investments in health plays as input in achieving sustainable and inclusive economic growth, the Commission hopes to develop a framework of action to advance health outcomes and shape health markets in Africa. ECA proposes to:

(i) Leverage the AfCFTA in facilitating regional pooled procurement across specific cluster markets with identified interest

(ii) Facilitate and advocate from the policy angle local production of selected and identified pharmaceutical drugs and products

(iii) Ensure quality standards of identified medicines and products for pooled procurement and local production

It is against this background and in line with the objectives specifically to advocate from the policy angle for pooled procurement and local production essential medicines that ECA would like to invite supplier(s) of MCH product(s) to realize Africa's vision in line with the AfCFTA agenda to fulfill the unmet needs of pilot member countries by increasing access to affordable and reliable supply of quality assured medicines. This is a call for an action to address the challenges of medicines shortage that the region is facing due to the low volume of procurement that may not sufficiently attract the suppliers when the procurement is conducted by each country individually. The support of regional efforts to increase the volume and quality assurance of procurement will in turn increases access to quality products that will reduce maternal and infant mortality. ECA and partners are pleased to invite the manufacturers and suppliers of essential medicine with additional potential to support COVI_19 related products to submit an expression of interest for evaluation.

3. Immediate objectives

The purpose of this TOR is to invite manufacturers essential medical products listed in section 4 below to express their interest in participating in the pooled procurement initiative. Interested manufacturers fulfilling the requirement outlined in section 6 will undertake pooled procurement for volume discount as part of the regional pooled procurement framework for Small Island Developing States pilot of AfCFTA-anchored project on Africa Pharmaceutical Pooled Procurement, led by ECA.

This initiative will assist Africa to achieve it's vision in line with the AfCFTA agenda to fulfill the unmet needs of pilot member countries by increasing access to affordable and reliable supply of quality assured medicines. This is a call for an action to address the challenges of medicines shortage that the region is facing due to the low volume of procurement that may not sufficiently attract the suppliers when the procurement is conducted by each country individually. The support of regional efforts to increase the volume and quality assurance of procurement will in turn increases access to quality products that will reduce disease-specific mortality. ECA and partners are pleased to invite the suppliers of essential medicines to apply to evaluation.

The steps involved are:

1. The terms of reference (TOR) is published with a deadline for submission.
2. Manufacturers express interest in participating by submitting applications as per the requirements in this TOR before the deadline.
3. Evaluation/ review of the applications by the ECA and partners' quality assurance specialist (or designated secretariat) that serves as the point of contact between the applicant and the technical review panel (TRP). Additional information may be requested.
4. Selection of manufacturers with approval of their products with the relevant authorities or regional bodies, as applicable including WHO prequalification program or by a regulatory agency within the ICH member regions or by regulatory agency within the African harmonization regions (e.g., IGAD, EAC, SADC, ECOWAS, etc)
5. Review of selected manufacturers' compliance to cGMP requirements to include desk assessment, remote verification, and visits to the manufacturing sites to validate application may be needed.
6. Notification and sharing of pooled procurements demand for volume discounts on essential products.

4. Medical Products included in this expression of interest

The recommended active ingredients, dosage forms and strengths ("Formulations") listed in this document are according to the recommendations made by member countries participating in the pooled procurement process.

Phase 1: Immediate Need

- *Oxytocin injection 10 International Units (IU), 1ml*
- *Misoprostol 25 microgram tablet*

- misoprostol 200 microgram tablet (Misoprostol administered either orally, sublingually or vaginally depending on the indication)
- *Mifepristone 200 mg tablet (only to be used in combination with misoprostol)*
- mifepristone 200 mg tablet co-packaged with 4 tablets of misoprostol (Mifepristone (200mg) administered orally; misoprostol (4X200µg) administered either sublingually or vaginally)
- *Zinc sulfate [Dispersible tablets 10mg, 20mg, and oral liquid 10mg per unit of dosage forms]. Other Zinc salts (i.e., gluconate, acetate and citrate) containing 10mg or 20mg elemental Zinc are also invited for submission)*
- *Amoxicillin Dispersible tablets 125mg, 250mg and 500mg (scored)*
- *Amoxicillin Suspension 250mg*
- *Heat stable Carbetocin, injection 100 microgram/ml – in 1 ml*

Phase 2: Future Need: other products

In addition to MCH products invitation will potentially expand in the future to include medicines that are included in the WHO Essential Medicine List/ National Essential Medicine List and that are commonly used in the majority of the participating countries. Please refer to the list below. These formulations are included either in the WHO Model List of Essential Medicines (EML) 21st list, 2019, and/or in the National Essential List of SIDS region.

Priority Medicines for Pooled Procurement		
1	**ANTI-BACTERIALS [INCLUDING ANTI-TB]**	
1.1	Amoxicillin	Powder for oral liquid: 125 mg / 5ml; 250 mg / 5 ml; Capsules / Tablets: 250 mg; 500 mg. Powder for injection: 250 mg/vial; 500 mg/vial; 1 g/vial
1,2	Amoxicillin + Clavulanic acid	Suspension: 125 mg amoxicillin + 31.25 mg clavulanic acid/5ml; 250 mg amoxicillin + 62.5 mg clavula**nic** acid/5ml. Tablet: 500 mg Amoxicillin + 125 mg clavulanic acid / 5ml Powder for injection: 500 mg Amoxicillin + 100 mg clavulanic acid; 1000 mg Amoxicillin + 200 Clavulanic acid /vial
1.3	Ampicillin	Powder for injection: 500 mg/vial; 1 g /vial.
1.4	Benzylpenicillin	Powder for injection: 600 mg [1 million IU] / vial; 3 g [5 million IU]/ vial.
1.5	Cefazolin	Powder for injection: 1 g/ vial.
1.6	Cefotaxime	Powder for injection: 250 mg / vial
1.7	Ceftriaxone	Powder for injection: 250 mg/vial; 1 g/vial.
1.8	Ciprofloxacin	Oral liquid: 250 mg/5 ml [anhydrous]; Tablet 250mg. Solution for IV infusion: 2 mg/ ml
1.9	Clotrimazole	Cream 1%: 20g tube; 30g tube, 50g tube
1.10	Cloxacillin	Capsule: 500 mg; 1 g. / vial Powder for injection: 500 mg / vial. Powder for oral liquid: 125 mg / 5ml.
1.11	Doxycycline	Oral liquid: 25 mg/5 ml; 50 mg/5 ml [anhydrous]. Capsule / Tablet; 50 mg.; Powder for injection: 100 mg/vial
1.12	Gentamicin	Injection: 10 mg; 40 mg / 2ml vial.
1.13	Meropenem	Powder for injection: 500 mg/ vial; 1 g / vial
1.14	Metronidazole	Injection: 500 mg / 100 ml vial. Oral liquid: 200 mg / 5 ml; Tablet: 200 mg; 500 mg Suppository: 500 mg; 1 g.
1.15	Piperacillin +	Powder for injection: 2 g + 250 mg / vial; 4 g + 500 mg /vial

	Tazobactam	
1.16	sulfamethoxazole + trimethoprim	Injection: 80 mg + 16 mg/ml in 5ml ampoule; 80 mg + 16 mg/ ml in 10 ml ampoule.; Oral liquid: 200 mg + 40 mg /5 ml.; Tablet: 100 mg + 20 mg; 400 mg + 80 mg; 800 mg + 160 mg.
1.17	Vancomycin Injection	500mg vial
1.18	Isoniazid + pyrazinamide + rifampicin	Tablet: 75 mg + 400 mg + 150 mg.
1,19	Ethambutol + INH + Pyrazinamide + Rifa	Tablet: 275 mg + 75 mg + 400 mg + 150 mg.
1.20	ethambutol +INH + rifampicin	Tablet: 275 mg + 75 mg + 150 mg.
2	**ANTI-CANCER [AND ASSOCIATED MEDICINES]**	
2.1	Actinomycin D	Injection: 500mcg/vial
2.2	Allopurinol	Tablet 100mg
2.3	Basiliximab, 20mg. Injection, Vial	Injection: 20mg / vial
2.4	Bleomycin	Powder for injection: 15 mg (as sulfate) in vial
2.5	Capecitabime	Tablet: 150 mg; 500 mg.
2.6	Carboplatin	Injection: 50 mg/5 mL; 150 mg/15 mL; 450 mg/45 m; 600 mg/60 ml
2.7	Cisplatin	Injection: 50 mg/50 mL; 100 mg/100 Ml
2.8	Cyclophosphamide	Powder for injection: 500 mg in vial. Tablet: 25 mg, 50 mg.
2.9	Cytosine Arabinoside	Injection: 100mg/vial; 1000mg/vial
2.10	Daunorubicin	Injection: 20mg / vial
2.11	Dexamethasone	Injection: 4 mg/ml in 1- mL ampoule (as disodium phosphate salt). Oral liquid: 2 mg/5 ml.; Tablet: 2 mg; 4 mg.
2.12	Docetaxel	Injection: 20 mg/ ml; 40 mg/ml
2.13	Doxorubicin	Powder for injection: 10 mg/vial; 50 mg/vial.
2.14	Eptifibatide	Injection: 750mcg/ml, 100ml
2.15	Etoposide	Capsule: 50 mg, 100 mg.
2.16	Fluorouracil	Injection: 50 mg/ml in 5- mL ampoule
2.17	Interferon Alpha 2a	Injection: 3miu / vial
2.18	Methotrexate	Powder for injection: 50 mg/vial; Tablet: 2.5 mg
2.19	Paclitaxel	Powder for injection: 6 mg/ml.
2.20	Rituximab, 100mg Injection, Vial	Injection: 100mg vial
2.21	Prednisolone	Oral liquid: 5 mg/ml.; Tablet: 5 mg; 25 mg.
2.22	Temozolamide, 100mg	Capsules: 100mg, blister pack
2.23	Trastuzumab, 150mg Injection, Vial	Injection: 150mg / vial
2.24	Vinblastine	Powder for injection: 10 mg/vial.
2.25	Vincristine	Powder for injection: 1 mg/vial; 5 mg /vial.
2.26	Vinorelbine	Injection: 10 mg/mL in 1- mL vial; 50 mg/5 mL in 5- mL vial
3	**ANTI-HEPATITIS**	
3.1	Entecavir	Oral liquid: 0.05 mg/ Ml. Tablet: 0.5 mg; 1 mg
3.2	Tenofovir Disoproxil Fumarate DF)	Tablet: 300 mg
3.3	Sofosbuvir	Tablet: 400 mg
3.4	Sofosbuvir + Velpatasvir	Tablet: 400 mg + 100 mg

3.5	ledipasvir + sofosbuvir	Tablet: 90 mg + 400 mg.
3.6	sofosbuvir+ daclastavir	Tablet: 400 mg +30mg, 60mg
3.7	Daclatasvir	Tablet: 30 mg; 60 mg
4	**ANTI-RETROVIRALS**	
4.1	Abacavir + lamivudine	Tablet (dispersible, scored): 120 mg (as sulfate) + 60 mg.
4.2	Doletugravir	Tablet: 50 mg
4.3	Doletugravir + lamivudine + Tenofovir	Tablet: 50 mg + 300 mg + 300 mg (disoproxil fumarate equivalent to 245 mg Tenofovir disoproxil)
4.4	Efavirenz + Emtricitabine + Tenofovir	Tablet: 600 mg + 200 mg + 300 mg (disoproxil fumarate equivalent to 245 mg Tenofovir disoproxil).
4.5	efavirenz + lamivudine + Tenofovir	Tablet: 400 mg + 300 mg + 300 mg (disoproxil fumarate equivalent to 245 mg Tenofovir disoproxil)
4.6	Emtricitabine + Tenofovir	Tablet: 200 mg + 300 mg
4.7	lamivudine + zidovudine	Tablet: 30 mg + 60 mg.
4.8	Lopinavir + ritonavir LPV/r)	Oral liquid: 400 mg + 100 mg/5 Ml. Tablet (heat stable): 100 mg + 25 mg; 200 mg + 50 mg., Solid oral form: 40 mg + 10 mg
4.9	Raltegravir	Tablet (chewable): 25 mg; 100 mg. Tablet: 400 mg Granules for oral suspension: 100 mg in sachet
4.10	Emtricitabine + Tenofovir	Tablet: 200 mg + 300 mg
4.11	Isoniazid+ Pyridoxine + Sulfamethoxazole +Trimethoprim	Tablet (dispersible, scored)300 mg + 25 mg + 800 mg + 160 mg
5	**NON-COMMUNICABLE DISEASES [OTHER]**	
5.1	Bisoprol	Tablet: 1.25 mg; 5 mg.
5.2	Amlodipine	Tablet: 5 mg
5.3	Hydrochlorothiazide	Oral liquid: 50 mg/5 ml. Solid oral dosage form: 12.5 mg; 25 mg.
5.4	Ibuprofen	400mg. Tablets
5.5	Lisinopril + amlodipine	Tablet: 10 mg + 5 mg; 20 mg + 5 mg; 20 mg + 10 mg
5.6	Lisinopril + hydrochlorothiazide	Tablet: 10 mg + 12.5 mg; 20 mg + 12.5 mg; 20 mg + 25 mg
5.7	Losartan	Tablet: 25 mg; 50 mg; 100 mg
5.8	Methyldopa	Tablet: 250 mg.
5.9	Furosemide	Injection: 10 mg/ mL in 2- mL ampoule. Oral liquid: 20 mg/5 ml.; Tablet: 40 mg.
5.10	Nifedipine	20mg Tablet
5.11	Omeprazole	Powder for injection: 40 mg in vial Powder for oral liquid: 20 mg; 40 mg sachets
5.12	Ranitidine	Injection: 25 mg/ mL (as hydrochloride) in 2- mL ampoule. Oral liquid: 75 mg/5 mL (as hydrochloride). Tablet: 150 mg (as hydrochloride).
5.13	Metoclopramide	Injection: 5 mg (hydrochloride)/ mL in 2- mL ampoule. Oral liquid: 5 mg/5 mL [c]. Tablet: 10 mg.
5.14	Ondansetron	Injection: 2 mg base/ mL in 2- mL ampoule (as hydrochloride). Oral liquid: 4 mg base/5 ml.; Solid oral dosage form: Equivalent 4 mg base; 8 mg base; and 24 mg base.
5.15	Paracetamol	Tablet: 500mg; Syrup: 125mg/5ml
5.16	Insulin soluble	Injection: 40 IU/ mL in 10- mL vial; 100 IU/ mL in 10- mL vial.

5.17	Insulin intermediate acting	Injection: 40 IU/ mL in 10- mL vial; 100 IU/ mL in 10- mL vial (as compound insulin zinc suspension or isophane insulin).
5.18	Gliclazide	Solid oral dosage form: (controlled-release tablets) 30 mg; 60 mg; 80 mg.
5.19	Metformin	Tablet: 500 mg (hydrochloride).
5.20	Salbutamol	Inhalation (aerosol): 100 micrograms (as sulfate) per dose. Injection: 50 micrograms (as sulfate)/ mL in 5- mL ampoule. Metered dose inhaler (aerosol): 100 micrograms (as sulfate) per dose. Respirator solution for use in nebulizers: 5 mg (as sulfate)/ ml.
5.21	Sodium Valproate	500mg EC Tablet
5.22	Glucose	Injectable solution: 5% (isotonic); 10% (hypertonic); 50% (hypertonic).
5.23	Glucose with Sodium Chloride	Injectable solution: 4% glucose, 0.18% sodium chloride; 5% glucose, 0.9% sodium chloride; 5% glucose, 0.45% sodium chloride
5.24	Sodium Chloride [normal saline]	Injectable solution: 0.9% isotonic (equivalent to Na+ 154 mmol/L, Cl- 154 mmol/L).
5.25	Water for injection	2- mL; 5- mL; 10- mL ampoules
6	**VACCINES [LIFE CYCLE ROUTINE IMMUNIZATION]**	
6.1	BCG vaccine with diluent	10 or 20 dose vial
6.2	Botulinum Toxin Type A	100 IU/ vial
6.3	Diphtheria, Pertussis, Tetanus, H. influenzae Type B Conjugate Vaccine [adsorbed].	10 dose vial
6.4	Diphtheria and Tetanus Vaccine [Pediatric, adsorbed]).	10 or 20 dose vial
6.5	Trivalent Influenza vaccine.	Single dose
6.6	Hepatitis A Vaccine inactivated for children and adolescents	0.5 ml single dose
6.7	Hepatitis A Vaccine inactivated for adults	0.5ml single dose
6.8	Hepatitis B-DNA Recombinant Adsorbed(Pediatric)	10mcg/0.5ml, single or 10 dose vial
6.9	Measles, Mumps (Jeryl Lynn or its derivative) & Rubella Live Attenuated	Single dose
6.10	Meningitis Conjugate Vaccine ACW135Y Powder & Solution for Injection.	Single dose and 10 dose
6.11	Rotavirus Vaccine.	50 dose vial
6.12	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed). Single dose	Single dose
6.13	Polio inactivated vaccine of suitable	0.5ml single dose

	strains of poliomyelitis virus Type 1, 2 and 3	
6.14	Polio oral vaccine bivalent Type	20 dose vial with dropper
6.15	Tetanus Toxoid Vaccine Adsorbed. 10/20 dose vial	10 or 20 dose vial
6.16	Typhoid Vaccine Polysaccharide x 0.5 ml. Single dose	0.5ml single dose
6.17	Human Papilloma Virus	0.5 ml vial [dose]
6.18	Yellow Fever Vaccine. 10 dose vial	Single or 10 dose vial

5. Deliverables include

A Complete application and related documents submitted to ECA. All the documents listed under the minimum requirements including the pre-assessment questionnaires and its annexures must be submitted by the applicant.

6. Requirements for submission of the application

To apply for the expression of interest, the following documentation must be submitted in English

1) A cover letter expressing interest in submitting the product application to ECA Expert Review Panel for evaluation.
2) An acceptance letter from WHO prequalification program or accepted by a regulatory agency within the ICH member regions or accepted by a regulatory agency within the African harmonization regions (e.g., IGAD, EAC, SADC, ECOWAS etc) confirming that the submission/ dossier for the product has been accepted for review, and stating the approving agency reference number assigned to the specific product included in the EOI.
3) An acceptance letter from WHO prequalification program or regulatory agency within the ICH member regions or regulatory agency within African harmonization region (e.g., IGAD, EAC, SADC, ECOWAS) confirming that the manufacturing site and production line where the product is manufactured comply with all aspects of good manufacturing practice (GMP).
4) A completed pre-assessment application questionnaire (Form A) in response to each product with all the annexes stated in the pre-assessment application.
   To facilitate an assessment, a word format of the pre-assessment template should be included and documents and their corresponding annex or attachment need to match their content in the pre-assessment questionnaire. Pre-assessment questions (Form A) should be completed for each product stated under section 4 above.
5) In lieu of annexes, reference can be made to the dossier submitted and accepted as described under item number (2). In the event the annexes are updated this should be submitted with the note to the changes or updates.

7. Eligibility for submission

To be considered eligible for application the following criteria must be fulfilled.

- The product dossier is accepted by WHO prequalification program or by regulatory agencies within the ICH member regions or regulatory agencies within the African harmonization regions (e.g., SIDS, IGAD, EAC, SADC) and the application reference number assigned to the specific product included in the terms of reference (TOR) is available. **AND**
- The manufacturing site is accepted or audited and received favorable opinion for acceptance from WHO prequalification program **OR** regulatory agencies within the ICH member countries **OR** regulatory agencies within the African harmonization countries (e.g., IGAD, EAC, SADC) confirming that the site and production line where the product is manufactured comply with all aspects of current good manufacturing practice (cGMP).

8. Eligibility-Completeness and Approval

Completeness of submission application. Completeness of the application and related documents submitted to ECA is determined by the ECA and partners' quality assurance specialist (or designated secretariat) that serves as the point of contact between the applicant and the technical review panel (TRP). All the documents listed under the submission requirement including the pre-assessment questionnaires and its annexures must be submitted by the applicant. Incomplete submissions will not be forwarded to the technical review panel.

Approval of Submitted documents. The eligibility of the submissions will be made by ECA and its partners. It is the TRP's responsibility to review and advise ECA and partners on the eligibility of the product based on a risk-benefit assessment of the product information submitted.

ECA and partners, on the advice of the TRP, may request additional data.

9. Instruction for submission of application

All documents should include a soft copy of submission either via CD or a USB key and should be submitted with a sealed envelope/package, clearly marked and addressed as follows:

United Nation Economic Commission for Africa

Attn: Tender Opening Committee/ Bid Opening Unit

Menelik Ave, Addis Ababa, 3001, Ethiopia

Tel: +251-115445053

EOI Number: _____

Ali Assaad

Closing Date & Time: _____

Name of the Proposer: _____

10. Confidentiality

All information provided by manufacturers will be received by the ECA and shared with the technical review panel (TRP) to facilitate the evaluation of the application and provision of advice to the ECA on the pooled procurement process and in principle, the information will be shared under a confidentiality agreement with the regulatory agencies comprised of the African harmonization regions (e.g., IGAD, EAC, etc).

Information provided by manufacturers, review findings and advice provided by the expert panel in connection with this expression of interest will be shared with and used by the ECA implementing partners and pilot countries regulatory agencies thus: Seychelles, Madagascar, Comoros, Mauritius, Djibouti, Eritrea, Sudan, and Rwanda, anchored by Kenya and Ethiopia.

Form A- Product Information to be Provided by Applicant

Pre-Assessment Questionnaire

Please fill out one separate form for each pharmaceutical product

Section 1: Administrative Section

1.1 Product identification

Active pharmaceutical ingredient(s) (use INN if any):	Click here to enter text.
Generic name of the product:	Click here to enter text.
Trade (proprietary) name (if any):	Click here to enter text.
Dosage form:	Choose an item.
Other: (Please Specify)	Click here to enter text.
Strength per dosage unit:	Click here to enter text.
Route of administration:	Choose an item.
Other: (Please Specify)	Click here to enter text.

1.2 Manufacturer identification

Name, address and activities of the manufacturer and manufacturing site(s) or contract manufacturer(s):

Name of company:	Click here to enter text.
Manufacturing license, date and expiry date (if any)	Click here to enter text.
Physical address (complete details required):	Click here to enter text.
Primary Point of Contact Name:	Click here to enter text.
Telephone number:	Click here to enter text.
Fax:	Click here to enter text.
Website:	Click here to enter text.
Email:	Click here to enter text.
Activity conducted on site (e.g., manufacturing, packaging, etc.)	Click here to enter text.

1.3 Supplier identification

*(Complete only if **not identical** to information in Section 1.2)*

Name of company:	Click here to enter text.

Physical address (complete details required):	Click here to enter text.
Telephone number:	Click here to enter text.
Fax:	Click here to enter text.
Website:	Click here to enter text.
Email:	Click here to enter text.
Link with the product:	Choose an item.
Other (Please Specify)	Click here to enter text.

1.4 Regulatory (licensing) status

1.5.1	In the **country of manufacture**, select the item below that most closely describes the status of the product and provide a copy of the license in **Annex A** (if applicable).		
	☐ Product is registered and currently marketed		
	License No: Click here to enter text.		
	☐ Product is registered for marketing, but currently not marketed		
	License No: Click here to enter text.		
	☐ Product is not registered (*Please clarify*): Click here to enter text.		
	➢ Please attach a certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863; an earlier version is not acceptable) in**Annex B**.		
	➢ If a CPP cannot be obtained from the national medicines regulatory authority (NMRA), please state the reason and send an equivalent document, if any. Click here to enter text.		
	➢ Submit recent, as well as, historical deficiency letter(s) issued by WHO Prequalification Programme (PQP) or SRA in relation to the specific product dossier in **Annex C**.		
1.5.2	List the **other countries** where the product is registered and is currently marketed *(please provide registration number)* and provide a copy of the license in **Annex D.** Click here to enter text.		
1.5.3	WHO prequalification status (if applicable)		
	This product is prequalified by WHO/PQP.[1]	☐ YES	☐ NO
	If yes, please attach a copy of the relevant WHO/PQP acceptance letter signed by your company in **Annex E**.		
1.5.4	If submitted for prequalification but not yet approved,		
	Indicate date of submission	Click here to enter a date.	

[1] WHO Prequalification website: http://apps.who.int/prequal/.

Include a copy of the WHO acceptance letter for product dossier review, mentioning the WHO reference number assigned by WHO for this specific product in **Annex F.**

1.5 Packaging Information

1.6.1	Description and materials used for primary packaging (for example, HDPE bottle, Alu-Alu strip, neutral glass vial, etc.) and pack size (quantity of units per pack): **Annex G**				
1.6.2	Description, pack size and material used for secondary packaging materials: **Annex H**				
1.6.3	Primary packaging label language (attach a copy in **Annex I**):				
	☐ Bilingual English/French	☐ English	☐ French	☐ Other (Please Specify) Click here to enter text.	
1.6.4	Secondary packaging label language (attach a copy in **Annex I**):				
	☐ Bilingual English/French	☐ English	☐ French	☐ Other (Please Specify) Click here to enter text.	
1.6.5	Patient information leaflet/Package insert (attach a copy in **Annex J**):			☐ YES	☐ NO
	For oral powder for suspension and powder for injection, in-use periods and storage conditions after reconstitution should be stated on the product label/leaflet.				

Section 2: Active pharmaceutical ingredients

(If there is more than one active pharmaceutical ingredient or more than one API manufacturer is used, please replicate this section for each manufacturer.)

2.1 Manufacturing site GMP status

2.1.1	Manufacturer (name, physical address and country) / manufacturing site: Click here to enter text.		
2.1.2	GMP inspections carried out by an NMRA:		
		NRA of country of origin	Any other inspection of PIC/S member
	GMP certificate no.	Click here to enter text.	Click here to enter text.
	Valid until	Click here to enter text.	Click here to enter text.
	Country	Click here to enter text.	Click here to enter text.
2.1.3	➢ Please attach the recent/valid GMP certificates/letter(s) of compliance in **Annex K.**		
2.1.4	Other GMP inspections carried out by (include information for all that apply in the last 5 years):		
	Agency	Date of Audit	Outcome
	WHO Prequalification Programme	Click here to enter text.	Click here to enter text.
	UNICEF Supply Division	Click here to enter text.	Click here to enter text.

	MSF International	Click here to enter text.	Click here to enter text.
	ICRC	Click here to enter text.	Click here to enter text.
	Other (specify)	Click here to enter text.	Click here to enter text.

2.2 API Specifications

2.2.1	Standard	Edition	Year Published
	BP	Click here to enter text.	Click here to enter text.
	USP	Click here to enter text.	Click here to enter text.
	Ph.Int.	Click here to enter text.	Click here to enter text.
	In-house	Click here to enter text.	Click here to enter text.
	Specifications additional to those in the pharmacopoeia referred to above (e.g. dissolution, syringe ability) explain:	Click here to enter text.	Click here to enter text.
	Other (specify)	Click here to enter text.	Click here to enter text.
	➢ Please attach copies of release and shelf-life specifications for the API in **Annex L.**		
	➢ If analytical methods are in-house, different from BP, USP and Ph.Int., attach a copy of the analytical method and analytical validation data in the same in **Annex M.**		
	➢ Please attach a copy of the certificate of analysis for the three last batches released in **Annex N.**		
2.2.2	Suitability of monograph for API		
	Are you in a possession of the Certificate of Suitability to the monograph of the European Pharmacopoeia (CEP) for APIs?	☐ YES	☐ NO
	If yes, please attach a copy in **Annex O1.**		
	Certificate No.: Click here to enter text.		
2.2.3	Open part of drug master file (DMF) registered in (country): Click here to enter text.		
	Do you have a Technical file:	☐ YES	☐ NO
	If Yes, please attach in **Annex O2**		

2.3 Method of manufacture and process validation

2.3.1	Has the manufacturing process for each standard batch size been validated?	☐ YES	☐ NO
	If no, please clarify: Click here to enter text.		
	If yes, please provide details of process validation status in the table below:		
	The batch size of the validated batches (minimum, maximum size in kilograms)	Click here to enter text.	

	The batch numbers of the validated batches	Click here to enter text.	
	Manufacturing dates of the validated batches	Click here to enter text.	
	Reference number for the process validation report	Click here to enter text.	
	If processes are yet to be validated, the reference number for the process validation protocol should be indicated	Click here to enter text.	
	➢ Provide a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters in **Annex P**.		
2.3.2	Is the manufacturing process train dedicated to the product of interest?	☐ YES	☐ NO
	If no, has the cleaning process been validated?	☐ YES	☐ NO
	➢ Provide a copy of the cleaning validation protocol and data to support the effectiveness of the cleaning procedure in **Annex Q**.		

Additional information for sterile products

2.3.3	Select the type of sterile processing: Choose an item.		
	Describe the method of sterilization used including conditions such as temperature, time, and pressure, if applicable: Click here to enter text.		
2.3.4	Have there been any sterility test failures in the last two years?	☐ YES	☐ NO
2.3.5	In the past two years, how many media fill batches have been filled on the equipment that is used for the manufacture of the product of interest? Click here to enter text.		
2.3.6	In the past two years, how many media fill units have been filled on the equipment that is used for the manufacture of the product of interest? Click here to enter text.		
2.3.7	In total, for all media fills manufactured during the past two years, how many failures have you had in batches and number of units showing positive growth?		

Number of Failed Batches	Number of Failed Units
Click here to enter text.	Click here to enter text.

2.3.8	Has there been any media fill failures resulting in re-validation?	☐ YES	☐ NO
	➢ Provide the data on validation of the sterile aspects of the product, including recent media fill validation data as applicable in **Annex R**.		

Section 3: Finished pharmaceutical product

3.1 Manufacturing site GMP status

3.1.1	Manufacturer (name, physical address and country) / manufacturing site: Click here to enter text.

3.1.2	GMP inspections carried out by an NMRA:		
		NRA of country of origin	Any other inspection of PIC/S member
	GMP certificate no.	Click here to enter text.	Click here to enter text.
	Valid until	Click here to enter text.	Click here to enter text.
	Country	Click here to enter text.	Click here to enter text.
	➢ Please attach the recent/valid GMP certificates/letter(s) of compliance in **Annex S.**		
3.1.3	Other GMP inspections carried out by (include information for all that apply in the last 5 years):		
	Agency	Date of Audit	Outcome
	WHO Prequalification Programme	Click here to enter text.	Click here to enter text.
	UNICEF Supply Division	Click here to enter text.	Click here to enter text.
	MSF International	Click here to enter text.	Click here to enter text.
	ICRC	Click here to enter text.	Click here to enter text.
	Other (specify)	Click here to enter text.	Click here to enter text.

3.2 Finished pharmaceutical product specifications

3.2.1	Standard	Edition	Year Published
	BP	Click here to enter text.	Click here to enter text.
	USP	Click here to enter text.	Click here to enter text.
	Ph.Int.	Click here to enter text.	Click here to enter text.
	In-house	Click here to enter text.	Click here to enter text.
	Specifications additional to those in the pharmacopoeia referred to above (e.g. dissolution, syringe ability) explain:	Click here to enter text.	Click here to enter text.
	Other (specify)	Click here to enter text.	Click here to enter text.
3.2.2	➢ Please attach copies of release and shelf-life specifications for the API in **Annex T.**		
3.2.3	➢ If analytical methods are in-house, different from BP, USP, and Ph.Int., attach a copy of the analytical method and analytical validation data in **Annex U.**		
3.2.4	➢ Please attach a copy of the certificate of analysis for the three last batches released in **Annex V.**		

3.3 Finished pharmaceutical formulation

3.3.1	Please provide the formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any and excipients). Please also indicate the standard for each ingredient (e.g. BP, USP, in-house). Mention specifically if the product is a fixed-dose combination (FDC) or co-packaged: **Annex W**

3.3.2	Please state inactive ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. contains alcohol 10%, paraben…….): **Annex W**

3.4 Method of manufacture and process validation

3.4.1	Has the manufacturing process for each standard batch size been validated?	☐ YES	☐ NO
	If no, please clarify: Click here to enter text.		
	If yes, please provide details of process validation status in the table below:		
	The batch size of the validated batches (minimum, maximum size in kilograms)	Click here to enter text.	
	The batch numbers of the validated batches	Click here to enter text.	
	Manufacturing dates of the validated batches	Click here to enter text.	
	Reference number for the process validation report	Click here to enter text.	
	If processes are yet to be validated, the reference number for the process validation protocol should be indicated	Click here to enter text.	
	➢ Provide a flow diagram and brief narrative describing the manufacturing and control process of this product with relevant parameters in **Annex X**.		
3.4.2	Is the manufacturing process train dedicated to the product of interest?	☐ YES	☐ NO
	If no, has the cleaning process been validated?	☐ YES	☐ NO
	➢ Provide a copy of the cleaning validation protocol and data to support the effectiveness of the cleaning procedure in **Annex Y**.		

Additional information for sterile products

3.4.3	Select the type of sterile processing: Choose an item.		
	➢ Describe the method of sterilization used including conditions such as temperature, time, and pressure, if applicable: Click here to enter text.		
3.4.4	Have there been any sterility test failures in the last two years?	☐ YES	☐ NO
3.4.5	In the past two years, how many media fill batches have been filled on the equipment that is used for the manufacture of the product of interest? Click here to enter text.		

3.4.6	In the past two years, how many media fill units have been filled on the equipment that is used for the manufacture of the product of interest? Click here to enter text.

3.4.7	In total, for all media fills manufactured during the past two years, how many failures have you had in batches and number of units showing positive growth? Number of Failed Batches: Click here to enter text. Number of Failed Units: Click here to enter text.		
3.4.8	Has there been any media fill failures resulting in re-validation?	☐ YES	☐ NO
	➢ Provide the data on validation of the sterile aspects of the product, including recent media fill validation data as applicable in **Annex Z**.		

3.5 Stability of finished product

3.5.1	Is stability testing data available?	☐ YES	☐ NO
	If yes, please provide the protocol and the report for accelerated and long-term stability testing, including: • type and material of container • conditions (temperature/ relative humidity/duration of stability study) • number of batches involved in the study (minimum three) • batch sizes for each lot tested • date of beginning of the study • study conclusions These can be provided in **Annex AA**.		
3.5.2	Was the stability testing done on a product of the same formula, same API source, manufactured on the same site and packed in the same packaging material as the product that will be supplied?	☐ YES	☐ NO
	If no, describe the differences: Click here to enter text.		
3.5.3	Please specify whether stability studies have been done or are ongoing with <u>all declared API sources</u>:	☐ YES	☐ NO
	➢ Submit a declaration in **Annex BB** that stability studies have been done or are being done with all declared API sources.		
	If no, explain why: Click here to enter text.		
3.5.4	Do you have ongoing stability data for this product?	☐ YES	☐ NO
	➢ Attach status report of any ongoing stability studies in **Annex CC**.		
3.5.5	Shelf-life as it appears on packaging:		
	☐ 2 years	☐ 3 years	☐ 4 years	☐ 5 years	☐ Other (please specify): Click here to enter text.
3.5.6	Specific storage conditions for this product as they appear on the packaging and based on stability studies (e.g. “Do not store above 30 °C – Protect from light”):		
	Temperature: Click here to enter text.		

	Light	Click here to enter text.
	Humidity	Click here to enter text.
	Other (specify): Click here to enter text.	Click here to enter text.
3.5.7	Product suitable for use in the following ICH Climatic Zones:	
	☐ Zone I	☐ Zone II
	☐ Zone III	☐ Zone IVa
	☐ Zone IVb	☐ Other (please specify): Click here to enter text.
3.5.8	For oral powder for suspension and powder for injection, or injection that may be further diluted, or multidose containers, provide in-use stability data and storage conditions after reconstitution and/or dilution in **Annex DD**.	

Section 4: Safety/efficacy and/or therapeutic equivalence

(WHO Technical Report Series (TRS), No. 902, Annex 11/ TRS No. 937, Annex 7 or recent version)

4.1 For innovator products

- Please attach a summary of pharmacology, toxicology, and efficacy of the product in **Annex EE**.

4.2 For generic products: therapeutic equivalence

4.2.1	☐ Demonstrated	☐ Not demonstrated
	☐ Not relevant (please explain why): Click here to enter text.	
4.2.2	If demonstrated by in vivo bioequivalence studies:	
	Study period: From: Click here to enter a date.	To: Click here to enter a date.
	Reference Product Information:	
	Generic name:	Click here to enter text.
	Dosage form:	Click here to enter text.
	Strength:	Click here to enter text.
	Brand/trade name:	Click here to enter text.
	Manufacturer:	Click here to enter text.
	Manufacture site:	Click here to enter text.
	Batch number:	Click here to enter text.
	Expiry date:	Click here to enter text.
	Study Protocol Information:	

	Contract research organization	Click here to enter text.

	(CRO) name:	
	Country of study:	Click here to enter text.
	Number of volunteers:	Click here to enter text.
	Study design (describe in detail):	Click here to enter text.
	Bio batch size:	Click here to enter text.
	Bio batch number:	Click here to enter text.
	Bio batch API(s) source(s):	Click here to enter text.
	Study results:	Click here to enter text.
	Study conclusion:	Click here to enter text.
	➢ Attach schematic representation of study design in **Annex FF.**	
	➢ Attach graphic/pictorial representation of summary study results in **Annex GG.**	
	➢ Provide a copy of the report of the proof of therapeutic equivalence (BE study), in **Annex HH**.	
	➢ For bioequivalence studies, indicate the stringent regulatory authority (SRA)/ WHO/PIC/S inspection status of the Contract Research Organisation (CRO) (if the CRO has ever undergone inspections in relation to current or other studies).	
4.2.3	If demonstrated by comparative in vitro dissolution tests according to conditions described in WHO BCS classification document (WHO Technical Report Series, No. 937, or later)	
	Reference Product Information:	
	Generic name:	Click here to enter text.
	Dosage form:	Click here to enter text.
	Strength:	Click here to enter text.
	Brand/trade name:	Click here to enter text.
	Manufacturer:	Click here to enter text.
	Manufacture site:	Click here to enter text.
	Batch number:	Click here to enter text.
	Expiry date:	Click here to enter text.
	Name and contact details of laboratory performing tests: Click here to enter text.	
	Study Results:	
	F2 (similarity factor) value (standard 50–100%): Click here to enter text.	
	F1 (difference factor) value: Click here to enter text.	
	Study conclusion: Click here to enter text.	
	➢ Provide a copy of the report of the proof of therapeutic equivalence, comparative dissolution	

	profile, dissolution tests, and others, if any, in **Annex II**.	
4.2.4	By another method (please describe the method and the study conclusion, briefly):	
	☐ Yes	☐ No (explain): Click here to enter text.

4.3 Commitment

	The product used in the therapeutic equivalence study is essentially the same as the one that will be supplied (same materials from the same suppliers, same formula and same manufacturing method):	☐ YES	☐ NO
	If no, explain what the differences are and justify that the differences do not have any impact on the bioavailability: Click here to enter text.		

Section 5: Commitment and authorization

5.1 Commitment

I, the undersigned, ***(POSITION IN THE COMPANY, E.G. GENERAL MANAGER, AUTHORIZED PERSON, RESPONSIBLE PHARMACIST)***, acting as responsible for the company ***(NAME OF THE COMPANY)***, certify that the information provided (above) is correct and true,

(*If the product is marketed in the country of origin, select the appropriate box below*)

☐ and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in ***(country of origin)***, including formulation, method and site of manufacture, sources of active and excipient starting 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. formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the finished product and starting material, packaging, shelf-life, indications, product information*)

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.

Signature: _____ Date: _____

5.2 Power of attorney

The manufacturer authorizes a distributor to submit the questionnaire

Signature: _____ Date: _____

Distributor (Signed by Distributor for Manufacturer under power of attorney)

Please provide a copy of the power of attorney in **Annex JJ**.

5.3 Authorization for sharing information with other agency

I, the undersigned confirm that ***INSERT COMPANY NAME*** has no objection to each Agency confidentially sharing information in this questionnaire, any of its annexes and/or the results of its review of such information and annexes (including its corresponding recommendations) with the other Agencies and with other interested organizations for procurement purposes.

I, the undersigned, certify that the information provided above is accurate, correct, complete, up-to-date and true at the time of submission.

Full Name (Printed): _____

Full Title in Company: _____

Company Name: _____

Signature: _____ Date: _____

Company seal/stamp:

Section 6: Attachments/annexes

Attachments or Annexes to the questionnaire should be in PDF format and should be well indexed to facilitate review.

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

☐ A. Copy of product registration and market status– Licence No (1.5.1)

☐ B. Certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863. An earlier version is not acceptable) (1.5.1)

☐ C. Recent as well as historical deficiency/acceptance letters issued by PQP/SRA in relation to the specific product dossier (1.5.1)

☐ D. Copy of product registration and market status– Licence No (1.5.2)

☐ E. Copy of the relevant WHO Prequalification acceptance letter signed by your company (1.5.3)

☐ F. WHO acceptance letter for product dossier review mentioning the WHO reference number assigned by WHO for this specific product (1.5.4)

☐ G. Description and composition of primary packaging materials (1.6.1)

☐ H. Description and composition of secondary packaging materials (1.6.2)

☐ I. Copy of primary and secondary packaging / label (1.6.3)

☐ J. Patient information leaflet / package insert (1.6.5)

☐ K. GMP certificate of the API manufacturer(s) from the country of origin (2.1.3)

☐ L. Copy of the internal API(s) specification(s) (2.2.1)

☐ M. Validated analytical methods if analytical methods for API are in-house analytical method, different from BP, USP and Ph.Int. (2.2.1)

☐ N. Copy of the certificate of analysis for the three last batches released (2.2.4)

☐ O1. Copy of the certificate of suitability to the European Pharmacopoeia (CEP) and its annexes (2.2.5)

☐ O2. Attach a copy of the Technical file (2.2.6)

☐ P. Flow diagram and brief narrative describing the manufacturing and control process of this API with relevant parameters (2.3.1)

☐ Q. Copy of the cleaning validation protocol (2.3.2)

☐ R. Data on validation of the sterile aspects of the product including recent media fill validation data, as applicable (2.3.8)

☐ S. Recent/valid GMP certificates/letter of compliance of the FPP manufacturer (3.1.3)

☐ T. Copies of release and shelf-life specifications for FPP (3.2.2)

☐ U. If in-house specification is different from BP, USP and Ph.Int., attach copy of the in-house finished product specifications and also validated analytical methods (3.2.3)

☐ V. Copy of the certificate of analysis for the three last batches released (3.2.4)

☐ W. Formulation of the product USE THE ATTACHED FORM (complete qualitative and quantitative composition including active ingredient(s) and excipients) (3.3.1)

☐ X. Flow diagram and brief narrative describing the manufacturing and control process of this FPP with relevant parameters (3.4.1)

☐ Y. Copy of the cleaning validation protocol (3.4.2)

☐ Z. Data on validation of the sterile aspects of the product including recent media fill validation data as applicable (3.4.8)

☐ AA. Protocol and report for accelerated and long-term stability testing (3.5.1)

☐ BB. Declaration that stability studies have been done or are being done with all declared API sources (3.5.3)

☐ CC. Status report of any ongoing stability studies (3.5.4)

☐ DD. In-use stability data and storage conditions after reconstitution for oral powder for suspension, powder for injection, or injection that may be further diluted, or multidose containers (3.5.8)

☐ EE. Summary of pharmacology, toxicology and efficacy of the product (4.1)

☐ FF. Graphic/pictorial representation of summary study results (4.2.2)

☐GG. Copy of the report of the proof of therapeutic equivalence (BE study) comparative dissolution profile, dissolution tests, and others if any (4.2.2)

☐ HH. Schematic representation of study design (4.2.2)

☐II. Study protocol summary (4.2.3)

☐ JJ. Copy of the power of attorney (5.2)

Annex W: Formulation of the product

Qualitative Composition

Please provide the formulation of the product, complete qualitative and quantitative composition, including active ingredient(s), overages (if any), and excipients that may not appear in the final formulation (e.g purified water, solvents, gases, etc.). Please also indicate the standard for each ingredient (e.g. BP, USP, in-house). Mention specifically if the product is a fixed-dose combination (FDC) or co-packaged: Click here to enter text.

Component Name	Standard / Grade (e.g. USP, BP, JP, etc.)	Function in Formulation	Supplier
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Quantitative Composition

mg/unit	Component Name	Theoretical Amount to Dispense (g)	Overage (%)	Amount to Dispense per Batch (g)
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