Countries have a right, and a duty, to ensure that medical devices distributed in their countries are of adequate quality for use. There is a vast range of medical devices and drugs on the market, and resources to support the task are relatively scarce. Condoms supplied by UNFPA have already been through extensive quality checking and surveillance. The duty to ensure good quality of condoms can thus be discharged by accepting condoms based on test results supplied by UNFPA.

Duplication of the lot by lot testing already conducted by the independent labs (and the factories) would be a poor use of scarce resources, which could be redirected to checking on other medical products which have not been subjected to the same high level of scrutiny as the condoms supplied by UNFPA, or to purchase of more commodities.

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Governments have a duty to ensure that their population is receiving male condoms that meet international quality standards. UNFPA takes stringent measures to ensure that condoms purchased for in-country distribution are of the highest practicable quality and reliability. The steps taken are:

1. Prequalification of factories, consisting mainly of a detailed technical inspection and product testing
2. Stipulation of product conformance with stringent requirements (WHO and ISO)
3. Independent sampling and acceptance testing of each lot
4. Periodic analysis of factory performance from test history
5. Discretionary post-market testing based on field experience.

Evidence suggests that male latex condoms that are stored in good conditions will remain safe and effective throughout their shelf life. The UNFPA approach to condom purchasing and quality has been developed in consultation with the World Health Organization, and is based on the WHO Specifications for condom procurement (Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010).

UNFPA contracts highly experienced laboratories to do condom testing. These laboratories are doing condom testing continuously, and have internationally recognised accreditation. They participate in regular inter-laboratory comparisons, and have a sufficient volume of testing work to be able to recognise problems as they occur.

Methods of Medical Device Quality Assurance

Male condoms are a Class II medical device in most countries. Governments and large volume purchasers have a number of options available for assuring themselves that the quality of medical devices is as required. These include:

1. Factory inspections and certifications
2. Approval on the basis of documentation
3. Pre-shipment testing
4. Post-shipment testing (Testing in receipt)
5. Post-market surveillance (Testing on products in the distribution chain)

Lot by lot testing is generally reserved for critical products, where there is a history of quality problems. Condoms fall into this category, and UNFPA has chosen to conduct lot by lot pre-shipment testing. Many countries have their regulatory approach on the factory’s documentation (usually supplemented by post-market surveillance), rather than testing.

Conclusion

Background

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WHAT IS PRE-SHIPMENT TESTING?
Pre-shipment testing or examination involves the following steps:
1. Sending an independent sampler to the factory where a lot is shipment is ready for export. The sampler is required to follow the guidelines according to sampling procedures. The sampler sends the samples to UNFPA’s lab.
2. The lab performs the tests according to UNFPA’s requirements, the WHO specification and ISO 4832.
3. The results are sent to UNFPA and a decision is made on whether the lot is acceptable. Conformity with the technical requirements is not accepted and will be rejected by lot that needs the quality criteria.

WHAT IS POST-SHIPMENT TESTING?
Post-shipment testing is carried out after the goods arrive in-country but before the condoms are released for distribution.

ADVANTAGES OF PRE-SHIPMENT TESTING
Pre-shipment testing is the first line of defence in the following advantageous ways:
1. Ability to stop unacceptable products from leaving the factory and being shipped to countries.
2. Elimination of delays due to shipping and customs, allowing any necessary replacements to be provided at the minimum possible time.
3. Confirming testing in every requirement, specialized, accredited laboratories.
4. Consolidating test results so individual results can be interpreted with the aid of other results from the same factory, allowing early warning of problems.
5. Reduced cost of testing.
6. Reduced cost of dealing with failed lots.

WHAT ARE THE ADVANTAGES OF POST-SHIPMENT TESTING?
The main advantage of post-shipment testing is that it can discover damage caused during shipping of the product. While this appears important, and may be so for shipments of consumables, maintenance, calibration, training and technicians’ wages. Accreditation, if obtained, is also expensive, but may be needed to maintain credibility in the eyes of donors.

SHOULD POST-SHIPMENT TESTING BE USED ON UNFPA CONDOMS?
No, there is a need for a clear, identified reason for suspending a particular lot due to problems with storage or transport. However, there may be a need to deviate from UNFPA standards for sampling procedures. The sampler sends the sample to UNFPA’s lab.

WHAT IS POST-SHIPMENT TESTING?
Post-shipment testing is a process of testing condoms after they arrive in-country, but before the condoms are released for distribution.

WHY ARE THERE PROBLEMS WITH POST-SHIPMENT TESTING?
In some countries, post-shipment testing is done well. Regrettably, there have been problems in other countries. These have included:

• National laboratory or laboratory going to conduct the post-shipment testing has ISO 9001 certification, but the quality system is not completely implemented at the laboratory.
• Procurement Services Branch is informed of the requirements prior to order placement; however, the person responsible for the order is not adequately familiar with the quality assurance process, and the requirements are not properly communicated to the quality engineers and technicians in the orders.
• Testing results from the same factory, allowing early warning of problems.
• Accreditation, if obtained, is also expensive, but may be needed to maintain credibility in the eyes of donors.

If post-shipment testing is required by the Ministry of Health despite the very thorough UNFPA’s laboratories’ exhaustive testing and pre-shipment testing system, UNFPA may agree provided:
• The cost of this additional testing is included in the total cost of the order andUNFPA is not responsible for covering the cost.
• National laboratory or laboratory going to conduct the post-shipment testing has ISO 9001, accreditation from the responsible body.
• The test protocol to be used in compliance with ISO/WHO specifications.

WHAT IS LABORATORY ACCREDITATION?
Laboratory accreditation is a scheme of approving laboratories that conduct tests. The technical part of the audit is conducted by a person experienced in the field of testing, and it verifies the laboratory’s technical competence to continue to do its work.

There is an international agreement on mutual recognition among many national accreditation organizations. These organizations audit each other to ensure uniform, adequate standards of assessment. UNFPA only uses the services of internationally accredited laboratories for its testing schemes. In many countries, factory inspection and approval is also too costly and complex, leaving testing as an effective way of ensuring quality.

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WHAT IS THERE A ROLE FOR POST-SHIPMENT TESTING?
If post-shipment testing is required, the Ministry of Health provides it to UNFPA in written form. Post-shipment testing and pre-shipment testing system contains, UNFPA may agree provided:
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Ships that post-shipment testing is being done on products that have had pre-shipment testing, doesn’t delay the delivery of the product. Not only is the delayed delivery of the product. But it could also be done if there were significant evidence-based problems with the quality of the product. Exempting products which have had pre-shipment testing save’s resources, and avoids legal disputes.

In-country resources may be better directed to post-market surveillance, where samples are tested and conformity is ensured. To the expense of post-market surveillance, UNFPA quality assurance process with prequalification and pre-shipment testing of male condom.

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