Conclusion

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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POST-SHIPMENT
Testing of Male Condoms

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POST-SHIPMENT
Testing of Male Condoms

Background

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. Occasional 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 on receipt)
5. Post-market surveillance (checking 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 base their regulatory approach on the factory's documentation (usually supplemented by post-market surveillance), rather than testing.

WHAT IS PRE-SHIPMENT TESTING?

Pre-shipment testing as conducted by UNFPA consists of the following steps:

- Sending an independent sampler to the condom factory when a lot or shipment is ready for shipment. The sampler takes random samples from each lot according to ISO standards for sampling procedures. The sampler sends the samples to UNFPA's chosen lab.
- The lab inspects and tests the condoms according to UNFPA's requirements, the WHO specifications and ISO 4074.
- The results are sent to UNFPA and a decision is made as to whether each lot is acceptable. Condoms which fail any of the critical performance requirements are not accepted and will be replaced by a lot that meets the quality criteria.

WHAT IS POST-SHIPMENT TESTING?

It is the practice of testing condoms after they arrive in-country, but before the condoms are released for distribution.

ADVANTAGES OF PRE-SHIPMENT TESTING

While each approach has its own advantages and disadvantages, pre-shipment testing for a large volume supplier has the following advantages:

1. Ability to stop unacceptable products from leaving the factory and being shipped to countries
2. Elimination of delays due to shipping and clearance, allowing any necessary replacements to be provided in the minimum possible time.
3. Concentrating testing in very experienced, specialised, 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 testing costs due to the use of high volume facilities
6. Reduced cost of dealing with failed lots.

UNFPA's pre-shipment testing is integrated with its prequalification process, which involves a technical inspection of the factory. As UNFPA purchases large quantities of condoms from several factories, it is also able to compare the results of a factory at different times and to compare the results of different factories.

WHAT ARE THE ADVANTAGES OF POST-SHIPMENT TESTING?

The main advantage of post-shipment testing is that it can discover damage caused during shipment of the products. While this appears important, and may be so for shipments of unknown origin, UNFPA's prequalified factories are all required to conduct real time shelf life studies at 30°C. If products conform with the shelf life requirements, it is extremely unlikely that they will be seriously harmed during shipping.

SHOULD POST-SHIPMENT TESTING BE DONE ON UNFPA CONDOMS?

No (unless there is a credible, identified reason for suspecting a particular lot due to problems with storage or shipping conditions).

As indicated above, the condoms supplied by UNFPA have been made by factories which have been inspected and prequalified by UNFPA. Each lot has been tested by an independent highly experienced, internationally accredited condom testing lab. The accreditation of the lab is recognised in all countries subscribing to ILAC (International Laboratory Accreditation Cooperation).

In addition, UNFPA's factories all conduct in-process and final release testing on each lot of their condoms.

Part of the factory prequalification process is the evaluation of the factory's real time shelf life study. Factories whose products do not have adequate shelf life are not accepted. As the shelf life is assessed at 30°C, it is unlikely that a few weeks at elevated temperatures during the day in transit will cause the condoms to deteriorate. UNFPA is currently conducting a pilot on monitoring temperature conditions in containers during transit.

Further sampling and testing is generally counterproductive, for the following reasons:

1. It duplicates work already done by a competent independent lab as well as the factory
2. It implies lack of confidence in the donor
3. It is costly (the cost must come either from the donor or from the country)
4. It may delay release of needed supplies
5. It can result in disputes between the supplier and testing laboratory on the one hand, and the national lab on the other[1].

It is far preferable for the recipient country to recognise and accept the testing and quality assurance program operated by UNFPA. The approach of mutual recognition is now widely used throughout the world for the quality control of medicines and medical devices.

The cost of operating a local testing lab is not limited to the lab and its premises. It extends to 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.

1 Testing is destructive and done on a sample. It is inevitable that different samples will, at times, give different results. Thus the results of two labs can differ, with neither being wrong. It is also possible to take a sample which gives a "fail" result from an acceptable lot, and to take one which gives a "pass" result from an unacceptable lot. This applies to all testing based on samples. As the pre-shipment testing process screens out products found unacceptable by the UNFPA independent testing lab, the in-country lab will never see product that has not been passed by the independent laboratory. The only possible conflict between the two labs is that the in-country lab may reject a lot accepted by the independent lab.

If post shipment testing is required by the Ministry of Health despite the very thorough UNFPA quality assurance process with prequalification and pre-shipment testing of male condoms, UNFPA may agree provided:

- Procurement Services Branch is informed of the requirements prior to order placement;
- The cost of the additional testing is included in the total cost of the order and UNFPA is not responsible for covering this cost;
- National laboratory or laboratory going to conduct the post-shipment testing has ISO 17025 accreditation from an acceptable body;
- The test protocol to be used is in compliance with ISO/WHO specifications.

WHAT IS LABORATORY ACCREDITATION?

Laboratory accreditation is a scheme of approving laboratories that involves both technical and quality systems audits. 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 conduct the tests concerned. The quality systems part is conducted by a systems auditor, and effectively covers those parts of ISO 9001 that are relevant to testing labs.

The audits are done in accordance with ISO 17025, an international standard specially written to ensure laboratory proficiency. In order to be approved, laboratories must also have an effective equipment calibration programme and training programme.

There is an international agreement on mutual recognition among many national accreditation organizations. These organizations audit each other, in order to ensure uniform, adequate standards of assessment. UNFPA only uses the services of internationally recognized accredited laboratories.

HAVE THERE BEEN 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:

- Poor sampling techniques
- Wrong handling of samples
- Incorrect testing techniques
- Inadequate calibration and maintenance of equipment
- Not having the correct equipment
- Not using the appropriate specifications and standards.

In some cases, this has resulted in mandatory destruction of high quality condoms. Such incidents can erode the willingness of donors and NGOs to participate in condom supply programs in the country concerned. There have been instances of international donor organizations agreeing to destroy condoms which they (and the manufacturer) believe to be of good quality because of the difficulties of resolving the issue in any other way.

If the requirement for post-shipment testing causes a delay in product release, this can cause a shortage of supplies, and risks to public health.

IS THERE A ROLE FOR POST-SHIPMENT TESTING?

Post-shipment testing may be suitable for products which are not part of a pre-shipment testing scheme. In many countries which rely on donor-provided condoms for the public sector, there is also a private sector, which needs some surveillance. Testing is a valid approach in these cases, especially for countries which do not have the regulatory infrastructure to review factory dossiers and certification documents. For most developing countries, factory inspection and approval is also too costly and complex, leaving testing as an effective means of assuring quality.

Exempting products which have had pre-shipment testing saves resources, and avoids disputes.

Condom testing is expensive to set up and maintain, and lab technicians may not retain their testing skills unless they are doing it all the time. Thus there is a case for sending samples to a specialised condom lab in another country.

If post-shipment testing is to be done on products that have had pre-shipment testing, it could be done at random on a small percentage of lots, to verify that the pre-shipment testing result is still valid. It could also be done if there were significant evidence-based grounds to doubt the continuing validity of some results (e.g. extended delays in Customs clearance with storage in a very hot location). In the event of any doubt, the matter should be discussed with UNFPA, with the intention of resolving the apparent contradiction. This approach is akin to auditing, with selective additional surveillance directed according to a risk analysis. In these cases, the sampling would need to be done randomly and restricted to the lot or lots concerned.

In-country resources may be better directed to post-market surveillance, where samples are tested at random from the distribution network, to ensure that they are fit for use at the point of final distribution, or in response to consumer complaints.