



**World Health  
Organization**

# **WHOLESALE DISTRIBUTOR INFORMATION QUESTIONNAIRE**

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September 2017

*Wholesale distributor questionnaire (version #1 – Sept. 2017)*

## 1. General information on the company

Company Name	
Postal address	
Physical address (*)	
Trade register number	
VAT number	
Date of establishment	
Telephone	
Fax number	
Web site URL	
Contact email address	

(\*) If the premises are not all located at the same physical address, mention it clearly in the table (one row per address; add as many rows as needed).

## 2. Regulatory status and certification(s)

### 2.1 License

2.1.1. Is your company licensed by the relevant regulatory authority?

☐ Yes ☐ No

Please attach a copy of the license

Please indicate the date of the last audit or technical visit of the national authority: (dd/mo/yyyy)

### 2.2 Good Distribution Practice (GDP)

2.2.1 Are the company and its premises regularly assessed against Good Distribution Practice guidelines?

☐ Yes ☐ No

2.2.2 If "Yes", please specify the name of the authority that carried out the GDP inspections and the international reference standards (national GDP, EU GDP, WHO GDP, USP GDP, etc.)

Authority: ..... Referential: .....

Please attach a valid copy of the GDP certificate to the questionnaire

## 2.3 ISO certification

2.3.1 Is your company ISO certified?

☐ Yes      ☐ No

2.3.2 If “Yes”, please attach copy(ies) of the valid ISO certificate(s) to the questionnaire

## 2.4 Other Certifications

2.4.1 Is your company “approved” as wholesaler distributor by an international organization (please tick the boxes)?

- ☐ UNICEF Supply Division
- ☐ UNFPA
- ☐ GDF
- ☐ INTERNATIONAL COMMITTEE OF THE RED CROSS (ICRC)
- ☐ DG ECHO
- ☐ USAID
- ☐ OFDA
- ☐ The Global Fund
- ☐ Medecins Sans Frontieres (MSF)
- ☐ Others (please specify) .....
- .....
- .....

2.4.2. Please attach a copy of the letter of approval issued by the organization(s) mentioned above.  
If you are not able to provide such a letter of approval please explain why:

.....  
.....  
.....

2.4.3 If requested, would you accept to provide WHO with a copy of the audit or technical report performed by the organization(s) mentioned above?

☐ Yes      ☐ No

## 3. Range of products

3.1. What type of products does your company supply to your customers?

- ☐ Multi source essential medicines
- ☐ Medical kits
- ☐ Innovator medicines (branded)
- ☐ Medical devices
- ☐ Chemical reagents
- ☐ Medical Equipment (X-ray, autoclaves, sonographer, etc.)
- ☐ Other products (please specify) .....

## 4. (Pre)qualification

### 4.1 Pharmaceutical products

On what basis does your company (pre)qualify its sources of pharmaceutical products?

- **GMP assessment of the manufacturing site**

4.1.1. Do you assess the manufacturing site with your own team of inspectors ? ☐ Yes ☐ No

4.1.2 Do you appoint external experts to perform the GMP audits? ☐ Yes ☐ No

4.1.3 Do you recognize the GMP approvals of third parties? ☐ Yes ☐ No

4.1.4 If "Yes", please specify which GMP approvals you recognize (tick the boxes below)

☐ WHO PQ

☐ PIC/S

☐ US FDA

☐ UNICEF

☐ ICRC

☐ others (please specify).....

- **Assessment of the pharmaceutical product dossier**

4.1.5 Do you have your own product questionnaire ? ☐ Yes ☐ No

If "Yes", please attach a copy

4.1.6 Do you use the Interagency Finished pharmaceutical product questionnaire<sup>1</sup>? ☐ Yes ☐ No

4.1.6 Do you recognize the technical approvals of other agencies? ☐ Yes ☐ No

If "Yes", please specify which approvals you recognize (tick the boxes below)

☐ Pre-qualification by the WHO

☐ US FDA tentative approvals

☐ Approvals by Stringent Regulatory Authorities (SRA)

please specify your definition of SRA

.....  
 .....

<sup>1</sup> Model Quality Assurance System for Procurement Agencies. WHO Technical Report Series, No. 986, 2014, Annex 3  
<http://apps.who.int/medicinedocs/documents/s21492en/s21492en.pdf>

☐ Other agencies

If "Yes", please mention below the names of the agencies that you recognize

.....  
 .....

4.1.7 Do you maintain a list of (pre)qualified manufacturers of pharmaceutical products? ☐ Yes ☐ No

If "Yes", would you accept to provide WHO with a copy of the current list?

4.1.8 Do you maintain a list of (pre)qualified pharmaceutical products? ☐ Yes ☐ No

If "Yes", would you accept to provide WHO with a copy of the current list?

4.1.9 If so requested, would you accept to share your GMP audit reports and your product dossiers with WHO?

☐ Yes ☐ No

## 4.2 Medical devices

4.2.1 On which basis do you (pre)qualify your sources of medical devices?

• **Assessment of the manufacturing site** ☐ Yes ☐ No

Do you assess the manufacturing site with your own team of inspectors? ☐ Yes ☐ No

Do you appoint external experts to perform the audits? ☐ Yes ☐ No

• **ISO certification of the manufacturing site** ☐ Yes ☐ No

If "Yes", please clarify your requirements in terms of ISO certification (norms, certification body, etc.)

.....  
 .....  
 .....

• **CE marking** ☐ Yes ☐ No

If "Yes", please clarify your requirements in terms of CE marking (norms, notification body, etc.)

.....  
 .....  
 .....

• **Other "stringent" authorizations** ☐ Yes ☐ No

If "Yes", please clarify your requirements (name of the authorities you recognize, norms, proof of approvals, copy of certificates, etc.)

.....  
 .....  
 .....

4.2.2 Do you maintain a list of (pre)qualified manufacturers of medical devices? ☐ **Yes** ☐ **No**

If "Yes", would you accept to provide WHO with a copy of the current list? ☐ **Yes** ☐ **No**

## 5. Quality control and monitoring

5.1 How do you control the quality of your (pre)qualified sources of pharmaceutical products?

5.1.1. Pre-shipment QC testing ☐ **Yes** ☐ **No**

If "Yes",

☐ Systematic control (100%)

☐ Randomly (spot check)

If randomly, please explain your sampling procedure

.....

.....

.....

Please clarify your requirements and selection procedures of the QC laboratory for the testing

.....

.....

.....

5.1.2. At reception ☐ **Yes** ☐ **No**

If "Yes",

☐ Systematic control (100%)

☐ Randomly (spot check)

If randomly, please explain your sampling procedure

.....

.....

.....

Do you have your own (internal) QC laboratory for the testing ☐ **Yes** ☐ **No**

.....

.....

.....

If "no" please clarify your requirements and selection procedures of the QC laboratory for the testing

.....

.....

.....

5.4 How often do you re-assess the manufacturing sites for pharmaceutical products?

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 .....

5.5 How often do you re-assess your (pre)qualified pharmaceutical products?

.....  
 .....

5.6 How often do you re-assess the manufacturing sites for medical devices?

.....  
 .....

## 6. Registration

Many countries require the registration of the pharmaceutical products by their regulatory authority before authorizing the importation of the products.

6.1 Are you able to collect all the necessary technical information from the manufacturers and submit it to the Regulatory Authority of the country of destination?

☐ Yes ☐ No

6.1 Are you able to obtain a Certificate of Pharmaceutical Product (CoPP - WHO type) from the NRA (National Regulatory Authority) of the country of manufacture for each pharmaceutical product supplied to WHO?

☐ Yes ☐ No

If "yes", please attach an example of recent CoPP

## 7. Contact details for responsible persons

Responsibility	contact detail	Telephone and mobilephone	E-mail
Quality Assurance		Tel: Cell:	
Regulatory Affairs		Tel: Cell:	
Commercial/business and general inquiries		Tel: Cell:	
Logistic and supply chain		Tel: Cell:	

## 8. Personnel

8.1 Total number of employees: .....

8.2 Total number of pharmacists: .....

8.3 Number of employees in QA department: .....

## 9. Financial Turnover

9.1 Turnover in US \$                      Latest fiscal year                      .....

Latest fiscal year – 1                      .....

Latest fiscal year – 2                      .....

## 10. Other documents

Please attach the following documents to the questionnaire:

1. Company brochure
2. Site Master File
3. Organization Chart

## 11. WHO audit

The verification of the compliance with WHO GDP and the WHO MQAS is part of WHO Quality Assurance Policy for Procurement of Pharmaceutical Products.

Regardless of the authorization by the national regulatory authority or by any other body, WHO can commission an independent expert to conduct an audit of the premises.

11.1 The company agree in principle and commits to facilitate the access of the experts to the premises.

☐ **Yes**

☐ **No**



## 12. Commitment

I hereby certify that the information given in this questionnaire and the attachments is true and correct.

**Date** .....

**Signature** .....

**Name and Position** .....