World Health Organization

DRAFT WORKING DOCUMENT FOR COMMENTS:

World Health Organization/United Nations Population Fund Recommendations for condom storage and shipping

Please send your comments to **Dr Sabine Kopp**, Team Lead, Norms and Standards for Pharmaceuticals, Technical Standards and Specifications (gigantev@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) before **20 August 2020**. Please use our attached Comments Table for this purpose.

Our 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 all our draft guidelines, please send your email address to jonessi@who.int and your name will be added to our electronic mailing list.

SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.804/Rev.1:

World Health Organization/United Nations Population Fund Recommendations for condom storage and shipping temperatures

Description of activity	Date
The United Nations Population Fund (UNFPA) identified the need to update the existing *Procedure for assessing the acceptability, in principle, of male latex condoms for purchase by United Nations agencies*, 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.	
Informal discussions amongst UNFPA and WHO specialists on the management of this updating process.	May – September 2018
Presentation of a possible updating process of the prequalification guidance for contraceptive devices and condoms at the Fifty-third ECSPP.	18 October 2018
Following the recommendation of the Fifty-third ECSPP meeting, various phases of reworking and restructuring of the specific texts by UNFPA.	November 2018 – May 2019
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.	Mid-July 2019

Compilation of comments received by WHO.	September 2019
Review of comments received by a group of specialists. Preparation of discussion document.	October 2019
Presentation to the Fifty-fourth ECSPP in Geneva, Switzerland.	14-18 October 2019
Review of comments received by a group of specialists. Preparation of discussion document.	October 2019-May 2020
Mailing of working document for public consultation, including to the EAP and UNFPA specialists, inviting comments and posting of the working document on the WHO website.	May 2020
Compilation of comments received by WHO.	August 2020
Review of comments received by a group of specialists. Preparation of discussion document.	September 2020
Presentation to the Fifty-fifth ECSPP in Geneva, Switzerland.	12-16 October 2020
Further follow-up action as required.	

World Health Organization/United Nations Population Fund Recommendations for condom storage and shipping temperatures

Background

The report of the Fifty-fourth meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in 2019 (*1*)) stated the following:

> *As agreed at the ECSPP meeting in October 2018, the United Nations Population Fund (UNFPA) and WHO have separated out different aspects of the current procedure for contraceptive devices and condoms and are developing seven different documents:*
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> - *prequalification programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices;*
> - *technical specifications for male latex condoms;*
> - *specifications for plain lubricants;*
> - *condom quality assurance;*
> - *guidance on testing of male latex condoms;*
> - *recommendations for condom storage and shipping temperatures; and*
> - *guidance on conducting post-market surveillance of condoms.*
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> *All seven documents were restructured and revised in the first half of 2019, then sent to the EAP and put out for public consultation in July 2019. The comments received were reviewed by a group of specialists in October 2019, prior to being presented to the ECSPP. At UNFPA's request, the ECSPP focused on the first three documents (on UNFPA's Prequalification Programme guidance, condom quality assurance and specifications for plain lubricants), noting that all comments have been addressed. It suggested some further minor revisions, including recommending changes to clarify that, while the specifications for plain lubricants are principally targeted at procurement agencies, they may also be used by regulators for*

public procurement. The next steps for the remaining four documents include incorporating comments from the latest consultations and then bringing them back to the ECSPP for possible adoption at its next meeting in 2020.

The Expert Committee adopted the following guidelines:

- *World Health Organization/United Nations Population Fund Prequalification Programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices (2);*
- *World Health Organization/United Nations Population Fund technical specifications for male latex condoms (3); and*
- *World Health Organization/United Nations Population Fund specifications for plain lubricants (4).*

The Expert Committee further recommended proceeding with the next steps as discussed.

This is one of the four remaining working documents in this series.

1. During shipment
2. Warehouse storage

References

Further reading

1. During shipment

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

The average mean kinetic temperature[1] (MKT) 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. Ideally, data loggers can calculate the mean kinetic temperature either automatically or by using software supplied with the data loggers after data has been downloaded.

2. Warehouse storage

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

Long-term (i.e. one month to a year) average storage temperature should be less than 30 °C. Short-term (i.e. up to one month) temperature excursions should not exceed 40 °C. The recommended limit for short term exposure is cumulative over the total period of storage.

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 MKT of the most extreme climate in climatic zones III and IV[3]. 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

[1] Temperatures during shipping can be monitored using data loggers. Most modern data loggers can automatically calculate and print out the mean kinetic temperature (MKT) (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 MKT. If, during shipping, the MKT exceeds 30 °C and/or peak temperatures exceed 50 °C, a risk assessment should be conducted to assess whether or not the properties of the condoms in the consignment have been compromised. Random sampling and testing of condoms for burst properties is recommended to support the risk assessment.

[3] More details on the climatic zones can be found in *WHO Stability testing of active pharmaceutical ingredients and finished pharmaceutical products* (*5*)

storage and shipment, and the rationale for choosing 30 + 5/ -2 °C as the storage temperature for stability studies, is given in the Technical Basis Paper of the WHO/UNFPA *technical specifications for male latex* condoms (*3*).

Since the shelf-life of the condoms will have been determined at 30 + 5/ -2 °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 shipping 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. It should be ensured that the floor of the storage area is paved with concrete and the walls and floor should not get damp due to seepage of water or rain water condensate. The ambient temperature in the warehouse should be recorded.

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).

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

References

1. WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020 (WHO Technical Report Series, No. 1025; https://www.who.int/publications-detail/978-92-4-000182-4, accessed 20 May 2020).

2. World Health Organization/United Nations Population Fund Prequalification Programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020: Annex 9 (WHO Technical Report Series, No. 1025; https://www.who.int/publications-detail/978-92-4-000182-4, accessed 20 May 2020).

3. World Health Organization/United Nations Population Fund Technical specifications for male latex condoms. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020: Annex 10 (WHO Technical Report Series, No. 1025; https://www.who.int/publications-detail/978-92-4-000182-4, accessed 20 May 2020).

4. World Health Organization/United Nations Population Fund Specifications for plain lubricants. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report. Geneva: World Health Organization; 2020: Annex 11 (WHO Technical Report Series, No. 1025; https://www.who.int/publications-detail/978-92-4-000182-4, accessed 20 May 2020).

5. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-second report. Geneva: World Health Organization; 2018: Annex 10 (WHO Technical Report Series, No. 1010; https://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS1010annex10.pdf, accessed 20 May 2020).

Further reading

- UNFPA-published Condom programming for HIV prevention—An operations manual for programme managers and PATH's procurement capacity toolkit: Tools and resources for procurement of reproductive health supplies and safe disposal and management of unused, unwanted, contraceptives (http://www.unfpa.org/resources/safe-disposal-and-management-unused-unwanted-contraceptives, accessed 20 May 2020).

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