UNFPA Public Assessment Reports for Contraceptive Devices - Condoms and IUDS

Background

UNFPA Public Assessment Reports (UNFPA PARs) are key, publicly available documents detailing the procedures used to prequalify manufacturers as suppliers of contraceptive devices, which include male and female condoms and copper bearing IUDs, to UNFPA and other procurement agencies. The reports document the reviews, inspections, prequalification product testing and all other activities undertaken when manufacturers of contraceptive devices are prequalified by UNFPA.

The UNFPA PARs are intended to provide insight and transparency about the processes followed in the prequalification of any product provider. The WHO/UNFPA Prequalification programme harmonises its activities with those of the WHO Prequalification process, and thus the UNFPA PARs follow the same philosophy and structure as WHO PARs prepared for the suppliers of essential medicines. The PAR will describe the steps undertaken by the UNFPA prequalification team to ensure that all manufacturers supplying contraceptive devices under the UNFPA prequalification scheme meet stringent quality standards to ensure that the products they supply are of acceptable quality, are safe and effective, and provide value for money.

Parts of a UNFPA PAR

The structure and format of UNFPA PARs are based on WHO PARs but are modified to take into account the different nature of contraceptive devices and the different regulatory procedures and standards that apply to these products.

A UNFPA PAR consists of the following eight parts:

Part 1: Abstract
Part 2a: All accepted presentations of the product or product types
Part 2b: Appearance of product (i.e. photographs of examples)
Part 3: User information instructions
Part 4: Information for purchasers, procurement agencies, distributors and healthcare professionals
Part 5: Labelling
Part 6: Scientific discussion
Part 7: Prequalification Process
Part 8: Post-Prequalification

Steps in developing a UNFPA PAR

Following the prequalification of a manufacturer or the following steps are undertaken:

Step 1: The manufacturer submits documents required for the PAR as part of the initial submission for evaluation for prequalification to UNFPA.
Step 2: UNFPA compiles the draft PAR when the prequalification assessment and inspections have been completed.

Step 3: UNFPA forwards the draft PAR to the manufacturer for review. (Documents are exchanged in electronic format by the applicant and UNFPA, generally by email.)

Step 4: The manufacturer reviews and comments on (annotates) the draft PAR, in particular to ensure that the PAR does not contain any proprietary or confidential information.

Step 5: The manufacturer returns the annotated draft PAR to UNFPA.

Step 6: UNFPA reviews the annotated text — Steps 3 to 6 may need to be repeated if an item requires further clarification — and finalizes the PAR.

Step 7: If the manufacturer meets the prequalification requirements, UNFPA accepts the manufacturer for inclusion in the WHO/UNFPA List of Prequalified Manufacturers (i.e. prequalifies it), publishes the PAR and informs the manufacturer accordingly.

Step 8: Within three months after acceptance/publication of the PAR, the manufacturer provides a mock-up of the final user information leaflet for purchasers, procurement agencies, distributors and healthcare professionals.

Guidance relating to development of contents of UNFPA PAR

Part 1: The Abstract should be short, summarising briefly the manufacturer’s details, the products manufactured and date of prequalification. Any restrictions on the prequalified products supplied should be listed.

Part 2a: This is basically a list of the different products manufactured that are covered by prequalification. Details for inclusion in the list include, for example with male condoms, colour, size, shape, flavour, scent, and texture variations that are produced by the manufacturer and are covered in their scope of prequalification. If appropriate, any intended target market or population differences for the products should be included, for example, smaller condoms intended primarily for adolescents.

Part 2b: This is essentially a set of photographs of the products included in the prequalification - to be considered for female condoms and IUDs

Part 3: User information for contraceptive devices will generally follow the requirements specified in the relevant WHO/UNFPA specification and associated International Standards. Any information or instructions that are specific to the products being supplied must be detailed.

Part 4: This shall include a general description of the purpose of the product along with any limitations relating to the use of the product, including approved shelf life. Information about any specific target group(s) for the product along with a summary of the evidence supporting the use of the product by the specified target group(s) should be included.

Part 5: Labelling will generally follow the requirements given in the relevant WHO/UNFPA specification and associated International Standards. Any changes to the specified labelling must be detailed and explained.
Part 6: The scientific discussion should explain the scientific rationale behind any special uses, labelling or requirements for the product. For generic products such as male latex condoms the scientific discussion can be limited to a simple statement that the product is intended to be used to prevent pregnancy and the transmission of sexually transmitted infections. Any claims relating to improved protection, improved user acceptance or compliance, or any other unique feature of the product must be supported by clinical evidence, some of which may be based on published information. This section should also include the justification of shelf-life and storage conditions i.e. the summary of stability studies.

Part 7: The general prequalification process should be described briefly and objectively. This for the most part can be achieved by the use of tables giving the dates for key elements of the prequalification process, such as the submission of the original product dossier and other requested information, completion of the technical review of the product dossier and submitted information, dates of inspection, dates of any follow up communications between the UNFPA and the manufacturer, the dates of sampling and testing of the prequalification product samples, the dates of any reports, and the date of prequalification approval. It is not necessary to include details of any CAPAs raised and the responses to those CAPAs. Similarly, details of the manufacturing processes, materials used, equipment used, etc, should not be included in the PAR. The PAR must not contain any information that is regarded as proprietary to the manufacturer.

An example of a suitable Part 7 report is included in Annex A.

Part 8: This should list any changes made to the products or prequalification status of the manufacturer following prequalification, if applicable for example, if a specific product type is no longer manufactured this should be noted in Part 8.
Annex A: Example of a PAR Part 7 Report
UNFPA PAR: Part 7 February 2018

Manufacturer: Universal Latex Industries, Sao Paulo, Brazil
Product: OK Latex condoms

I Background Information on the Procedure

1. Submission of the dossier

The company, Universal Latex Industries, Sao Paulo, Brazil, submitted a product dossier in January 2017 for prequalification to supply OK Latex Condoms.

Manufacturer history of prequalification

<table>
<thead>
<tr>
<th>Date of prequalification</th>
<th>Products included in the scope of prequalification</th>
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A list of the condoms manufactured by the company and included in the scope of their prequalification is given in Part 2a of this report.

2. Regulatory Status

The condoms have regulatory clearance for marketing as follows:

ANVISA authorisation for marketing in Brazil (Certificate No 12345 dated 18 June 2015 valid until 17 June 2018)

USFDA 510(k) clearance for marketing in the US 510(k) Number K123454 dated 15 August 2016

CE Mark clearance for marketing in the EU (CE Certificate No CE 12345 issued by ABC Notified Body, dated 19 September 2016 valid until 18 September 2021).

3. Assessment of the manufacturer

<table>
<thead>
<tr>
<th>Month</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2017</td>
<td>The submitted information was screened for initial completeness, and subjected to a detailed technical review</td>
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<tr>
<td>March 2017</td>
<td>Additional information relating to raw material suppliers and details of the manufacturing operation was requested from the manufacturer.</td>
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<tr>
<td>April 2017</td>
<td>Following a satisfactory review of the additional information, a recommendation for scheduling a factory inspection was given.</td>
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<tr>
<td>Date</td>
<td>Description</td>
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<tr>
<td>June 2017</td>
<td>The factory inspection was undertaken. Three lots of selected products were randomly sampled during the inspection and submitted to an independent accredited laboratory for prequalification testing.</td>
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<tr>
<td>September 2017</td>
<td>An inspection report, including the analysis of the prequalification product testing results was issued. Additional information was requested from the manufacturer on a number of specific points relating to SOPs, testing procedures and quality data.</td>
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<tr>
<td>November 2017</td>
<td>The manufacturer’s responses were received for review.</td>
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<tr>
<td>October 2017</td>
<td>The submitted information was reviewed and a request for further clarification on a number of points was made.</td>
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<tr>
<td>November 2017</td>
<td>The manufacturer submitted the requested clarification/additional information.</td>
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<tr>
<td>December 2017</td>
<td>After reviewing the additional information, the manufacturer was recommended for prequalification.</td>
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<tr>
<td>January 2018</td>
<td>UNFPA prequalified the manufacturer and added them to the list of prequalified manufacturers for male latex condoms.</td>
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II General Conditions for the Prequalification

Manufacturer, Commitments and Inspection Status

Manufacturer

Universal Latex Industries
Industrial Trading Estate
Sao Paulo
Brazil

Commitments for Prequalification

None that has an impact on the benefit-risk profile of the contraceptive device.

Inspection status

The site inspected was certified to ISO 13485:2016 and ISO 14001:2015

Conditions or restrictions regarding supply and use

There are no restrictions regarding supply and use of the medical device.

Further information is available at:


https://www.unfpaprocurement.org/documents/10157/37547/UNFPA+Female+Condom+Prequalification+List/05feba45-4893-474a-81d4-7b61e4f68ae7