WHO/UNITED NATIONS POPULATION FUND (UNFPA)

RECOMMENDATIONS FOR CONDOM STORAGE AND SHIPPING TEMPERATURES

(July 2019)

DRAFT FOR COMMENTS

Please send any comments you may have to Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (kopps@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) by 20 September 2019.

Working documents are sent out electronically and they will also be placed on the WHO Medicines website (http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/) for comments under the “Current projects” link. If you wish to receive our draft guidelines, please send your email address to jonessi@who.int and your name will be added to our electronic mailing list.

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Please send any request for permission to:

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**SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.804:**

**WHO/UNITED NATIONS POPULATION FUND (UNFPA)**

**RECOMMENDATIONS FOR CONDOM STORAGE AND SHIPPING TEMPERATURES**

<table>
<thead>
<tr>
<th>Description of activity</th>
<th>Date</th>
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<tbody>
<tr>
<td>UNFPA identified the need to update the existing <em>Procedure for Assessing the Acceptability, in Principle, of Male Latex Condoms for Purchase by United Nations Agencies</em>, adopted by the Forty-second WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) meeting and published as Annex 2 in the WHO Technical Reports Series, No. 948, 2008. The text had been developed by the UNFPA and WHO specialists.</td>
<td>May – September 2018</td>
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<td>Informal discussions amongst UNFPA and WHO specialists on the management of this updating process.</td>
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<td>Presentation of a possible updating process of the prequalification guidance for contraceptive devices and condoms at the Fifty-third ECSPP.</td>
<td>18 October 2018</td>
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<tr>
<td>Following the recommendation of the Fifty-third ECSPP meeting, various phases of reworking and restructuring of the specific texts by UNFPA.</td>
<td>November 2018 – May 2019</td>
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<tr>
<td>Mailing of working document for public consultation, including to the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (EAP) and UNFPA specialists, inviting comments and posting of the working document on the WHO website.</td>
<td>Mid July 2019</td>
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<tr>
<td>Compilation of comments received by WHO.</td>
<td>September 2019</td>
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<td>----------------------------------------</td>
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<tr>
<td>Review of comments received by a group of specialists. Preparation of discussion document.</td>
<td>October 2019</td>
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<tr>
<td>Presentation to the Fifty-fourth ECSPP in Geneva, Switzerland.</td>
<td>14-18 October 2019</td>
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<td>Further follow-up action as required.</td>
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BACKGROUND

Extract from the Fifty-third World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) meeting report:

“Ms Seloi Mogatle and Dr William Potter from the United Nations Population Fund (UNFPA) gave an update on the prequalification guidance for contraceptive devices and condoms at the Fifty-third Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) that took place at the World Health Organization (WHO) headquarters in Geneva, Switzerland, October 2018. The UNFPA had contacted WHO to inquire how best to start a process to update the process of the following texts that were adopted by the ECSPP and published in 2008. The Expert Committee agreed to the importance of updating these materials in view of the changes in the contraceptive field globally over the previous decade. The two organizations committed to work together to bring the documents up-to-date. It was suggested by UNFPA to separate out the current existing procedure for condoms to include the following aspects:


5. Condom Quality Assurance and Annexes.


7. Condom Storage and Transportation.

9. *Public Assessment Reports for Contraceptive Devices - Condoms and Intrauterine devices (IUDs).*

UNFPA also raised the issue of specifications for lubricants (both water-based and silicon-based) which needs to be considered when developing the new guidelines.

The Expert Committee supported the development of the relevant documents in consultation with the WHO Secretariat, the preparation of these for public consultation and took note that they will be reported back to the Expert Committee.”

The following documents are undergoing a public consultation as part of this series:


6. QAS/19.806 - WHO/UNFPA Specifications for Plain Lubricants.

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1. During shipment
2. Warehouse storage

1. DURING SHIPMENT

Store condoms in dry conditions away from direct sources of heat and sunlight.

The average mean kinetic temperature\(^1\) during shipment should not exceed 30 °C. Peak temperatures should not exceed 50 °C\(^2\). The use of data loggers to monitor all shipments that originate, terminate or transit hot climatic zones is recommended.

2. WAREHOUSE STORAGE

Store in well ventilated, dry conditions away from direct sources of heat including sunlight.

Long-term average storage temperature should be less than 30 °C. Short-term temperature excursions should not exceed 40 °C.

Condom factories prequalified by UNFPA will have provided evidence to verify the claimed shelf-life of the product. The shelf-life is determined by a real-time study, conducted at a specific temperature (30 +5/ -2 °C) because this is the mean kinetic temperature of the most extreme climate in climatic zones III and IV. Research has demonstrated that properly packaged good-quality condoms stored at average temperatures in tropical climates do not deteriorate during storage. More information about the recommendations for storage and

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\(^1\) Temperatures during shipping can be monitored using data loggers. Most modern data loggers can automatically calculate and printout the mean kinetic temperature (in some cases, data has to be downloaded and analysed using provided software).

\(^2\) Brief, short term temperature excursions up to 50°C have limited impact on mean kinetic temperatures.

Since the shelf-life of the condoms will have been determined at 30 °C, air-conditioned storage is not necessary but it would be an advantage in hot climates, if available. In hot climates, it is important that condoms are stored in a well-ventilated environment away from direct sunlight and other sources of heat in order to minimize the exposure of the condoms to high temperatures. Similar precautions should be taken during transportation and delivery. In general, the storage temperature should be as low as can practically be achieved. Condoms stored outdoors in shipping containers are particularly vulnerable as the temperatures inside containers can be substantially above ambient temperatures resulting in faster deterioration.

Storage time in containers should be minimized. The condoms are sealed in individual foil packages, which are themselves packed in cardboard. The cardboard storage containers are vulnerable to moisture and should be stored in a dry storeroom away from walls and placed on pallets to protect against rising damp. Ideally, cartons should be stored at least 10 cm off the floor, 30 cm away from the walls and stacked no more than 2.4 metres high.

Condoms are fully protected by the individual foil package. However, cosmetic damage to the foil and damage to the outer packaging can make the product appear damaged and therefore less acceptable to the user. Contaminants of any sort (e.g. powders or liquids) should be avoided.

Condoms should be left in their original cartons and inner boxes until needed for distribution. The cartons should be positioned so that the lot number and expiry date are visible. The cartons should be identified and their locations recorded to ensure that specific lots can be located. Lots should be released on a first expiry—first out basis (FEFO).

Damaged or expired condoms should be kept separately and clearly segregated. Disposal of such condoms should be in accordance with local procedures for the disposal of damaged medical devices.

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