Female condom technical review committee report

Scientific and technical requirements to formulate a female condom generic specification and prequalification scheme

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Abbreviations

AQL	acceptable quality level
FC	female condom
LOD	limit of detection
MFV	maximum fill volume in cm^3
PD	Product dossier
PSA	Prostate specific antigen
RHR	Department of Reproductive Health and Research
SMF	Site Master Files
STI	sexually transmitted infection
UNFPA	United Nations Population Fund
WHO	World Health Organization

1. Background

There are several new female condom products in various stages of development, of which, some have entered the market. To date, however, only one product has been approved for bulk procurement for public sector programmes. Manufacturers of these new female condoms urgently need support and guidance to enable them to undertake the required research, quality assurance testing and clinical trials for country regulatory and bulk procurement approvals. In December 2010, the World Health Organization, Department of Reproductive Health and Research (RHR). The United Nations Population Fund (UNFPA) and FHI 360 convened a workshop for manufacturers, donors and international agencies to review and discuss the requirements and procedures to produce and procure quality-assured female condoms for the public sector and social marketing of female condoms. This included reviewing the issues that must be addressed to support the research, design, development, safety, efficacy, quality assurance, regulation, procurement and promotion of female condoms. The workshop was also intended to ensure that manufacturers have the information required to be able to make informed decisions regarding entering the female condom market.

As a result of this workshop a list of actions items was developed that reflected the dialogue and needs expressed during the four days of the workshop. All participants agreed that in order to expedite the prequalification process WHO/RHR should work with UNFPA:

- to reconvene the Female Condom Technical Review Committee and offer to undertake a technical review of female condom manufacturing Product Dossiers (PD) and Site Master Files (SMF) to determine which products, if any, could be recommended for bulk procurement by UNFPA;
- to undertake this process in collaboration with UNFPA as part of the prequalification process with each submission from a manufacturer being considered as a response to the Expression of Interest;
- to provide confidential reports to each manufacturer, who submitted site master files and product dossiers for review, regarding the outcome of the technical review process that detail precisely what action is needed, if any, the manufacturer to complete both the technical review process and the prequalification process;
- to continue the WHO/UNFPA technical review process through electronic communication until a final decision is made regarding whether or not a product can be prequalified.

2. Rationale to reconvene the WHO/UNFPA Female Condom Technical Review Committee

The WHO/UNFPA Female Condom Technical Review Committee was first convened 16–18 January 2006 to review the data on the safety, efficacy and performance of female condoms. The Committee's mandate was to review the evidence on female condom failure modes to correct and harmonize the multiple definitions, draft and publish the definitions for female condom failure modes. The Committee also formulated a review criteria and structured a process to review the design, clinical issues and technical issues, manufacturing process and quality assurance and testing processes for three female condoms submitted for review. This process resulted in the prequalification of one female condom – the FC2 produced by the Female Health Company.

It was agreed at the Bangkok meeting to reconvene the Committee to undertake the following:

- Convene technical experts to determine the scientific and technical requirements required to initiate the formulation of a female condom specification and prequalification scheme for bulk procurement.
- Convene the Female Condom Technical Review Committee to undertake a detailed analysis of manufacturing product dossiers and site master files in order to provide guidance to female condom manufacturers on how to fulfil the requirements for prequalification by UNFPA for bulk procurement.

3. Preparation for the scientific and technical review of female condoms

Female condoms have been available on both the public and private sector market since the early 1990s. The challenge for the public sector is the paucity of products at a price that makes bulk procurement and distribution in countries a viable option. In addition, for years there has been no international standard, although, one is under development by the International Organization for Standardization (ISO) Technical Committee for Non Systemic Contraceptives and Sexually Transmitted Infections. In January 2010 the final draft International Standard was circulated for review and approval by the ISO Committee.

To date, there is no procurement specification for the female condom. It was not possible to prepare one in advance, including but not limited to the designs and materials used to manufacture the female condom can differ significantly, there is no harmonized process for clinical evaluation of the female condom and because there was no consensus on an international standard. However, to establish a prequalification process for the female condom it is necessary to have a procurement specification. Therefore one of the key tasks of the technical experts during this meeting was to review the technical basis for the female condom to determine if it was feasible to establish a generic specification. The Committee was then tasked with drafting a generic specification that included the tests and testing procedures to support the procurement of a quality-assured product.

A technical basis paper, prepared in advance, provided an analysis of the issues that must be considered when establishing the general, safety, efficacy and performance criteria for the female condom, including materials and component parts. It also defines the parameters for clinical evaluation and the tests and testing procedures that must be used to be assured of the quality and integrity of the product and packaging. The technical basis paper will be updated as a result of the meeting and the conclusions and recommendations made by the experts.

In addition to the technical basis paper, the following documents were prepared as guidance for the manufacturers to enable submission of Product Dossiers and Manufacturing Site Master Files for review during a second meeting:

- WHO/UNFPA Scientific and technical requirements for the review of the female condom for bulk procurement;
- Female Condom: Requirement for the Product Dossier (PD) and Site Master File, Summary (SMF);
- Guidance document on how to undertake a clinical evaluation of the female condom.

Therefore, the purpose of this meeting was to review the technical basis for the female condom in order to develop a generic specification that included the general, performance, design and packaging requirements; the clinical evaluation of the product; the tests and testing methods by which they will be assessed; and, the definition of critical and non-critical visual defects.

In turn, the development of the generic specification will result in a review of the structure and content of the requirements for the Draft Product Dossier and Draft Site Master File requirements in order to harmonize with the generic specification, tests and testing methods. The revision of these materials will lead to establishing the criteria for the review of female condom product dossiers and site master files in order to determine whether or not they can be included in the prequalification scheme.

The team of experts supporting the WHO/UNFPA Female Condom Technical Committee are experienced in condom research, design, manufacture and testing, as well as public sector procurement and regulation. Refer to Annex 1 for list of participants.

4. Objectives

- To initiate the review of the technical basis for the female condom specification in order to determine the scientific and technical requirements.
- To review requirements for a female condom prequalification scheme and revise the draft Product Dossier, Site Master File and Prequalification Scheme.
- Review the criteria and guidance on how to undertake a clinical evaluation of female condom.
- To review the requirements to establish a prequalification scheme.
- To determine criteria for review of manufacturer submissions by the 11–14 April 2011 Female Condom Technical Review Committee.

5. Structure and format of the meeting

The agenda for the meeting was developed to provide ample time for participants to identify, review, debate and reach consensus on key issues raised regarding the technical basis paper and other background materials prepared for the meeting. The first day focused on identifying the issues and then the remainder of the meeting generated intense discussion around clarifying each issue and reaching consensus. For some topics, such as clinical evaluation and tests and testing requirements, the meeting participants divided into small groups in accordance with their expertise. Refer to Annex 2 for the meeting agenda.

6. Published female condom reports, scientific articles, and clinical studies

In addition to the core meeting documents, peer-reviewed articles and published studies were used as additional reference documents. In addition, the draft international standard, ISO/FDIS 25841.2 was used to ensure that any guidance document that was produced was based on this document.

7. Key issues discussed

7.1 Format and function of a female condom specification document

The Committee considered the feasibility of developing a specification for female condoms based on the general principles used in the development of the WHO/UNFPA Specification for male latex condoms. To assist in this task, a brief review of the definitions of a standard and specification was conducted in order to determine whether it was possible to develop a female condom specification within the parameters of its definition.

A **standard** is a set of generic requirements for a category of products that are generally performance based and are not design specific. A standard also specifies the test methods than shall be used to assess compliance of the product with the requirements of a standard or specification.

A **specification** defines requirements for a specific product. It may include additional requirements to those specified in a standard. It is not necessarily applicable to all types of products in a specific category. A specification can also reflect the purchaser's requirements for the product.

Given the wide variety of possible female condom designs it was agreed that it would not be possible to develop a single specification that could be used for public sector purchase. It was recognized, however, that could be a generic specification covering all female condom designs. Unlike the WHO/UNFPA Specification for male latex condoms, the generic specification for female condoms will not specify actual requirements for many of the design and performance parameters Instead it will define the properties that the manufacturers have to specify and the procedures for setting requirements for these properties.

The Committee agreed that three tiers of documentation are required to adequately specify a female condom for public sector distribution:

Tier 1 – Product specification set by manufacturer; this will include all the specific requirements for that product

Tier 2 – WHO/UNFPA Generic Specification; this specifies the parameters that have to be specified and the procedures to be used to set these parameters.

Tier 3 – Procuring body's specification outlining program and purchase specific needs (conformance/ design specification)

It was agreed to rename the current draft document *WHO/UNFPA Scientific and technical requirements for the review of the female condom for bulk procurement* to *WHO/UNFPA Female Condom Generic Specification.*

7.2 Key issues in development of a "Female condom generic specification"

A number of key issues relating to requirements for a generic specification were discussed. These included:

Equivalence

An important question when determining the type of clinical evaluation required for a female condom is the degree to which it is equivalent to a marketed, approved product that can be used as a control. The Committee agreed that there are three possible categories of equivalence:

1. The new product is virtually identical in design and materials of construction to an existing marketed and/or approved device. In such cases it may be possible to distribute the female condom without any further clinical evaluation.

2. The new product is similar in design and function to an existing marketed and/or approved device but cannot be considered virtually identical (for example different materials are used). In such cases the effectiveness of the female condom can be evaluated in a clinical functionality study.

3. The new product is so significantly different that a full clinical evaluation, such as a contraceptive efficacy study, is required.

Specific design characteristics required for products to be classified in the appropriate category will be included in the Generic Specification.

Clinical studies

The different types of clinical evaluations that could be conducted on female condoms were discussed in detail.

The current draft of the *WHO/UNFPA Female Condom Specification* indicates that, "for novel designs of female condoms that cannot be considered equivalent to an existing marketed product that has an established efficacy rate, a contraceptive efficacy rate is required". A contraceptive efficacy study determines the pregnancy rate associated with the product. To date, a contraceptive efficacy study has only been carried out on one female condom, the FC1. The programming benefit of having such data for products was recognized by the team. However, the vast resources required in carrying out such studies and the related potential inability for manufacturers to undertake the studies was also recognized. Therefore, based on this criterion, a contraceptive efficacy study would be required for some female condom designs in order to be accepted for bulk procurement.

The team discussed alternative to contraceptive efficacy studies. One suggestion posed was the use of Prostate Specific Antigen (PSA) studies. It was agreed that although PSA studies are promising, these are still costly to conduct and a number of issues, such as the establishment of threshold PSA within the vagina that indicates leakage, need to be resolved before the method can be adopted as an alternative to contraceptive efficacy studies. Another alternative is collecting pregnancy and STI (sexually transmitted

infection) data be gathered through a retrospective study. However, this would require a product to gain significant market acceptance before such studies can be carried out.

The other major issue regarding clinical studies that was discussed was their applicability if a significant change is made to the design of the product. If a significant change is made to the products following the clinical trial, the data from that trial is no longer relevant to the product. Therefore, it must be clearly communicated to manufacturers what is considered a significant change and the implication of a design change.

It was acknowledged that with the current state of knowledge, contraceptive efficacy studies remain important for the effective promotion of female condoms. WHO, UNFPA and partner organizations recognize the value of such studies in female condom market development and agreed to work towards securing funding to support them.

Failure modes

Standardized definitions of female condom failure modes were developed at the 2006 WHO Technical Review Committee meeting and were subsequently published. Updated failure modes were published in the 2010 article, *Female condom technology: new products and regulatory issues.*[1] Published failure modes were derived from known products on the market. New products can potentially introduce new failure modes. For example, designs that have external or internal retention features that could potentially detach from the sheath component during use introduce new types of failures modes that are not currently considered to be important. Therefore, failure modes must continue to be routinely updated to accommodate for changes in the market.

7.3 Amendments and additions to be made to draft WHO/UNFPA Scientific and technical requirements for the review of the female condom for bulk procurement

A complete summary of the changes to the generic specification agreed at the meeting can be found in Sections 9–13 of this report.

8. Conclusions, key recommendations, and future actions

- A WHO/UNFPA Female Condom Generic Specification will be drafted to reflect the decisions and recommendations made at the meeting.
- The product dossier and site master files requirements will be updated to reflect the conclusions of the meeting and subsequent updates to the document.
- Requirements for the inspection of the female condom manufacturing sites will be drafted to reflect the key issues identified by the Technical Review Committee.
- The draft WHO/UNFPA Female Condom Generic Specification will undergo a technical review through virtual and real time meetings with relevant stakeholders in preparation for publication.
- The WHO/UNFPA Female Condom Generic Specification will be first published electronically in order to accelerate the publication, reduce cost, and enable easer inclusion of amendments that are expected to be identified in the document's formative period.
- Revised criteria for technical review of the manufacturer product dossier and site master file submissions for the 11–15 April 2011 Female Condom Technical Review Committee meeting were developed to reflect changes agreed in the WHO/UNFPA Generic Specification for Female Condoms. It was determined that the following process would be carried out:
- First, a review of the decisions made during the 5-8 April 2011 Female Condom Technical Review Meeting will be conducted. Procedures and methods used to assess the 2011 submissions would be

1 Beksinska, M, Smit J, Joanis C, Usher-Patel M, Potter W. Female condom technology: new products and regulatory issues. *Contraception*, 2010, 83:316–321.

primarily based on the criteria used in 2006, but will be updated to take into account changes in ISO/FDIS 25841.2 and the draft WHO/UNFPA Generic Specification.

- Advisers will be split into two groups that represent the technical and clinical expertise to review the remaining submissions. Smaller submissions will be reviewed first.
- Once submissions have been review by the two groups, findings and recommendations for each submission will be discussed as a whole.

9. Observations and recommendations for the Female condom generic specification, Introduction

9.1 Clinical investigation

Contraceptive efficacy study

- For products that are deemed as being required to undergo a contraceptive efficacy study, a recommendation will be made for a 6 month study in accordance with other barrier contraceptive methods. Manufacturers may report a 12 month rate, in which case the method by which this is calculated must be indicated.
- Acceptance criteria for a contraceptive efficacy study must be agreed prior to commencement of the study.

Functionality study

The following criteria were accepted for a functionality study:

- Randomized controlled clinical investigation comparing the new female condom to a marketed female condom that has a known pregnancy rate established in a contraceptive efficacy study. If a marketed female condom with a known pregnancy rate is not available then a marketed female condom that has been proved to be non-inferior to a device with a known pregnancy rate can be used as the control.
- The total clinical failure rate of the new female condom shall be shown to be non-inferior to the total clinical failure rate of the marketed female condom.
- To demonstrate non-inferiority, the upper bound of the 95% confidence interval for the difference in total failure rate between the test and marketed female condoms (test condom rate minus marketed condom rate) shall be less than or equal to 3%.
- The upper and lower bound shall be calculated using a method that accounts for the unique characteristics of data such as: (1) each study participant may contribute data from more than one female condom use; and (2) possibly low coital act rates.
- The marketed female condom total clinical failure rates shall not be lower than 1%:
  - It must be made clear that the non-inferiority requirement applies to the total failure rate obtained by adding together the rates for all the individual failure modes.
  - A minimum total failure rate for the marketed condom is specified to ensure that an appropriate study population has been used. Some level of failure is expected for the marketed condom. An outcome with a rate below 1% could indicate problems with the study design or study population. A footnote will be included to explain why this is needed in the generic specification.
  - The choice of 3% for the non-inferiority margin is based on experience with studies of this type.

10. Observations and recommendations for WHO/UNFPA Scientific and technical requirements for the review of the female condom for bulk procurement

10.1 General requirements

The following observations and recommendations for the "General Requirements" were reached.

Barrier properties

- It was agreed that it will not be required to undertake viral barrier studies (Phi-X174 test) for condoms made of natural rubber latex by a dipping process having a minimum thickness of 55 microns.
- Condoms made from other materials or made from natural latex rubber but thinner than 55 microns will be subject to the barrier property test using the Phi-X174 phage or equivalent.
- For the barrier property test, the following outcomes would be considered acceptable:
  - The viral leakage rates for all condoms are less than the limit of detection (LOD), which should be as specified in annex H of ISO/FDIS 25841.2.
  - Not more than 20% of the tested condoms have a viral leakage rates that are higher than twice the LOD.
  - All results are less than twice the LOD.
  - If some of the results for individual condoms from the barrier property test are significantly higher than the LOD, it indicates that there may be issues with the specific condoms. If so, manufacturers will be asked to address possible condom integrity issues.

Shelf-life

- The methods for determining shelf-life and respective stability studies will be based on the methods described in ISO/FDIS 25841.2. However, for accelerated studies, as outlined in Annex L of ISO/FDIS 25841.2, a justification must be given for the method used to extrapolate the shelf-life claims.
- The current draft document states, "the claimed shelf-life shall be not less than three years and not more than five years". It was determined that the shelf-life claim can be extended up to seven years subject to suitable stability studies. The minimum shelf-life will remain at three years.
- If the condom or any key component is made from a moisture sensitive material, then the product should packed in aluminium foil. If the packaging is not a barrier to moisture, then the humidity during the real time stability study must be controlled at (75±5)% relative humidity. However, if the package is a barrier to moisture, there is no need to control the humidity during stability studies.
- There remains no special requirements for determining the shelf-life of retention and insertion features. It was recognized that ancillary components, such as sponges may have different deterioration properties than the condom's primary components. Therefore, it may be valuable to do further research on this.

10.2 Performance requirements

The following observations and recommendations were made for the various performance requirements.

Bursting volume and pressure

- Manufacturers may specify how the airburst test is undertaken, including the length of condom that is inflated, which should be at least 90% of the nominal length of the condom. However, WHO/UNFPA reserves the right to challenge the length specified by the manufacturer.

- The airflow rate for inflation should be (27 ± 3) dm^3/min. Manufactures may use an alternative suitable inflation rate in accordance with the product specification but the choice of a different inflation rate has to be fully justified.
- The current draft states that "manufacturers shall specify whether any insertion or retention features should be removed before the condom is tested". This will be amended to indicate that removable internal retention features and insertion devices shall be removed.
- It will be specified that the mandrel be a minimum of 25 mm in diameter and that a mandrel used for male condom testing is not suitable.
- It shall be indicated that the mandrel clamp should be used in a manner that does not cause the condom to crease when gripped. The clamp will be recommended to be a minimum of 50 mm in diameter.
- It will be recommended that the device is clamped by the film as close to the open end as possible. If necessary, the external retention feature may be detached carefully by cutting or using a different method that is most appropriate.
- Any condom found to be leaking shall be removed and replaced it with a fresh one. All condoms that are replaced need to be recorded.
- Manufacturers will be asked to provide the following information in the product specification for the inflation test.
  - Details of any preconditioning of the condoms prior to testing
  - Details of how the condom is clamped (Indicating if the film or external retention feature is clamped
  - Inflation length
  - The inflation length shall be specified by the manufacture and should be at least 90% of the nominal length of the condom.
  - Airflow rate
  - Specified temperature range for testing.
- For condoms made from natural latex the relative humidity does not need to be controlled.
- Products made from materials that are known to be moisture sensitive such as polyurethanes and synthetic rubbers need to be preconditioned by storing for 24 hours at (25 ± 5)°C and (55 ± 5)% relative humidity centigrade will be indicated.

Freedom from holes and visible defects

- The following decisions were agreed for the freedom from holes test:
  - An electrical conductivity test to determine freedom from holes will not be permitted.
  - If possible, testing should be conducted with the external retention feature remaining attached.
  - Non-visible holes that are within 10mm of the open end of the condom will not be considered non-conforming. The distance from the open end where non-visible holes are permitted has been decreased from that specified in the male latex condom WHO/UNFPA specification, because the female condom is intended to protect the female's outer genitalia.
  - If any hole or tear is noticed in the region within 10 mm of the open end then further testing of that condom shall be discontinued and the condom noted as being non-conforming.
  - A plug will be used for the rolling test.
  - A temporary support for the condom during filling will be permitted to prevent excessive stretching that could occur with some designs and materials.

- It was agreed that a maximum fill volume of water must be specified based on the design of the condom. Without a specified maximum fill volume, some known female condoms would continue to stretch and expand as the device is filled with water. Therefore, the generic specification will indicate that water should be added to the condom until it reaches its maximum fill volume. The maximum fill volume is to be determined by use of the following equation:

  $MFV = 1.75\ l\ w^2/1000\ \pi$

  In the equation l is the nominal length of the condom in mm, w is the average nominal width of the condom and MFV is the maximum fill volume in cm^3.

Package integrity

- There are many different types of packaging used for known female condoms on the market. Therefore, specifying a single test for package integrity is not possible. To accommodate the diversity of packaging, modifications to the specified test method will be permitted and alternative test methods may be specified.
- Justification and validation of the effectiveness of any alternative test method must be provided to demonstrate that package integrity is acceptable and lubricant does not leak from the package.

Internal and external retention features

- An additional section for the "Performance Requirements" table shall be added addressing internal retention features. The text will indicate that performance tests may be required for retention features in order to verify that the features perform in accordance with the manufacturer's specification.
- The decision to make this addition to the "Performance Requirements" was prompted by concern about certain features on product designs. Examples of such designs and tests that may be required are as follows:
  - Lubricant absorption tests for condom designs that have sponges serving as internal retention features (the sponge may absorb the lubricant reducing its effectiveness).
  - Recovery or memory test for sponges used as internal retention devices on some female condom designs (slow recovery after compression may reduce the effectiveness of the retention device in use).
  - If internal retention feature is connected to the condoms sheath, a test may be required to verify that the feature is not easily removed from the sheath.

10.3 Design requirements

The following recommendation and observations were made for the various "Design requirements".

Essential features

- All dimensions should be specified by the manufacturer (the dimensions will be unique to each condom design). Requirements for dimensions will primary reflect those in the ISO/FDIS 25841.2. It will be indicated that if necessary, the internal retention features and any insertion device may be removed when determining dimensions. For some condom designs, this will enable greater accuracy in achieving nominal measurements.
- It will be clearly indicated through the "Design Requirements" table that the design of the condom including any dimensions and retention/insertion features cannot be changed significantly following the clinical trial. The specification of the condom must be consistent with that in force at the time that the the clinical trial samples were made.

Colour, odour and flavour

- The design requirement for colour, odour, and flavour will reflect those in the WHO/UNFPA specification for male latex condoms.

- The WHO/UNFPA Generic Specification will provide the safety requirements for colour, odour and flavour to ensure that a change in one of the characteristics does not negatively affect the safety and performance of the condom.
- A footnote will be included that will state that price and specifications regarding these items should be decided between the purchaser and manufacturer at the purchase order stage.
- If a non-standard colour, odour, or flavour is requested the following must be provided by the manufacturer:
  - pigment type
  - indication that attribute is suitable for medical devices
  - safety data sheet.

Width

- The nominal widths of known female condom designs vary significantly. In addition, some known female condom designs are shaped in a manner so that the condom's width varies significantly at different points along the sheath. To accommodate for these factors, it will be specified that the measurement of the width of the female condom shall be taken to the nearest mm at three different points along the condom that represent 25%, 50%, 75% of the nominal length of the device from its open end.
- If necessary, the external retention features should be removed in order to obtain an accurate measurement at the point closest to the open end of the device.
- Any internal retention feature and insertion device shall be removed to facilitate measurement.

Length

- Remove any detachable internal retention features and, if applicable, insertion device and test according to ISO/FDIS 25841.2.
- Do not remove or adjust external retention feature.
- Measurement to be taken to the nearest millimetre.

Thickness

- Foot diameter that appears in ISO/FDIS 25841.2 will be deleted and only the foot pressure (22 ± 5) kPa, will be specified.
- It will be specified that lubricant may be removed by using an acceptable method of doing so, such as wiping.
- Measurements of thickness will be taken at the same locations as specified for the determinate of width. This will yield a total of nine measurements (three locations along the length of the condom and three measurements around the circumference of the condom at each of these locations).

Quantity of lubricant

- The amount of lubricant on or supplied with the condom shall be specified by manufacturer with a tolerance of ± 10 mg.
- For pre-lubricated condoms, a compatibility and safety statement for the condom and lubricant must be made. Due to the complexity and cost associated with testing lubricants, laboratories will not be required to nor encouraged to conduct the tests on a lot-by-lot basis.

Individual package materials and markings

- The package should not have any adverse affect on the condom during storage.
- The word distort shall be removed as it currently appears in this section.

- Comment on strips will be deleted.
- Comment on lamination will be deleted.
- Provisions will be included that will stipulate easy opening of packaging, such as a "nick".
- Strongly recommend that a statement relating to the safety and effectiveness of the condom be included.
- Manufacturers name can be added if required by the purchaser.
- A statement will be added stating that, "an obvious notch to open the package that does not affect the integrity of the package or ability to read the instructions".
- If the month and year of product being manufactured and the month and year of expiration is to be printed on the package, this is to be specified by the purchaser.

Additional features to be included under "Design Requirements"

External retention feature

- It will be required that the manufacturer provide an adequate specification for the external retention feature.
- For designs for which the external retention feature is classified as a "ring" the following is required:
  - Specify all dimensions (width, thickness, diameter).
  - Characterize stiffness of material used to make the external retention feature, for example by specifying the tensile modulus at 50% elongation.
- For designs whose external retention feature are not classified as "rings" such "flanges" design requirements to be specified by the manufacturer must be determined. Again these specifications should include a specification for stiffness such as a flexural modulus.

Insertion feature

- It will be required that any insertion device be safe and not damage the integrity of the sheath.
- Any testing done on the insertion device must be provided by the manufacturer.
- Additional design requirements may be required and determined at a later time.

11. Observations and recommendations for Female condom generic specification, Packaging for shipment

The following recommendation and observations were made for the various "Packaging for shipment".

Consumer packs

There were no requirements for the consumer packaging included in the initial draft of the specification document. The follow recommendations were made by the experts and advisers.

- It is recommended that the header for section 2.4 of the current draft be changed to read "Packaging requirements for shipment".
- The header, "Consumer packs" shall be changes to "Consumer packaging".
- Consumer packages should include information on the type of lubricant that can be used with the condom.
- Directions on the type of lubricant to be used that is compatible with the condom should be included.
- The individual primary package must include legible visual instructions.
- A footnote will state that the consumer pack is sometimes referred to as the "wallet pack".

- Any package containing a latex female condom, must provide warning regarding latex allergy risk.
- Only the expiration date of FC will appear on packaging. Too many dates printed on packages is associated with a risk of confusion by user. Distribution date will not be indicated on consumer packaging. Date of distribution can be indicated on the package and/or outer box upon request by the buyer at the PO stage.
- Distribution date will not appear on consumer package.
- Further packaging requirements for the consumer packages may be specified by the buyer.

Inner boxes

- Information sheet in the inner box in the secondary/consumer carton is to be specified by the buyer.
- Remove from current draft the advice to withdraw the penis soon after ejaculation leaving the FC in place after the vagina.
- Strong recommendation to put leaflets in the inner box if requested by the buyer.
- Replace: "Stop and check if the user feels the FC slipping into the vagina".
- Acceptable types of additional lubricant based on the type of material of the condom.
- Move the paragraph "the inner boxes shall be packed into plastic…" to the section on inner boxes.

Exterior shipping cartons

- Add: description of content to exterior boxes
- Add: Information should be printed on two adjacent sides
- Change: "topical medicines" to "topical products".

Additional items discussed for "packaging for shipment"

- Disability accommodation in packaging
  - The subject of disability accommodation will be addressed in the Generic Specification through a statement.
  - When packaging the product, assessment of the needs of the disabled community should be considered. The purchaser can then determine special packaging requirements to meet needs as seen fit.
  - Requirements regarding Braille etc. will be determined at the purchase order stage.
- Environmental considerations for packaging
  - Statement will be included in Generic Specification that there is no known biodegradable packaging available that will offer adequate protection for the needs of natural rubber latex condoms.
  - Optional items that will be included in technical information.

12. Observations and recommendations for Female Condom Generic Specification, Summary of tables

The observations and recommendation for this section were primarily related to its format and how information could be better presented in order to more effectively convey the information.

- It was recommended that the title of this section of the document be changed to, "Summary tables: Prequalification and LOT-by-LOT testing".
- Remove Table 1 and add a cross-reference to table 7 in section 4.3 into the current Table 3 in the Summary of Tables.

- A draft table titled “Summary of prequalification tests information” is included in the current draft. The table reflects a similar one that exists for male latex condoms. A preliminary review of this table identified the below amendments that must be made and all represent a deviant from the similar table for male latex condoms.
- First column of the table will re-titled “characteristic”.
- A title for the table shall be determined. A suggested title is: “Summary of Prequalification Evaluation and Tests”.
- Insert table on “Classification of defects in packaging and marking of packaging for delivery”.
- A fourth column titled “Requirements” that indicates the AQL or other relevant requirement shall be added.
- Under the column, “sampling” for the characteristics design, colour, scent, the flavouring, and odour the amount was changed to “13 condoms”. The “Requirement” for these items will be according to the manufacturer’s product specifications.
- Information will be divided into multiple tables by subject. One table will indicate pre-assessment criteria while another will indicate performance requirements for prequalification.
  - “Classification of defects in packaging and marking of packaging for delivery”
  - “Information required for prequalification”
  - “Summary of prequalification tests information”.

13. Observations and recommendations for Female condom generic specification, Workmanship and visible defects

13.1 Critical visible defects

Critical visible defects are those that may adversely affect the performance of the female condom. The following amendments were identified to be made in the current draft document.

Retention features

- The word faulty shall be removed from the first sentence.
- The words broken, cracked, missing, damaged, or severely distorted shall be added to the first sentence.
- A third sentence shall be added that states: “Any sharp edges that can damage the product or cause injury to the users”.

Crack marks

- A definition for “crack” shall be included in the glossary

Seams

- Shall read: “large lumps of material within the seam that can cause discomfort to the user”.

It was determined that the following critical visible defects shall be added to the WHO/UNFPA Female Condom Generic Specification.

Sponge

- Critical visible defects associated with sponges must be identified and added.

Insertion feature

- Any sharp edge, crack, or distortion that may damage the condom or cause device to fail. Addition critical visible defects may need to be identified.

Additional critical visible defects

- A statement shall be added to the bottom of the table stating: “any defect that is seen to adversely affect the product”.

13.2 Non-critical visible defects

Non-critical visible defects do not affect the performance and safety of the female condom but are undesirable to the user. Thus, non-critical visible defects are considered recommendations. The following amendment to the current draft were proposed:

Uneven colour

- Wording shall be changed to read: “minor streaking of the sheath of retention features and uneven colour or discoloration”.

Incorrect printing and expiration dates

- Items must be added as non-critical visible defects.

13.3 Imperfections

Imperfections do not affect the performance or acceptability of the condom and are not regarded as defect. The following changes to the identified imperfections were notes:

Seams

- Change title “Seams” to “Seam Imperfections”.
- To read: “minor creases close to the seams that have no impact on the airburst properties of the condom”.

13.4 Packaging defects

The following observations and recommendations were made for “Packaging Defects”.

Individual packages

- Illegible printing will be included as a packaging defect for individual packages.
- Currently, “no lubricant” is listed as a defect. A footnote indicating that according to their specification some female condoms may be un-lubricated.

Consumer packages

- Illegible printing will be included as a packaging defect for consumer packages.

Cartons and marking

- Illegible printing will be included as a packaging defect for cartons and marking.
- Partially filled cartons are listed as a defect. However, depending on the order size and its delivery times there may partially filled cartons. Therefore, this shall be removed as a defect.

The purchaser may choose to specify special packaging requirements at the purchase order stage that would create additional packaging defects. Instructions for reviewing packaging defects should be checked against the purchase order.

Annex 1. Technical review agenda

Tuesday 5 April 2011		
Chair: Katie Richey Rapporteur: Hayley Traeger, Facilitator		
09.00 - 09.30	Welcome and Introductions	Dr Michael Mbizvo, Director, WHO/RHR
09.30 - 09.45	Objectives and framework for the meeting Why develop a female condom specification	Maggie Usher-Patel, Scientist/IBP Secretariat, WHO/RHR Morton Sorensen, Deputy Chief Procurement, UNFPA
09.45 - 10.30	Discussion Female Condom Workshop: Next Steps Challenges with new products, technology, regulatory issues, acceptance, promotion and use	Maggie Usher-Patel, Scientist/IBP Secretariat, WHO/RHR Francis Ndowa, Coordinator, WHO/RHR/STI
11.00 - 12.30	Presentation and discussion Draft specification and review of the scientific and technical issues to be addressed	Dr William Potter, Technical Adviser for WHO/RHR
14.00 - 15.30	Presentation and discussion Draft specification and review of the scientific and technical issues to be addressed	Dr William Potter, Technical Adviser for WHO/RHR
16.00 - 17.00	Consensus on whether or not it is possible to develop a generic specification Consensus on the issues to be addressed	Maggie Usher-Patel, Scientist/IBP Secretariat, WHO/RHR Dr William Potter, Technical Adviser for WHO/RHR
17.00 Facilitators meeting		

Wednesday 6 April 2011		
Chair: Dr K Sivakumar Rapporteur: Hayley Traeger, Facilitator		
09.00 - 09.30	Laboratory Testing: Review of key issues relating to Airburst, Tensile, and Freedom from Holes Testing	Eli Carter, Director, Quality Assurance, FHI
09.30- 10.30	Laboratory Testing: Review of issues relating to condom design (retention mechanisms, packaging, lubricant compatibility, workmanship)	Eli Carter, Director, Quality Assurance, FHI
11.00 - 12.30	Group work: Working groups are assigned to review and make recommendations on specific issues	Working group
14.00 - 15.30	Plenary session: Feedback from working groups	Morton Sorensen, Deputy Chief Procurement, UNFPA
16.00 - 17.30	Preparation of recommendations and conclusions from day 1 and 2 Preparation of draft specification	Working groups
17.30 Facilitators meeting		

Thursday 7 April 2011		
Chair: Morten Sorensen Rapporteur: Hayley Traeger, Facilitator		
09.00 -09.15	Summary of conclusions and recommendations	Maggie Usher-Patel, Scientist/IBP Secretariat, WHO/RHR
09.15 - 09.45	Key issues: Specification requirements for stability including the sheath and ancillary components - retaining device, insertion devices and other components of the female condom	 Dr William Potter, Technical Adviser for WHO/RHR
09.45 - 11.30	Working group session	Working groups
11.30 - 12.30	Plenary feedback session	Dr Sivakumar, Technical Adviser for WHO/RHR
14.00 - 15.30	Lubricants Key issues and recommendations	Maggie Usher-Patel, Scientist/IBP Secretariat, WHO/RHR Dr William Potter, Technical Adviser for WHO/RHR
16.00 - 17.30	Summary of conclusions and recommendations	Dr K Sivakumar, Technical Adviser for WHO/RHR

Friday 8 April 2011		
Chair: Agnes Chidanyika Rapporteur: Hayley Traeger, Facilitator		
09.00 - 10.30	Challenges with the clinical evaluation of the female condom Key issues and recommendations	Dr William Potter, Technical Adviser for WHO/RHR Dr Tim Farley, Medical Officer, WHO/RHR/STI
10.30 - 12.30	Review of conclusions and recommendations reached Preparation of a draft specification	Dr William Potter, Technical Adviser for WHO/RHR Maggie Usher-Patel, Scientist/IBP Secretariat, WHO/RHR
14.00 -15.30	Review of conclusions and recommendations reached Preparation of a draft specification	Katie Richey, Technical Officer, WHO/RHR
16.00 - 16.30	Review of each section of the report and draft specification	Eli Carter, Director, Quality Assurance, FHI
16.30 - 17.00	Next steps	Morton Sorensen, Deputy Chief Procurement, UNFPA

Annex 2. List of participants

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