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**UNECA**

# REQUEST FOR EXPRESSION OF INTEREST (EOI)

**This notice is placed by UNECA. The accuracy, reliability and completeness of the contents of furnished information is the responsibility of UNECA. You are therefore requested to direct all queries regarding this EOI to UNECA using the fax number or e-mail address provided below.**

**Title of the EOI:**
Invitation to Manufacturers of Maternal, Neonatal and Child Health Medicines, Products and Equipment to submit an Expression of Interest (EOI) for the AfCFTA-anchored Pharma Initiative's Local Production Evaluation by the UN Economic Commission for Africa.

**Date of this EOI:** 30 March 2022 **Closing Date for Receipt of EOI:** 30 April 2022

**EOI Number:** EOIUNECA19624

**Beneficiary Country/Territory:** Africa

**Commodity/Service category:** Pharmaceuticals

**Address EOI response by fax or e-mail to the Attention of:** Eca-Pharma-Initiative@Un.Org

**Fax Number:**

**E-mail Address:** shiferaw3@un.org

**UNSPSC Code:** 41000000, 42000000, 51000000

## DESCRIPTION OF REQUIREMENTS

1.1 In line with Agenda 2063 and Sustainable Development Goas (SDGs), the main objective of the Pharma Initiative is to address socio-economic-related challenges facing African member countries relating to access to equitable, safe, and affordable medicines and the creation of fiscal space to the African Governments given the emerging trend of rising government debts. In addition, the Initiative leverages on the ratified AMA and the beginning of trading under the AfCFTA which brings on board a combined market of 1.3 billion people and gross domestic product (GDP) of $3.4 trillion, across all member states of the Africa Union.

1.2 The Pharma Initiative has a three-pronged approach; localized production; pooled procurement and a harmonized regulatory and quality framework focusing on maternal, neonatal and child health care (MNCH) products to address persistent challenges in MNCH burden, unmet needs, and access to reproductive health products across the select region. Further, the Initiative demonstrates the necessity and efficacy of investment in women's health as a key component of inclusive and sustainable economic development.

1.3 It is against this background and in line with the objectives stated above that ECA would like to invite manufacturers of MNCH product(s) to realize Africa's vision leveraging on AfCFTA and AMA to fulfill the

unmet needs of pilot member countries by increasing access to affordable and reliable supply of quality assured MNCH medicines.

Kindly refer to the attached ToR for detailed description of the Pharma inivitative and the evaluation requirement before applying.

**SPECIFIC REQUIREMENTS / INFORMATION (IF ANY)**

For instructions for submission of applications, kindly refer to the attached TOR.

**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 submit the Vendor Response Form of this EOI electronically (through the link available on the next page) before the closing date set forth above.***

# VENDOR RESPONSE

**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**.
- While companies can participate in solicitations after completion of registration at Basic Level, 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 should express your interest to this EOI electronically at:**
https://www.un.org/Depts/ptd/node/add/interest-expressed?EOI=EOIUNECA19624

**In case you have difficulties submitting your interest electronically, please contact shiferaw3@un.org directly for instructions.**

## 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 UNECA (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

AfCFTA-anchored
Pharma Initiative

# TERMS OF REFERENCE

Invitation to Manufacturers of Maternal, Neonatal and Child Health Medicines, Products and Equipment to submit an Expression of Interest (EOI) for the AfCFTA-anchored Pharma Initiative's Local Production Evaluation by the UN Economic Commission for Africa

**(Note: this is not a call for procurement of pharmaceuticals, rather a call for relevant manufacturers across the public and private sector to pilot selected strategies for improving access to maternal and child health essential medicines and commodities)**

**The deadline for submission of EOI is**

**30 APRIL 2022 AT 17:00 EAT**

**Late Submission of EOI will be rejected.**

## 1. Background:

1.1 To maximize the opportunities arising from African Continental Free Trade Agreement (AfCFTA) and African Medicines Agency (AMA), in recognition and support of the Accelerated Industrial Development of Africa (AIDA) and Pharmaceutical Manufacturing Plan for Africa (PMPA), 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, UNFPA and other relevant UN agencies commissioned an AfCFTA-anchored pharmaceutical Initiative (Pharma Initiative) in 10 select African countries of Comoros; Djibouti; Eritrea; Ethiopia; Madagascar, Mauritius, Kenya, Rwanda, Seychelles; and Sudan anchored by Intergovernmental Authority on Development (IGAD). In line with Agenda 2063 and Sustainable Development Goas (SDGs), the main objective of the Pharma Initiative is to address socio-economic-related challenges facing African member countries relating to access to equitable, safe, and affordable medicines and the creation of fiscal space to the African Governments given the emerging trend of rising government debts. In addition, the Initiative leverages on the ratified AMA and the beginning of trading under the AfCFTA which brings on board a combined market of 1.3 billion people and gross domestic product (GDP) of $3.4 trillion, across all member states of the Africa Union.

1.2 The Pharma Initiative has a three-pronged approach; localized production; pooled procurement and a harmonized regulatory and quality framework focusing on maternal, neonatal and child health care (MNCH) products to address persistent challenges in MNCH burden, unmet needs, and access to reproductive health products across the select region. Further, the Initiative demonstrates the necessity and efficacy of investment in women's health as a key component of inclusive and sustainable economic development.

1.3 Medicines and Vaccines consume a large proportion of African nation's healthcare budget. One of the reasons is related to issues of inefficient multiplicity of pharmaceutical procurement models, as well as long lead times for international orders, high transport, customs and tariffs, 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 have led to slow progress towards attainment of Sustainable Development Goals (SDGs). In addition, the current supply of medicines, vaccines and essential COVID-19 PPEs to Africans does not meet demand. Africa manufactures "less than 2 percent of the essential medicines it consumes" while it imports about 97 percent of its needs from outside the continent at an annual cost of USD14.5 billion.

1.4 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 the Agenda 2063". 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, vaccines, and PPEs.

1.5 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 for production through AfCFTA-anchored Pharmaceutical Initiative pilot project procurement resources if:

a) prequalified by WHO prequalification program, **OR**

b) approved for marketing authorization within Mature Level 3-4 Regulatory Authority Region which is also referred to as WHO and/or ICH recognized member countries, **OR**

c) 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**

d) approved and marketed within Small Island Development States (SIDS) **OR**

e) reviewed and listed by Global Drug Facility (GDF) - Stop TB Partnership and/or other procurement agencies participating in WHO ERP program, **AND**

f) accepted, reviewed, and permitted for use by an independent technical review panel (TRP) led by UNECA and WHO as described under item number 4 and 5 below.

1.6 In order to deliver and support the Accelerated Industrial Development of Africa (AIDA), an updated and revised Expression of Interest of listed MNCH medicines, products and equipment are required to guide local manufacturing under the Pharma Initiative in line with PMPA. It is against this background that the ECA through the Pharma Initiative is seeking the services of an Institutional Contractual Consultancy to support the Local manufacturing of listed Maternal, Neonatal and Child Health Medicines, Products and Equipment medicines, covid-19 vaccines, PPEs, and other mitigation products.

## 2. Objectives of the project

2.1 ECA is facilitating the Pharma Initiative 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:

a) Leverage the AfCFTA in facilitating regional pooled procurement across specific cluster markets with identified interest.
b) Facilitate and advocate from the policy angle local pharmaceutical production of selected and identified pharmaceutical drugs and products.
c) Ensure quality standards of identified medicines and products for pooled procurement and local production.

2.2 It is against this background and in line with the objectives stated above that ECA would like to invite manufacturers of MNCH product(s) to realize Africa's vision leveraging on AfCFTA and AMA to fulfill the unmet needs of pilot member countries by increasing access to affordable and reliable supply of quality assured MNCH medicines.

2.3 This is a call for an action to address the challenges of medicines shortage that the region is facing due to the low-capacity production that may not sufficiently meet market demands. The support of regional efforts to increase the volume and quality assurance of manufacturing/production will in turn increases access to quality products that will reduce maternal and infant mortality. ECA and partners are pleased to invite the manufacturers of pharmaceutical products and with additional potential to support COVID-19 pandemic mitigating products to submit an expression of interest for evaluation for eligibility to manufacture in Africa.

## 3. Purpose

3.1 The purpose of this Terms of Reference (TOR) is to invite African based manufacturers for essential Pharmaceutical and related medical products listed in section 4 below to express their interest in participating in the EOI for Manufacturers. Interested manufacturers fulfilling the requirement outlined in section will undertake Local production of selected products in line with WHO current GMP (cGMP) standards and WHO prequalification requirements as part of the AfCFTA-anchored Pharma Initiative. This assignment involves the provision by manufacturing firms and production services of a range quality APIs or FPP, PPEs listed in this entirely by one firm for another, under the brand or generic name or under use of contract manufacturing under GMP compliance and Prequalification Programme, and in line with AfCFTA framework.

3.2 Purchasing and distribution of stated pharmaceutical products and PPEs are NOT part of this assignment. This AfCFTA – anchored Pharmaceutical Initiative will assist Africa to achieve its 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.

3.3 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.

**3.4** The steps involved are:

a) The terms of reference (TOR) are published with a deadline for submission.

b) Manufacturers express interest in participating by submitting to ECA and partners, applications as per the requirements in this TOR before the deadline.

c) Evaluation/ review of the applications by the ECA and partners' quality assurance specialists (or designated secretariat) that serves as the point of contact between the applicant and the Technical Review Panel (TRP). Additional information may be requested.

d) 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.)

e) 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.

## 4. Pharmaceutical and related Medical Products included in this expression of interest

4.1 The recommended active ingredients, dosage forms and strengths ("Formulations") listed in this EOI document (See page 6 below – Maternal, Neonatal and Child Health Medicines and related commodities) are according to the recommendations made by member countries participating in the AfCFTA – anchored Pharmaceutical Initiative participating Member States.

Table 1: Maternal, Neonatal and Child Health Products

4.2 **Immediate Need**

a) Oxytocin injection 10 International Units (IU), 1ml

b) Misoprostol 25 microgram tablet

c) misoprostol 200 microgram tablet (Misoprostol administered either orally, sublingually, or vaginally depending on the indication)

d) Mifepristone 200 mg tablet (only to be used in combination with misoprostol)

e) mifepristone 200 mg tablet co-packaged with 4 tablets of misoprostol (Mifepristone (200mg) administered orally; misoprostol (4X200µg) administered either sublingually or vaginally)

f) 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)

g) Amoxicillin Dispersible tablets 125mg, 250mg and 500mg (scored)

h) Amoxicillin Suspension 250mg

i) Heat stable Carbetocin, injection 100 microgram/ml – in 1 ml

j) Ergometrine Injection 500 micrograms/ml

k) Labetalol Tablet 200 mg

l) Levonorgestrel - Releasing IUDs

m) Clomifene 50 mg Tablets

**4.3 Oral Contraceptive**

a) Ethinylestradiol + Desogestrel Tablets (30 micrograms + 150 micrograms

b) Ethinylestradiol + Levonorgestrel Tablets (30 micrograms + 150 micrograms

c) Levonorgestrel Tablet 30 micrograms

d) Levonorgestrel Tablet 30 micrograms

e) Levonorgestrel Tablet 750 micrograms

f) Norethisterone Tablet 350 micrograms

g) Norgestrel Tablet 75 microgram

h) Medroxyprogesterone Acetate Tablet 10 Mg

**4.4 Injectable Hormonal Contraceptive**

a) Medroxyprogesterone acetate Depot injection 150 mg/ml in 1ml vial

b) Medroxyprogesterone acetate + Estradiol Cypionate injection 25mg + 5 mg

c) estradiol valerate + norethisterone enanthate injection 50 to 200 mg

**4.5 Implantable Contraceptives**

Two – rod Levonorgestrel-releasing implant, each rod containing 75mg Levonorgestrel (150 mg in total)

**4.6 Barrier Methods**

a) Condoms

b) Diaphragms (Female Condoms

## 5. Other products

5.1 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 most 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.

Table 1: Future needs priority medicines for Local Production

| | | |
|---|---|---|
| **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.<br>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.<br>Tablet: 500 mg Amoxicillin + 125 mg clavulanic acid / 5ml<br>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.<br>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<br>Powder for injection: 500 mg / vial.<br>Powder for oral liquid: 125 mg / 5ml. |
| **1.11** | Doxycycline | Oral liquid: 25 mg/5 ml; 50 mg/5 ml [anhydrous].<br>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.<br>Oral liquid: 200 mg / 5 ml; Tablet: 200 mg; 500 mg<br>Suppository: 500 mg; 1 g. |
| **1.15** | Piperacillin + Tazobactam | Powder for injection: 2 g + 250 mg / vial; 4 g + 500 mg /vial |
| **1.16** | sulfamethoxazole + trimethoprim | Injection: 80 mg + 16 mg/ml in 5ml ampoule; 80 mg + 16 mg/ ml in 10 ml ampoule.<br>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).<br>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<br>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.<br>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.<br>Oral liquid: 20 mg/5 ml.; Tablet: 40 mg. |
| **5.10** | Nifedipine | 20mg Tablet |
| **5.11** | Omeprazole | Powder for injection: 40 mg in vial<br>Powder for oral liquid: 20 mg; 40 mg sachets |
| **5.12** | Ranitidine | Injection: 25 mg/ mL (as hydrochloride) in 2- mL ampoule.<br>Oral liquid: 75 mg/5 mL (as hydrochloride).<br>Tablet: 150 mg (as hydrochloride). |
| **5.13** | Metoclopramide | Injection: 5 mg (hydrochloride)/ mL in 2- mL ampoule.<br>Oral liquid: 5 mg/5 mL [c].<br>Tablet: 10 mg. |
| **5.14** | Ondansetron | Injection: 2 mg base/ mL in 2- mL ampoule (as hydrochloride).<br>Oral liquid: 4 mg base/5 ml.; Solid oral dosage form:<br>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.<br>Injection: 50 micrograms (as sulfate)/ mL in 5- mL ampoule.<br>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 vials |
| **6.2** | Botulinum Toxin Type A | 100 IU/ vial |
| **6.3** | Diphtheria, Pertussis, Tetanus, H. influenzae Type B Conjugate Vaccine [adsorbed]. | 10 dose vials |
| **6.4** | Diphtheria and Tetanus Vaccine [Pediatric, adsorbed]). | 10 or 20 dose vials |
| **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 vials |
| **6.12** | Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed). Single dose | Single dose |
| **6.13** | Polio inactivated vaccine of suitable strains of poliomyelitis virus Type 1, 2 and 3 | 0.5ml single dose |
| **6.14** | Polio oral vaccine bivalent Type | 20 dose vials with dropper |
| **6.15** | Tetanus Toxoid Vaccine Adsorbed. 10/20 dose vial | 10 or 20 dose vials |

| | | |
|---|---|---|
| **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 vials | Single or 10 dose vials |
| **6.19** | Covid – 19 Vaccine 10 dose vial | To be determined |

## 6. 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.

## 7. Requirements for submission of the application

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

a) A cover letter expressing interest in submitting the product application to ECA Technical Review Panel for evaluation.

b) 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.

c) 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 current good manufacturing practice (cGMP).

d) 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.

e) 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

8.1 To be considered eligible for application the following criteria must be fulfilled:

a) 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

b) 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

### 9.1 Completeness of submission application.

Completeness of the application and related documents submitted to ECA is determined by the ECA and partners' quality assurance specialists (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.

### 9.2 Approval of Submitted documents.

a) 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.

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

## 9. Instruction for submission of application via Secured Email

All documents should be submitted to the email address: eca-pharma-initiative@un.org .

1) Due to the ongoing COVID-19 pandemic, the UN Secretariat will only solicit submissions of applications **via electronic means**. Please be advised that the UN will neither require nor accept physical submission of applications, whether by courier, FedEx, DHL, personal delivery, or similar physical means. Electronic submissions of applications are legally binding if they are signed off by the authorized representative of the bidder.

2) The UN takes no responsibility for effective delivery of the electronic document.

3) While the UN shall take every reasonable step to ensure that it does not upload corrupt or unsafe documents, applicants should check any documents downloaded from the email for viruses prior to opening them. The UN will not be liable or responsible for the loss, damage, destruction, corruption, or illegibility of documents in any electronic application submission, however caused. The UN is also not able to consider electronic documents that are corrupt, infected, or otherwise unreadable.

4) For submission of applications via electronic means, the receipt timestamp is the date and time the submission has been received, as indicated by the log files of the email received. It is the sole responsibility of applicant to ensure that the UN Secretariat receives their applications and related documents on or before the prescribed deadline.

5) Applications **must** be submitted by electronic mail to the UN's dedicated email address at: eca-pharma-initiative@un.org **without** copying any UN staff. Please do not sent any application documents to the email address: shiferaw3@un.org. **If an application is sent to any UN email address other than** eca-pharma-initiative@un.org, either by direct email, by copy, or blind copy, **the application will be subject to disqualification.**

6) Due to file size constraints, each email including its attachments **must not** exceed **10 MB** (megabytes). Emails larger than 10 MB may not be successfully received. Therefore, applicants are advised to use We Transfer, OneDrive or Google Drive as applicable. Note to give the access right to eca-pharma-initiative@un.org before sharing the link for the documents.

7) Alternatively, applicants can send their documents with subsequent emails. The SUBJECT of each email application should read as follows:

**EOI2-PramaInitiative - *Company Name (first 2 words ONLY)* – Application- 1 of 3**

**EOI2-PramaInitiative - *Company Name (first 2 words ONLY)* – Application- 2 of 3**

**EOI2-PramaInitiative - *Company Name (first 2 words ONLY)* – Application- 3 of 3**

**PLEASE REFRAIN FROM MODIFYING OR INSERTING ANY OTHER WORDING IN THE EMAIL *SUBJECT***

## 10. Confidentiality

11.1 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 local production 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.).

11.2 Information provided by manufacturers, review findings and advice provided by the TRP 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.

**Appendices**

Form A: (see Next Page)

United Nations
Economic Commission for Africa

AfCFTA-anchored
Pharma Initiative

# Self-Assessment Questionnaire

# on

# Licensing and Good Manufacturing Practice Requirements for Pharmaceutical Manufacturing Companies

## Form A

## AfCFTA-Anchored Pharma Initiative's

## Local Production Evaluation

## by

## The United Nations Economic Commission for Africa

**BACKGROUND**

The following questionnaire has been designed for use in assessing the licensing and WHO GMP status of pharmaceutical manufacturing companies. Its aim is to assist a company with assessing its current GMP status and to highlight any areas where further efforts to raise the GMP standard may be required. If any or all manufacturing is contracted out, it is recommended that a copy of the questionnaire be sent to each external contractor to seek confirmation that they are in full compliance with the following requirements. This self-administered questionnaire (developed and adapted from WHO Good manufacturing practices for pharmaceutical products: main principles; Food Supplements Europe (FSE) Guide to Good Manufacturing Practice for Manufacturers of Food Supplements) must be completed by all pharmaceutical manufacturing companies participating in the AfCFTA-anchored Pharma Initiative led by United Nations Economic Commission for Africa and Partners. To facilitate an assessment, a word format of the questionnaire should be submitted, and documents and their corresponding annex or attachments need to match the content in the pre-assessment questionnaire.

**PRE-ASSESSMENT QUESTIONNAIRE**

| THEME | RESPONSE | |
|---|---|---|
| **SECTION A: COMPANY INFORMATION** | | |
| 1. Name of Company | | |
| 2. Address of Company: | | |
| 3. Telephone No | | |
| 4. Contact Name | | |
| 5. Email: | | |
| 6. Position within Company: | | |
| 7. Type of Business: | Manufacturing/ Packaging | |
| | Packaging only | |
| | Contract manufacturer/ Packer | |
| | Marketing | |
| 8. Does your company manufacture and/or pack medicines? | On-site | |
| | At another site within the group | |
| | Contract out manufacturing | |
| | Contract out packaging | |
| 9. No. of full-time employees: | | |
| 10. No. of part-time/seasonal employees: | | |
| 11. Does your company hold a company registration certificate under national company legislation? | YES: | NO |
| 12. Does your company hold a current manufacturing authorization under national medicines legislation? | YES: | NO: |
| - If Yes, please provide details and date of expiry: | | |
| 13. Does your company have a distribution license for the distribution of finished products? | YES: | NO: |
| 14. Does your company have a testing laboratory license? | YES: | NO: |
| 15. Does your company have the tax registration certificate required in the country of operation? | YES: | NO |
| 16. Does your company have updated audited financial records? | YES: | NO |

| | | |
|---|---|---|
| 17. Does your company comply with the environmental, health, and safety standard requirements in the country/region? | YES: | NO: |
| **SECTION B: QUALITY MANAGEMENT** | | |
| 18. Is your company registered/registering for an accredited quality system, e.g. ISO? | YES: | NO: |
| - If Yes, which one? | | |
| 19. Does the company have personnel specifically responsible for quality (e.g. Quality Control/Quality/Assurance Manager)? | YES: | NO |
| - If Yes, are the authority and responsibilities of this personnel clearly defined? | YES: | NO: |
| - Do these personnel have the authority to make independent decisions on product quality? | YES: | NO: |
| 20. Is there documented evidence for all lots (batches) of product that demonstrates that all steps during manufacture are being carried out as per the defined procedures and that the quantity and quality produced are as expected? | YES: | NO: |
| 21. Are reference samples retained of: | | |
| - Starting materials? | YES: | NO: |
| - Finished products in the final pack? | YES: | NO: |
| 22. Are there procedures in place to ensure the traceability of all raw material, intermediate and finished products? | YES: | NO: |
| 23. Do the traceability records allow for rapid identification of: | | |
| - the suppliers of the raw materials | YES: | NO: |
| - the complete manufacturing history of a lot of finished product | YES: | NO: |
| - the businesses to which finished products have been supplied? | YES: | NO: |
| 24. Is the information on traceability in a form that can be made available to the authorities on demand? | YES: | NO: |
| 25. Is there a Supplier Quality Assurance procedure in place, laying down the criteria for selection, approval, review, and ongoing approval, to ensure that the supplied products and services meet the expected requirements? | YES: | NO |
| 26. Are the Quality Assurance procedures of suppliers of raw and packaging materials monitored? | YES: | NO: |
| 27. Is there a system in place allowing rapid feedback to the purchasing department if concerns are raised on the quality of purchased materials? | YES: | NO: |
| 28. Is there a system in place allowing rapid feedback to the manufacturing department regarding modifications or corrective actions to be taken, if required? | YES: | NO: |
| 29. Are summaries of quality performance data and advice (where relevant) regularly given to manufacturing personnel? | YES: | NO: |

| | | |
|---|---|---|
| 30. Is there a system in place to ensure changes to relevant legislation are promptly noted and applied where applicable? | YES: | NO: |
| **SECTION C: PERSONNEL AND TRAINING** | | |
| **Training** | | |
| 31. Is 'on the job' training given to personnel? | YES: | NO: |
| 32. Are new employees given an induction course? | YES: | NO: |
| - If Yes, does the course include hygiene training? | YES: | NO: |
| 33. Is additional appropriate regular training offered to personnel? | YES: | NO: |
| 34. For full-time personnel, is their training subjected to formal review and assessment? | YES: | NO: |
| 35. Are individual training records kept and maintained? | YES: | NO: |
| 36. Have all relevant personnel who come into contact with raw materials/products, had training in basic hygiene, and hold the associated certification, where relevant? | YES: | NO: |
| 37. Do office, maintenance, and cleaning staff and any contractors who enter the production or storage areas receive food hygiene instructions? | YES: | NO: |
| 38. Are all employees issued with a Company handbook that includes hygiene rules? | YES: | NO: |
| **Hygiene** | | |
| 39. Is appropriate protective clothing provided to employees? | YES: | NO: |
| 40. Is there a requirement for protective outerwear to be removed when leaving the manufacturing areas? | YES: | NO: |
| 41. Are pre-employment medical checks carried out? | YES: | NO: |
| 42. Are all visitors made aware of the Company's hygiene policy? | YES: | NO: |
| 43. Is there a policy in place to ask visitors or contractors, before they enter any manufacturing areas, whether they have suffered or been in contact with any recent illness that may be a potential contamination risk to products? | YES: | NO: |
| 44. Is there a reporting procedure for staff suffering from, or who are in close contact with people suffering from, specific medical conditions? | YES: | NO: |
| 45. Is there a Return to Work procedure in place following illness or holidays abroad? | YES: | NO: |
| 46. Are there clear written policies in place: | | |
| - on the wearing of wristwatches and jewellery in the manufacturing areas? | YES: | NO |
| - on items of clothing or jewellery that may be allowed in the manufacturing areas for medical, ethnic, or religious reasons? | YES: | NO: |
| - on the wearing of make-up, associated items, and perfumed products in the manufacturing areas? | YES: | NO: |
| - on the carrying of loose items (pens, mobile phones etc.) in the manufacturing areas? | YES: | NO: |
| 47. Are procedures in place for handwashing? | YES: | NO: |

| | | | |
|---|---|---|---|
| 48. Is antibacterial cream, foam, or gel available for applying after hand washing for personnel working in areas of high microbiological sensitivity? | YES: | | NO: |
| 49. Is there a procedure in place to control glove issue, where relevant? | YES: | NO: | NA |
| **SECTION D: PREMISES AND EQUIPMENT** | | | |
| **Premises** | | | |
| 50. Is there a Maintenance Plan that ensures the condition of buildings (both internal and external) and equipment is regularly reviewed and action taken when necessary? | YES: | | NO: |
| 51. Is there an Environmental Monitoring program? | YES: | | NO: |
| **Ventilation and lighting** | | | |
| 52. Are manufacturing areas ventilated with a constant supply of appropriately filtered air? | | | |
| Are there shatterproof covers on lights in the following areas: | | | |
| - raw material storage area? | YES: | | NO: |
| - manufacturing areas? | YES: | | NO: |
| - finished products storage area? | YES: | | NO: |
| 53. Is there a formal glass and plastic breakage control (Brittle Materials) procedure? | YES: | | NO: |
| **Floors, walls, and ceilings** | | | |
| 54. Are the floors in the manufacturing areas made of an impervious and non-absorbent material? | YES: | | NO: |
| 55. Are they free from cracks and joints in areas where the product is exposed? | YES: | | NO: |
| 56. Do drains have trapped gullies and proper ventilation? | YES: | | NO: |
| 57. Are any open drainage channels shallow and easy to clean? | YES: | | NO: |
| 58. Are walls intact and free of faults and finished with a smooth impervious and easily cleaned material? | YES: | | NO: |
| 59. Are windows made of toughened glass or plastic? | YES: | | NO: |
| 60. Are there fly screens on windows that open? | YES: | | NO: |
| 61. Do window ledges slope away from the glass at an angle to prevent items being placed on them? | YES: | | NO: |
| 62. Do doors have smooth, non-absorbent, easy to clean and disinfect surfaces? | YES: | | NO: |
| 63. Does the ceiling construction in manufacturing areas prevent the accumulation of dirt / growth of mould/shedding of particles? | YES: | | NO: |
| **Floors, walls, and ceilings** | | | |
| 64. Is there a Site Hygiene Plan? | YES: | | NO: |
| - If Yes, is this plan regularly reviewed? | YES: | | NO: |
| 65. Are cleaning products stored in a location that is separate from the processing areas? | YES: | | NO: |
| 66. Is production waste collected in clearly identifiable receptacles for removal to specific collection points outside the buildings? | YES: | | NO: |
| 67. Is production waste removed from the manufacturing areas throughout the day? | YES: | | NO: |
| 68. How often is waste removed from the site? | DAILY: | | WEEKLY: |

| | | |
|---|---|---|
| 69. Does the disposal of waste comply with legislation on waste, as implemented nationally? | YES: | NO: |
| 70. Is all waste disposal appropriately documented? | YES: | NO: |
| **Receiving and dispatch areas** | | |
| 71. Do the receiving and dispatch areas provide protection from the weather for materials or product in transit? | YES: | NO: |
| 72. Is there a defined detoxing/debagging area for those materials which arrive in external packaging? | YES: | NO: |
| **Personnel hygiene facilities** | | |
| 73. Are the following provided: | | |
| - Changing facilities segregated from production area? | YES: | NO: |
| - Toilet and handwashing facilities segregated from manufacturing areas? | YES: | NO: |
| - Separate accommodation for clothing and footwear not being worn during working hours? | YES: | NO: |
| - First Aid facilities and an accident book? | YES: | NO: |
| - A rest and refreshment room segregated from the production area, for recreation and eating? | YES: | NO: |
| 74. Is the rest and refreshment room the only place where eating or drinking is allowed? | YES: | NO: |
| - If No, please specify other areas where eating or drinking is permitted: | | |
| 75. Is the whole site designated non-smoking? | YES: | NO: |
| - If No, please specify approved smoking areas: | | |
| **Pest control** | | |
| 76. Is Pest Control practiced? | YES: | NO: |
| 77. Is pest control contracted out? | YES: | NO: |
| - If No, are there appropriate procedures in place for in-house pest control? | YES: | NO: |
| 78. What steps are taken to protect against the entrance and harboring of vermin, birds, pests, and pets in all buildings on-site? | | |
| **Equipment** | | |
| 79. Are all surfaces and materials in contact with raw materials and finished product: | | |
| - Inert to the raw materials/product? | YES: | NO: |
| - Microbiologically cleanable, smooth ,and non-porous? | YES: | NO: |
| - Visible for inspection (or equipment is easily dismantled for inspection)? | YES: | NO: |
| - Easily dismantled and readily accessible for cleaning? | YES: | NO: |
| 80. Are there detailed cleaning procedures in place for all equipment? | YES: | NO: |
| 81. Is all equipment cleaned and serviced immediately after use? | YES: | NO: |
| 82. Are fumes from power-driven equipment, heaters etc. ventilated away from the manufacturing areas? | YES: | NO: |
| 83. Are there maintenance procedures in place for all equipment? | YES: | NO: |

| | | |
|---|---|---|
| 84. Is all equipment regularly serviced and calibrated? | YES: | NO: |
| - If Yes, are appropriate records maintained? | YES: | NO: |
| - Are these regularly checked to ensure calibration is up to date and equipment is working accurately? | YES: | NO: |
| 95. Are there procedures in place outlining the action to be taken in the event of a recognized malfunction of the inspection and testing equipment? | YES: | NO: |
| **Water supply** | | |
| 96. Is the water supply monitored and controlled? | YES: | NO: |
| 97. Is potable water used for all manufacturing purposes? | YES: | NO: |
| 98. Is the water that is used for all manufacturing purposes periodically analyzed, where required nationally? | YES: | NO: |
| 99. Where both potable and non-potable water are used on the premises, are the two water supplies clearly identified and kept separate from each other? | YES: | NO: |
| 100. If the products being manufactured are vulnerable to microbiological contamination, are filtering or disinfection systems installed on the water supply? | YES: | NO: |
| **SECTION E: PRODUCT AND PROCESS DEVELOPMENT** | | |
| 101. Are checks carried out on all new products to establish whether the ingredients and formulation are suitable, safe, and legal for all intended markets? | YES: | NO: |
| 102. Are the same checks as above carried out when any significant change is proposed e.g. change of raw material or equipment? | YES: | NO: |
| 103. Has stability been checked (either through actual stability tests or the use of previously confirmed data) and the shelf life correctly determined for: | | |
| - All products? | YES: | NO: |
| - Risk products? | YES: | NO: |
| 104. Is shelf life testing a requirement of the product development program? | YES: | NO: |
| 105. Are proposed labels checked to ensure they conform to all relevant labelling legislation? | YES: | NO: |
| 106. Are all proposed claims checked to ensure they comply with current legislation? | YES: | NO: |
| 107. For all new or revised products, is the appropriateness and legality of the packaging checked to ensure compliance? | YES: | NO: |
| 108. Are all new and revised products checked to ensure that the planned methods and procedures are suitable and that consistent quality products can be produced? | YES: | NO: |
| **SECTION 6: MANUFACTURE** | | |
| 109. Does each product have: | | |
| - A defined and authorized Master Formula? | YES: | NO: |
| - Defined and authorized Master Manufacturing Instructions? | YES: | NO: |
| - Related Standard Operating Procedures? | YES: | NO: |

| | | |
|---|---|---|
| 110. Are all instructions and operating procedures clear and unambiguous and written in the official working language of the manufacturing facility? | YES: | NO: |
| 111. Have appropriate trials been undertaken for each product to confirm that the formulation, methods, and procedures specified in the Master Manufacturing Instructions: | | |
| - are suitable for factory production? | YES: | NO: |
| - are capable of consistently yielding products within the Finished Product Specification? | YES: | NO: |
| 112. Are periodic checks undertaken to ensure the Master Manufacturing Instructions are being followed and that they are still applicable and relevant? | YES: | NO: |
| Have the following been developed and brought to the attention of all relevant personnel: | | |
| - Written operating procedures for each piece of equipment/instrument? | YES: | NO: |
| - Written instructions detailing the action to be taken in the event of stoppages, breakdowns, or other unexpected events? | YES: | NO: |
| - Formal procedures setting out the action to be taken in the event of foreign body contamination at any stage during the manufacturing process? | YES: | YES: |
| **Production** | | |
| 113. Prior to production commencing, are all materials, bulk containers, and major items of equipment to be used identified (e.g. labelled) with relevant information regarding the product to be processed? | YES: | NO: |
| 114. Does this identification also indicate the stage of manufacture and status, where applicable? | YES: | NO: |
| 115. Does the status label of the manufacturing area and equipment contain information regarding the previous product manufactured and the cleaning status when at rest? | YES: | NO: |
| **Raw materials** | | |
| 116. Are detailed specifications held for all raw materials? | YES: | NO: |
| 117. Are internal identification numbers allocated to all raw materials upon delivery? | YES: | NO: |
| 118. Are the contents of all containers identified? | YES: | NO: |
| 119. Are raw materials entering the premises quarantined until they are appropriately checked and a decision made on their status i.e. whether approved or rejected? | YES: | NO: |
| 120. Are all raw material lots (batches) tested? | YES: | NO: |
| - If No, specify what proportion are tested? | | |
| 121. Are Certificates of Analysis (CoA) for raw materials checked to confirm compliance with the specifications? | YES: | NO: |
| - If Yes, are periodic checks undertaken to verify the quality of the supplier's CoAs? | YES: | NO: |
| 122. Are stocks of raw materials in the storage areas: | | |
| | YES: | NO: |

| | | | |
|---|---|---|---|
| - Inspected regularly?<br>- Tested/sampled where appropriate? | YES: | NO: | |
| 123. Are the temperature and humidity for storing raw materials controlled and recorded? | YES: | NO: | |
| - If Yes, what are the tolerances? | | | |
| 124. Are there procedures in place for issuing raw materials from the store? | YES: | NO: | |
| 125. Is correct stock rotation followed when issuing raw materials from the store? | YES: | NO: | |
| 126. Is there a procedure in place for the reconciliation of the quantities of raw materials issued against the quantity of product manufactured? | YES: | NO: | |
| **Packaging and labelling materials** | | | |
| 127. Are packaging materials certified for food contact use (i.e. in conformance with current legislation on materials and articles in contact with food)? | YES: | NO | |
| 128. Are all aspects of current national packaging and packaging waste legislation complied with? | YES: | NO: | |
| 129. Is there a procedure in place to ensure that changes in product formulation are reflected in the label copy? | YES: | NO: | |
| 130. Are internal reference codes allocated to each delivery or lot/batch of packaging material? | YES: | NO: | |
| 131. Is packaging material entering the premises quarantined until it is appropriately checked and a decision made on its status i.e. whether approved or rejected? | YES: | NO: | |
| 132. Are stocks of packaging materials in store inspected regularly to check their condition? | YES: | NO: | |
| 133. Is stock rotation followed when issuing packaging materials from store? | YES: | NO: | |
| 134. Are all packaging materials inspected immediately before use? | YES: | NO: | |
| 135. Are procedures in place for: | | | |
| - the issue of packaging materials from store? | YES: | NO: | |
| - the return of part-used lots of packaging to store? | YES: | NO: | |
| - the re-sealing of part-used boxes of packaging, to prevent foreign body contamination? | YES: | NO: | |
| - the reconciliation of all printed packaging component stock from quantity issued, quantity used, wastage and that returned to store? | YES: | NO: | |
| - the removal and destruction of superseded packaging or labels? | YES: | NO: | |
| **Processing and packaging** | | | |
| 136. Are multiple packaging lines (where present) segregated to avoid the risk of cross-contamination? | YES: | NO: | NA |
| 137. Are the following checks always carried out before the start of any process: | | | |
| | YES: | NO: | |

| | | |
|---|---|---|
| - The name and appropriate reference to the product being processed is clearly displayed on each production line? | YES: | NO: |
| - The production area is clean and free from any items not relevant to the process to be undertaken? | YES: | NO: |
| - The correct materials and documents have been issued? | YES: | NO: |
| - The correct machine settings have been made? | YES: | NO: |
| - All plant and equipment is clean and ready for use? | YES: | NO: |
| 138. Are in-process conditions monitored (e.g. by sensory, instrumental and / or laboratory testing) | YES: | NO: |
| 139. Are samples analyzed: | | |
| - During production? | YES: | NO: |
| - After production? | YES: | NO: |
| - If Yes, are these samples tested: | | |
| - In-house? | YES: | NO: |
| - Contract Laboratory? | YES: | NO: |
| - Are the samples during production tested according to pre-set specifications? | YES: | NO: |
| - Are the samples after production tested according to pre-set specifications? | YES: | NO: |
| 140. Are intermediate products quarantined until checked and approved by Quality Control? | YES: | NO: |
| 141. Are packed finished products quarantined until checked and approved by Quality Control? | YES: | NO: |
| 142. Are there procedures in place for the management of non-conforming products? | YES: | NO: |
| **Disposal of waste and effluent** | | |
| 143. Is the disposal of printed packaging materials, raw materials, and reject products appropriately controlled? | YES: | NO: |
| 144. Is a reconciliation carried out on quantities of materials or products used and/or produced against those being disposed of? | YES: | NO: |
| 145. Are all waste materials and effluent disposed of by a route appropriate to the class of material? | YES: | NO: |
| **SECTION F: RECOVERY OR RE-WORKING OF MATERIALS** | | |
| 146. Is recovered material quarantined until checked by Quality Control and a disposition decision is made? | YES: | NO: |
| 147. Are there procedures in place for the following to be undertaken on recovered materials: | | |
| - Acceptance? | YES: | NO: |
| - Sampling? | YES: | NO: |
| - Tests? | YES: | NO: |
| - Treatments? | YES: | NO: |
| - Authorization or rejection? | YES: | NO: |
| 148. Is there a system in place to ensure that contaminated materials or products are not recovered, reworked, or re-processed but are destroyed? | YES: | NO: |

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| 149. Are there procedures in place to control the use of recovered or reworked materials? | YES: | NO: |
| 150. Are validated methods used for re-processing? | YES: | NO: |
| 151. Are finished products that have been returned from the market assessed and released by Quality Control before consideration is given for re-sale? | YES: | NO: |
| 152. Is the recovery, re-working or re-processing of materials or products clearly documented and these records retained for a designated period of time? | YES: | NO: |
| **SECTION G: STORAGE** | | |
| **Access to storage areas** | | |
| 153. Is access to material and product storage areas restricted to those working in these areas and to other authorized persons? | YES: | NO: |
| 154. Is there a formal list of persons who are authorized to access these areas? | YES: | NO: |
| 155. Is there a suitable curtain at all entrances and exits of the storage area? | YES: | NO: |
| 156. If the storage area connects to the manufacturing area, is a buffer area/pass box provided between the two areas? | YES: | NO: |
| **Temperature and lighting** | | |
| 157. Is temperature mapping and recording carried out in the storage area(s)? | YES: | NO: |
| 158. Do lighting appliances have shatterproof protective covers? | YES: | NO: |
| **Materials and product storage** | | |
| 159. Is a stock rotation system followed? | YES: | NO: |
| 160. Are all aisles in the storage area(s) kept clear? | YES: | NO: |
| 161. Are pallets regularly checked for structural integrity? | YES: | NO: |
| 162. Are packed products stored in conditions necessary for safe storage, appropriate to their specifications? | YES: | NO: |
| 163. Are stored materials and product clearly identifiable, even when stacked? | YES: | NO: |
| 164. Is there a specific quarantine area for material deliveries/product batches awaiting results of testing? | YES: | NO: |
| **Damaged goods** | | |
| 165. Is there a specific holding area for damaged goods, awaiting Quality Control inspection? | YES: | NO: |
| **Cleaning of storage areas** | | |
| 166. Are the storage facilities periodically inspected: | | |
| - For cleanliness? | YES: | NO: |
| - For pest infestation? | YES: | NO: |
| - To identify stock exceeding its shelf life? | YES: | NO: |
| 167. Are such inspections documented and any corrective actions noted? | YES: | NO: |
| 168. Are there procedures in place for cleaning of the storage premises and equipment? | YES: | NO: |

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| **SECTION H: TRANSPORT AND DISTRIBUTION** | | |
| 169. Are vehicle/container interiors inspected: | | |
| - before loading materials/products? | YES: | NO: |
| - on unloading materials/products? | YES: | NO: |
| 170. Do the inspections include checks for the following: | | |
| - Cleanliness? | YES: | NO: |
| - Moisture? | YES: | NO: |
| - Foreign materials? | YES: | NO: |
| - Insect or rodent infestations? | YES: | NO: |
| - Objectionable odours? | YES: | NO: |
| 171. Are contaminated vehicles and/or containers kept apart from those that are clean? | YES: | NO |
| 172. Are security measures in place that: | | |
| - Help deter tampering with goods in storage and distribution? | YES: | NO: |
| - Show whether any tampering has occurred? | YES: | NO: |
| 173. Is there a written procedure to deal with damages occurring to goods during storage and distribution? | YES: | NO: |
| 174. Are audits carried out on contracted-out transport facilities and procedures, where relevant? | YES: | NO: |
| 175. Are the relevant personnel informed when particular care is needed to reduce large temperature fluctuations during transport and delivery? | YES: | NO: |
| 176. Are fire appliances easily accessible and appropriate for use on the materials / products concerned? | YES: | NO: |
| 177. Are fork lift and other trucks used within the storage areas battery driven or otherwise equipped to prevent fume or fuel contamination? | YES: | NO: |
| **SECTION I: HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP)** | | |
| 178. Is there a HACCP system in place, as required under national regulations? | YES: | NO: |
| 179. Have all HACCP team members been trained in how to utilize the HACCP Principles? | YES: | NO: |
| 180. How many of the HACCP team members have received formal HACCP training? | | |
| 181. Has the HACCP system been verified by someone other than the person responsible for the monitoring and corrective actions? | YES: | NO: |
| 182. Is there a procedure in place to ensure the HACCP plan is amended as required if any changes occur, e.g. to formulation, supplier, process equipment etc.? | YES: | NO: |
| 183. Even if no obvious changes have been made, is your HACCP plan re-assessed at least once a year? | YES: | NO: |
| 184. How regularly is the HACCP standard operating procedure reviewed? | | |
| **SECTION J: STABILITY AND SHELF LIFE** | | |

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| 185. Are the products' shelf lives based on an assessment of relevant data? | YES: | NO: |
| 186. Is this data obtained from: | | |
| - An appropriate stability study on the specific product? | YES: | NO |
| - Extrapolation of data from stability studies on similar products? | YES: | NO: |
| - Bibliographical references from scientific literature? | YES: | NO: |
| - Combinations of the above? | YES: | NO: |
| 187. Are overages used to ensure claimed levels are met at the end of shelf life? | YES: | NO: |
| - If Yes, have these been assessed to ensure: | | |
| - The minimum overage required is used? | YES: | NO: |
| - The total input amount of ingredient does not exceed any recognized / legally defined upper safe levels? | YES: | NO: |
| 188. Are the appropriate tests undertaken to assess product stability under anticipated environmental storage conditions? | YES: | NO: |
| 189. Is microbiological testing carried out on: | | |
| - Products that have a high moisture content? | YES: | NO: |
| - Where it is known that raw materials may carry a high microbial load? | YES: | NO: |
| - If Yes to the above, does this include 'in use' testing? | YES: | NO: |
| 190. Are the following undertaken: | | |
| - Organoleptic assessments? | YES: | NO: |
| - Physical tests appropriate to the formulation composition and form? | YES: | NO: |
| - Chemical tests appropriate to the formulation composition and form? | YES: | NO: |
| **SECTION K: DOCUMENTATION** | | |
| 191. Is there a written procedure covering the complete documentation system? | YES: | NO: |
| - If Yes, does this include procedures for the: | | |
| - Issue of documents? | YES: | NO: |
| - Authorization of documents? | YES: | NO: |
| - Distribution of documents? | YES: | NO: |
| - Periodic review of documents? | YES: | NO: |
| - Revision of documents? | YES: | NO: |
| 192. Are relevant personnel given appropriate training on how to complete the documents? | YES: | NO: |
| - If Yes, is this training regularly reviewed? | YES: | NO: |
| 193. Are there safeguards in place to restrict the entering of data to authorized persons only? | YES: | NO: |
| 194. Are any amendments to documentation clearly corrected and authorized? | YES: | NO: |
| 195. Are superseded documents removed from active use and a copy retained, clearly marked as superseded? | YES: | NO: |

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| 196. Has a manual been prepared that describes the overall Quality Assurance system, the procedures employed, and the documents used? | YES: | NO: |
| - If Yes, is this manual: | | |
| - Fully integrated with the HACCP documentation? | YES: | NO: |
| - Accessible to all relevant personnel? | YES: | NO: |
| **Electronic documentation** | | |
| 197. Are there safeguards in place to ensure that: | | |
| - Data is entered correctly? | YES: | NO: |
| - Sufficient back-ups are made and retained? | YES: | NO: |
| - Unauthorized access is prevented? | YES: | NO: |
| 198. Are there procedures in place outlining the action to be taken in the event of system failure or breakdown? | YES: | NO: |
| 199. How often are all safeguards, backup systems, and procedures checked and updated? | | |
| **Retention of documents** | | |
| 200. In general, for how long are records retained? | | |
| 201. Has it been confirmed that this complies with any legal requirements? | YES: | NO: |
| 202. Are lot (batch) records retained for the shelf life of the product, plus one year? | YES: | NO: |
| 203. Is personnel data retained in accordance with national laws on such data? | YES: | NO: |
| 204. Is a Controlled Records List utilized? | YES: | NO: |
| 205. Are there safeguards in place to protect all documentation (both electronic and paper copy) in the event of a fire? | YES: | NO: |
| **SECTION L: COMPLAINTS PROCEDURE, PRODUCT RECALL, AND EMERGENCY PROCEDURE** | | |
| **Complaints** | | |
| 206. Are there procedures in place for handling product-related complaints? | YES: | NO: |
| 207. Are personnel appropriately trained to ensure that all complaints are recognized, communicated, and recorded? | YES: | NO: |
| 208. Are complaints, when received, assessed, and separated into those with no potential health impact and those that may have a health impact? | YES: | NO: |
| 209. Is the Quality Control Manager kept fully informed and closely consulted on all complaints relating solely to manufacturing issues? | YES: | NO: |
| 210. Is there a procedure in place for handling complaints specifically related to adverse events? | YES: | NO: |
| - If Yes, is there a designated person who is responsible for implementing and monitoring this procedure? | YES: | NO: |
| 211. Is complaint analysis carried out at periodic intervals? | | |
| - If Yes, at what frequency? | YES: | NO: |
| | YES: | NO: |

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| 212. Are summaries of complaints and / or trends sent to key senior personnel? | YES: | NO: |
| **Product withdrawal and recall** | | |
| 213. Are there procedures in place for: | | |
| - product withdrawal? | YES: | NO: |
| - product recall? | YES: | NO: |
| 214. Is there a nominated, responsible person and nominated deputies to coordinate recall activities? | YES: | NO: |
| 215. Has a crisis management team been established? | YES: | NO: |
| 216. Has the withdrawal/recall system been tested? | YES: | NO: |
| 217. Are there procedures in place regarding the proper treatment of withdrawn or recalled material or product? | YES: | NO: |
| **Emergency procedure** | | |
| 218. Are there procedures in place for responding to emergencies? | YES: | NO: |
| **SECTION M: SELF-INSPECTIONS** | | |
| 219. Is there a prearranged program for self-inspections of all systems? | YES: | NO: |
| - If Yes, how frequently are these conducted: | | |
| 220. Are records made of all: | | |
| - Observations? | YES: | NO: |
| - Corrective measures? | YES: | NO: |
| - The subsequent action taken? | YES: | NO: |
| 221. Are the self-inspections periodically reviewed by senior management? | YES: | NO: |
| **SECTION N: SUB-CONTRACTING OPERATIONS** | | |
| 222. Is your company a Contract Giver? | YES: | NO: |
| - If Yes: | | |
| - Is there a program for auditing the key suppliers i.e. those who supply 'risk' materials? | YES: | NO: |
| - Are all suppliers assessed by means of: | | |
| - A site audit? | YES: | NO: |
| - A self-assessment form? | YES: | NO: |
| - Are detailed product specifications agreed with every supplier? | YES: | NO: |
| - Are any special quality control/GMP requirements agreed with every supplier? | YES: | NO: |
| - Is there a technical agreement in place with every supplier? | YES: | NO: |
| 223. Is your company a Contract Acceptor? | YES: | NO: |
| - If Yes: | | |
| - Are detailed product specifications agreed with every customer? | YES: | NO: |
| - Are any special quality control / GMP requirements agreed with every customer? | YES: | NO: |
| - Is there a technical agreement in place with every customer? | YES: | NO: |
| **SECTION O: LABORATORY TESTING** | | |

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| 224.Is there an in-house company laboratory? | YES: | NO: |
| - If Yes, is the laboratory accredited? | YES: | NO: |
| - If Yes, please specify: | | |
| 225.Is all laboratory equipment and instrumentation regularly serviced and calibrated? | YES: | NO: |
| - If Yes, are appropriate records maintained? | YES: | NO: |
| 226.Are there written operating procedures for each piece of equipment / instrument? | YES: | NO: |
| 227.Is there adequate storage space for storage of samples at the appropriate temperature? | YES: | NO: |
| 228.Does your company use a contract laboratory? | YES: | NO: |
| - If Yes, is the laboratory accredited? | YES: | NO: |
| 229.Does the laboratory use appropriate analytical methods?: | | |
| - In-house laboratory | | |
| - Contract laboratory | | |
| Is the performance of the laboratory monitored and analyzed?: | | |
| - In-house laboratory | YES: | NO: |
| - Contract laboratory | YES: | NO: |
| **SECTION P: DECLARATION** | | |
| To the best of my knowledge and belief, the details given above are correct. | | |
| Signed | | |
| Date | | |
| Name | | |
| Position within company | | |
| **THE END!** | | |