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## Guidance Notes

### Introduction

#### Prequalification of suppliers

The Organisation of Eastern Caribbean States/Pharmaceutical Procurement Service (OECS/PPS) has revised its prequalification procedures to ensure that prequalified suppliers offer medical products that conform to World Health Organisation (WHO) standards. In particular, products must meet WHO Good Manufacturing Practice (GMP), Good Storage Practice (GSP), and Good Distribution Practice (GDP).

OECS/PPS will invite only tenderers that are prequalified and are listed in OECS/PPS suppliers' directory. In addition, OECS/PPS will implement the following policies:

- OECS/PPS reserves for itself or its designated agents to evaluate suppliers' premises to verify compliance with good practices and confirm information in the prequalification application
- OECS/PPS reserves the right to amend its prequalification procedure periodically and notify all suppliers before inviting bids.
- Prequalified suppliers that have not participated in two consecutive tenders will be deleted from OECS/PPS directory.
- Distributors/wholesalers are required to fill **Section 1** and must request each new manufacturer to complete **Section 2**, along with letters of authorisation. New manufacturers are those which have not yet been registered with PPS.

Documentation must be original and submitted in the prescribed format in English to the following address:

Organisation of Eastern Caribbean States  
Pharmaceutical Procurement Service  
P.O. Box 3093, La Clery  
Castries LC03 201  
Saint Lucia

Tele: 1-758-4525895/4556361  
Fax: 1-758-4530227  
Email: [pps@oeecs.int](mailto:pps@oeecs.int)

**Organisation of Eastern Caribbean States  
Pharmaceutical Procurement Service**

**Prequalification Form for Distributor/Wholesaler**

**Section 1**

Description	Response
<b>A. Profile</b>	
1. Supplier name:	
Year established:	
Form of company:	Individual <input type="checkbox"/> Partnership <input type="checkbox"/> Other <input type="checkbox"/> Specify _____
Business license number:	_____ Attach copy of license
Wholesaler licence number:	_____ Attach copy of license
2. Address:	
Telephone:	
Facsimile:	
Email:	
Website:	
3a. State the following in square metres as it relates to medical products.	Office space _____ sq. m Provide evidence, e.g., pictures, floor plan
3b. Do you manage and operate a warehouse for medical products?	Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, state the area in square metres. _____ M2. Attach pictures or floor plan.

B. Human Resource Management																	
Description	Response																
1. What policies do you have regarding human resource management?	<p>Manual <input type="checkbox"/></p> <p>SOP <input type="checkbox"/></p> <p>Policy <input type="checkbox"/></p>																
2. Describe your organizational structure regarding all staff involved in medical products supply chain management.	Attach organogram																
3. List your staff complement, e.g., position, training, qualifications, staff involved in medical products supply management.	<table border="1"> <thead> <tr> <th>Name</th> <th>Position</th> <th>Qualification</th> <th>Experience</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>Attach if necessary</p>	Name	Position	Qualification	Experience												
Name	Position	Qualification	Experience														
4. List the names and contact for two persons responsible for tendering and contracting.	<p>Name: _____</p> <p>Title: _____</p> <p>Tele: _____</p> <p>Email: _____</p> <p>Name: _____</p> <p>Title: _____</p> <p>Tele: _____</p> <p>Email: _____</p>																
5. Do you have a Code of Ethics?	<p>- Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Attach if applicable</p>																

Description		Response								
<b>C.</b>	<b>Financial System</b>									
1.	Which accounting standards are used to prepare financial statements?	<input type="checkbox"/> GAAP <input type="checkbox"/> IFRS <input type="checkbox"/> Other                      State _____								
2.	Is the company audited annually by a certified accounting firm?	Yes <input type="checkbox"/> No <input type="checkbox"/>  State the name of the accounting firm _____								
3.	Has the company ever received a “qualified audit opinion”?	Yes <input type="checkbox"/> No <input type="checkbox"/>  If yes, Explain:								
4.	Is there an internal audit function at your Company?	Yes <input type="checkbox"/> No <input type="checkbox"/>  If yes, to whom does the function report to? _____ _____ _____ _____								
5.	State sales turnover for medical products in the previous three years.	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Year</th> <th>Annual sales US\$</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </tbody> </table>	Year	Annual sales US\$						
Year	Annual sales US\$									

Description		Response												
<b>D.</b>	<b>Quality and prequalification</b>													
1.	Do you have a Quality Manual?	Yes <input type="checkbox"/> No <input type="checkbox"/>  If yes, please attach												
2.	Explain your quality assurance procedures for prequalifying manufacturers. For e.g., core values, screening tool, standards.	Description												
3.	Do you have Standard Operating Procedures (SOPs)?	<table style="width: 100%; border: none;"> <tr> <td style="width: 70%;"></td> <td style="text-align: center;">Yes</td> <td style="text-align: center;">No</td> </tr> <tr> <td>Storage</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Distribution</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>		Yes	No	Storage	<input type="checkbox"/>	<input type="checkbox"/>	Distribution	<input type="checkbox"/>	<input type="checkbox"/>			
	Yes	No												
Storage	<input type="checkbox"/>	<input type="checkbox"/>												
Distribution	<input type="checkbox"/>	<input type="checkbox"/>												
4.	List your prequalified manufacturers and attach the letter of authorization for each manufacturer.	<p><i>List of manufacturers</i></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 40%;">Name of manufacturer</th> <th style="width: 15%;">City</th> <th style="width: 20%;">Country</th> <th style="width: 25%;">National Regulatory Authority</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>Attach authorisation letter for each manufacturer</p> <p>Please request each new manufacturer to complete <b>Section 2</b> on the form.</p>	Name of manufacturer	City	Country	National Regulatory Authority								
Name of manufacturer	City	Country	National Regulatory Authority											
5.	Which products do you supply?	Attach list of products, e.g., catalogue												

Description		Response												
<b>Quality and prequalification cont'd</b>														
6.	Do you provide Certificates Of Analysis (COA) with each batch of medicine?	Yes <input type="checkbox"/> No <input type="checkbox"/>  Attach a sample of COA												
7.	Do you randomly test medicines at independent accredited quality control laboratories?	Yes <input type="checkbox"/> No <input type="checkbox"/>  List the name(s) and address(es) of the independent quality control laboratory. <table border="1" data-bbox="625 835 1365 1010"> <thead> <tr> <th>Name of Lab.</th> <th>City</th> <th>Country</th> <th>Accreditation body</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Name of Lab.	City	Country	Accreditation body								
Name of Lab.	City	Country	Accreditation body											
8.	Do you provide Certificates of Pharmaceutical Products (CPP) in WHO format?  (Optional)	Yes <input type="checkbox"/> No <input type="checkbox"/>  Attach a sample of a CPP												

Description	Response
<b>E. Monitoring and evaluating</b>	
<p>1. <i>Re-evaluation</i></p> <ul style="list-style-type: none"> <li>○ How do you monitor and evaluate the performance of manufacturers/ suppliers? For e.g., reliability, packaging, cold chain</li> </ul> <hr/> <ul style="list-style-type: none"> <li>○ What is the mechanism for suspending and withdrawing manufacturers?</li> </ul>	



Description	Response
<b>F.</b>	<b>Customer reference</b>
1.	<p>List two regional or international customers.</p> <p><input type="checkbox"/> Private sector      <input type="checkbox"/> Public sector</p> <p><b>Company 1:</b> _____</p> <p>Contact person: _____</p> <p>Address: _____</p> <p>_____</p> <p>_____</p> <p>Phone: _____</p> <p>Fax: _____</p> <p>Email: _____</p> <p>Website: _____</p> <p>=====</p> <p><input type="checkbox"/> Private sector      <input type="checkbox"/> Public sector</p> <p><b>Company 2:</b> _____</p> <p>Contact person: _____</p> <p>Address: _____</p> <p>_____</p> <p>_____</p> <p>Phone: _____</p> <p>Fax: _____</p> <p>Email: _____</p> <p>Website: _____</p>

## Certification

I, the undersigned, hereby declare that all the information given above is true, and I take full responsibility for all consequences that might arise from false or erroneous information. I will cooperate with any official of the OECS Ministries of Health in the Organisation of the Eastern Caribbean States and agents in performing personal inspection of my Company.

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Company stamp or seal

Email: \_\_\_\_\_

Tele: \_\_\_\_\_

## Section 2


### Prequalification form for Manufacturers

Description	Response																		
<b>A.</b>	<b>Profile</b>																		
1.	Manufacturer name:																		
	Year established:																		
	Form of company:	Individual <input type="checkbox"/>	Partnership <input type="checkbox"/>	Other <input type="checkbox"/> State _____															
	Business license	Business license number _____ Attach copy of license																	
2.	Address:																		
	Telephone:																		
	Facsimile:																		
	Email:																		
	Website:																		
<b>B.</b>	<b>Manufacturing, Regulatory and Quality information</b>																		
1.	Which products do you manufacture?	Attach list of products or product catalogue.																	
2.	Are all manufacturing operations (processing, packaging and labeling) carried out on site?	Yes <input type="checkbox"/> No <input type="checkbox"/>  If "No" list companies who perform any of the manufacturing processes of the products you provide.																	
		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 25%;">Company</th> <th style="width: 25%;">Address</th> <th style="width: 25%;">Product(s)</th> <th style="width: 25%;">Comments, e.g., type of operation</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>		Company	Address	Product(s)	Comments, e.g., type of operation												
Company	Address	Product(s)	Comments, e.g., type of operation																

Description	Response																		
<b>Manufacturing, Regulatory and Quality information cont'd</b>																			
3. Does your company possess any of the following certifications?	GMP certification <input type="checkbox"/> ISO certification <input type="checkbox"/> Other (Specify) <input type="checkbox"/>  Attach certificate of GMP or ISO certification																		
4. Have other Governments, Organisations or agency accredited your company?	Yes <input type="checkbox"/> No <input type="checkbox"/>  If "yes", fill in the information below. <table border="1" data-bbox="527 751 1305 1014"> <thead> <tr> <th>Agency</th> <th>Year</th> <th>outcome</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table> Attach document(s) stating outcome.	Agency	Year	outcome															
Agency	Year	outcome																	
5. How often is your company audited or inspected?																			
6. Do you maintain your own quality control laboratory?	Yes <input type="checkbox"/> No <input type="checkbox"/>																		
7. List name(s) and address(es) of quality control laboratories used in addition to, or in lieu of your own laboratory.	List of independent, accredited quality control labs. <table border="1" data-bbox="527 1541 1268 1717"> <thead> <tr> <th>Name of Lab.</th> <th>City</th> <th>Country</th> <th>Accreditation body</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>	Name of Lab.	City	Country	Accreditation body														
Name of Lab.	City	Country	Accreditation body																

Description		Response										
<b>Manufacturing, Regulatory and Quality information cont'd</b>												
8.	<p>Provide a brief description on the process and procedure regarding quality at your company.</p> <p>State quality control manager.</p>	<p>Name: _____</p> <p>Title: _____</p> <p>Tele: _____</p> <p>Email: _____</p>										
9.	<p>Are manufactured products registered and marketed locally?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If "No" state reason.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Product</th> <th style="width: 50%;">Reason</th> </tr> </thead> <tbody> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </tbody> </table>	Product	Reason								
Product	Reason											

Description		Response
<b>C.</b>	<b>Customer reference</b>	
1.	List two international businesses.	<input type="checkbox"/> Private importer <input type="checkbox"/> Public importer  <b>Company 1:</b> _____ Contact person: _____ Address: _____ _____ _____ Phone: _____ Fax: _____ Email: _____ Website: _____ <hr/> <input type="checkbox"/> Private importer <input type="checkbox"/> Public importer  <b>Company 2:</b> _____ Contact person: _____ Address: _____ _____ _____ Phone: _____ Fax: _____ Email: _____ Website: _____


End
