



UNFPA Quality Assurance Framework for the Procurement of Reproductive Health Commodities

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Acronyms

| | |
|---------|---|
| API | Active Pharmaceutical Ingredient |
| EMA | European Medicines Agency |
| ERP | Expert Review Panel |
| EOI | Expression of Interest |
| FEFO | First Expiry, First Out |
| GMP | Good Manufacturing Practice |
| HIV | Human Immunodeficiency Virus |
| ISO | International Organization for Standardization |
| IUD | Intrauterine Device |
| LTA | Long Term Agreement |
| MAH | Marketing Authorisation Holder |
| NGO | Nongovernmental Organizations |
| NQCL | National Quality Control Laboratory |
| PQP | Prequalification Programme |
| PSB | Procurement Services Branch |
| QA | Quality Assurance |
| RH | Reproductive Health |
| RHCS | Reproductive Health Commodity Security |
| SRA | Stringent Regulatory Authority |
| STI | Sexuality Transmitted Infection |
| UN | United Nations |
| UNFPA | United Nations Population Fund |
| WHO | World Health Organization |
| WHO/QSM | WHO Department of Essential Medicines and Health Products Quality and Safety of Medicines |

Preface

UNFPA's mandate is to deliver a world where every pregnancy is wanted, every childbirth is safe and every young person's potential is fulfilled. Through improving access to and availability of quality reproductive health commodities, UNFPA, in collaboration with partners aim to assist governments in promoting universal access to sexual and reproductive health and rights which includes access to reproductive health (RH) commodities. Procurement Services Branch is the procurement arm of UNFPA and focuses on the supply of internationally acceptable RH commodities and strengthening national systems in order to facilitate access to family planning and other sexual and reproductive health commodities.

The following RH commodities are procured by UNFPA PSB:

1. Male condoms
2. Female condoms
3. Copper-bearing IUDs (TCu 380A)
4. Hormonal contraceptives (pills, injectables, implants)
5. Essential life-saving medicines to support sexual, reproductive and maternal health
6. Medical devices, such as medical equipment, medical supplies and kits.

This document outlines the framework UNFPA PSB follows in assuring quality for the above commodities.

Part One: Introduction

1.1 UNFPA Procurement Services Branch

As the lead United Nations (UN) agency in expanding the possibilities for women and young people to lead healthy sexual and reproductive lives, UNFPA has been procuring contraceptives and related commodities for the developing world for more than 40 years. Today, UNFPA is the largest public sector procurer of RH commodities within the UN system. Procurement of RH commodities on behalf of UNFPA programmes and external entities, such as other UN agencies, governments and non governmental organizations (NGOs), is the main function of the Procurement Services Branch of UNFPA. UNFPA PSB is a headquarters office based in Copenhagen and is ISO 9001:2011 certified for Quality Management.

Structurally, UNFPA PSB is made up of 'clusters' that are co-ordinated within the branch to ensure quality commodities are delivered to countries. There is clear segregation of duties within this structure, with the Quality Assurance Team completely removed from all procurement functions to prevent conflict of interest and uphold objectivity of assessments, reviews and evaluations in line with the WHO Model Quality Assurance System for Procurement Agencies.

PSB operates in compliance with UNFPA financial rules and regulations and procurement procedures, and upholds public procurement principles of fairness, transparency and integrity in the management of public and donor funds. To ensure effective implementation of its activities and to address the needs of the organisation and clients, UNFPA PSB adheres to these principles by:

- Carefully determining evaluation criteria to consider costs and risk factors to ensure *best value for money*.
- Having detailed information about defined prequalification processes and procurement procedures, bidding opportunities and specifications publicly available online to ensure *transparency*.

- Giving adequate notice to the supplier community to allow them sufficient preparation time and publishing generic specifications to ensure *open and effective international competition*.

UNFPA procures products and services that are required to achieve UNFPA's mandate. This entails products that are recommended by WHO and are in WHO treatment guidelines.

1.2 Statement on Sustainable Procurement

In compliance with Secretary General Ban Ki-moon's statement that the UN should become more climate friendly and its activities more environmentally sustainable. UNFPA, as one of the leading organisations in the procurement of RH commodities, is determined to reduce its environmental footprint. For instance, in the National Health Service (NHS) - England, the 61%¹ of health sector greenhouse gas emissions are associated with procurement; in setting of Global Fund projects it is even over 80%². The Procurement Services Branch is working towards greener standards applied to procurement practices. The Quality Assurance team has defined a strategy whereby sustainability is a priority.

Through the development of UNFPA's Green Procurement Strategy, UNFPA encourages suppliers to work with the implementation of activities and improvement of processes in order to reduce the environmental impact of the RH commodity supply chain. However, this will require both the time and collaboration of all stakeholders involved in the process.

1 Carbon Footprint update for NHS in England, Dec. 2013

2 United Nations Development Programme: <http://www.eurasia.undp.org/content/dam/rbec/docs/Carbon-footprint-of-UNDP-Global-Fund-health-initiatives-in-Montenegro-and-Tajikistan.pdf>

As a first step towards this strategy, a guideline on *Safe Disposal and Management of Unused, Unwanted Contraceptives* has been developed. The document focuses on the main RH commodities supplied by UNFPA: male and female condoms, copper-bearing intrauterine devices and RH pharmaceuticals (including hormonal contraceptives). The guideline specifies and describes different ways in which to safely dispose of unused commodities, dependent on the available resources.

1.3 Quality Assurance at UNFPA Procurement Services Branch

The aim of the Quality Assurance Team at UNFPA PSB is to identify suppliers that meet international quality standards and requirements and ensure that RH commodities comply with the set standards.

This framework outlines the quality standards and requirements of the RH commodities procured by UNFPA; describes the quality assurance processes before, during and after procurement; recommends actions to be taken on receipt of the commodities; and

suggests considerations to be borne in mind throughout the supply chain, before use of the commodities.

The different steps in the supply chain are interconnected in relation to quality. During its life cycle, a product will pass through many hands, some of which will impact its quality. The life cycle approach, as it relates to procurement, assesses the following issues (see Figure 1):

1. The source of the raw materials for the product and the quality of those raw materials. The quality of ingredients that go into the product determine the quality of the finished product.
2. That the manufacturing process being followed by the manufacturer is in line with set international quality standards.
3. That quality control measures are in place.
4. That appropriate regulatory approvals and market clearances are in place.

Figure 1. Quality Assurance in the Supply Chain



5. That the logistics system supports and ensures *access and availability without compromising quality*.
6. That information for health care providers and end users is given in the appropriate format.

1.4 Capacity Development

The capacity development initiatives work towards increasing demand for, access to and utilisation of quality assured reproductive health products in the relevant countries.

Capacity development is focused on strengthening reproductive health commodity security systems in the recipient countries by enabling self-sustaining structures and mechanisms. Capacity development initiatives implemented by UNFPA PSB for the quality assurance of RH commodities are designed to respond to stakeholder needs.

Key Stakeholders in quality assurance include:

- Manufacturers
- National Regulatory Authorities
- National Quality Control Laboratories
- National Procurement Systems
- Healthcare Providers

UNFPA PSB also supports capacity development for a diverse pool of manufacturers to encourage continuous product improvement and to provide quality assured commodities.

UNFPA works with stakeholders in the following capacities:

- Strengthening national systems
 - *Quality Control Laboratories* – by providing technical assistance to support quality control testing of RH commodities in line with international standards and good laboratory management practices. A key component of this training programme is the gap analysis for ISO 17025 accreditation for testing contraceptive devices. Additional information on

the WHO prequalification programme for quality control laboratories for testing pharmaceuticals is covered as part of regional workshop trainings.

- *National Regulatory Authorities* – by introducing the WHO/UNFPA prequalification programmes, international standards, assessment processes and identification of areas of synergy in the interest of harmonising product standards.
- *National Procurement Systems* – training on public sector procurement principles and procedures for government counterparts.
- Improving sustainability.
- Collaborating and consensus building with global and national procurement agencies and wholesalers to procure quality assured products at the best value for money in adherence to procurement principles.
- Strengthening the capacity of manufacturers
 - Supporting manufacturers' participation in WHO prequalification programmes or similar programmes to provide technical advice and related guidance on improving good manufacturing practices (GMPs).
 - Facilitating knowledge sharing and technology transfer for off-patent products to aid manufacturers' ability to produce quality generic products.

Part Two: Quality Assurance by RH Commodity Category

2.1 Male Latex Condoms and Female Condoms

2.1.1 Introduction

UNFPA procures both male and female condoms. These barrier methods offer dual protection against pregnancy and sexually transmitted infections (STI), including human immunodeficiency virus (HIV), making them a key commodity for promoting sexual and reproductive health. Supplying quality assured male and female condoms is of utmost importance to UNFPA.

UNFPA procures condoms that conform to the most current versions of the WHO/UNFPA specifications for male latex condoms and female condoms. Male condoms procured by UNFPA come in a variety of sizes, shapes, colours, textures and flavours. The female condom is a relatively new commodity. Unlike the male condom, there are many different innovative designs of female condom, each one having its own unique features and specifications. Each design has some common features that include: a sheath that lines the vagina, external and internal retention devices, and a means of insertion. It is therefore not possible to specify it in the same manner as the male latex condom. However, detailed scientific and technical requirements must be met by manufacturers before they are approved for bulk procurement for the public sector and these are defined in the WHO/UNFPA Generic Specification for Female Condoms.

UNFPA only procures male and female condoms from manufacturing sites that have successfully completed the WHO/UNFPA prequalification processes for male and female condoms. WHO commenced the prequalification programme for male condoms in 2001 and this programme has expanded and grown over the years. In 2005, WHO delegated UNFPA to manage the implementation of this prequalification programme

for both male and female condoms but maintained its normative role of setting standards and guidelines.

2.1.1.1 Prequalification Programme for Male and Female Condoms

The WHO prequalification programmes aim to:

- Ensure high quality commodities
- Increase access to generic medicines and low cost devices
- Harmonise quality standards through pooled procurement
- Ensure safety and efficacy of commodities throughout their stated shelf-life

The main principles inherent in the WHO prequalification programmes are that:

- The programmes are voluntary and open to manufacturers from all geographical regions. Currently, there is no fee for manufacturers participating in the processes for male and female condoms.
- Transparency is key and information on the process and procedures is publicly available on the UNFPA and WHO websites, including lists of those products and manufacturers that have successfully completed the process.
- Confidentiality of all data, documentation and information submitted by the manufacturer is maintained throughout the process.

The prequalification process involves a number of stages with specific requirements. In summary, the stages are as illustrated in Figures 2 and 3.

Figure 2. Male Condom Prequalification Process

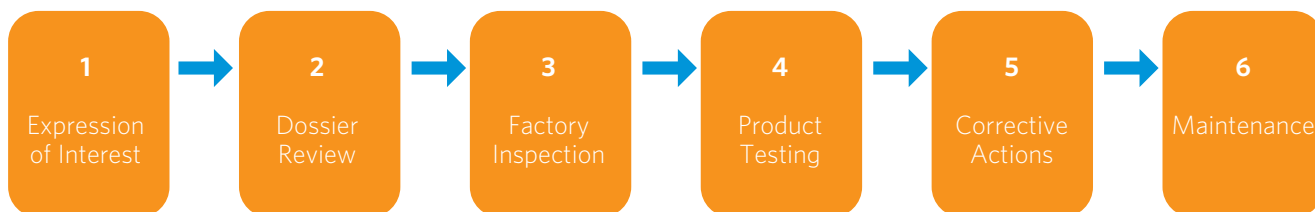
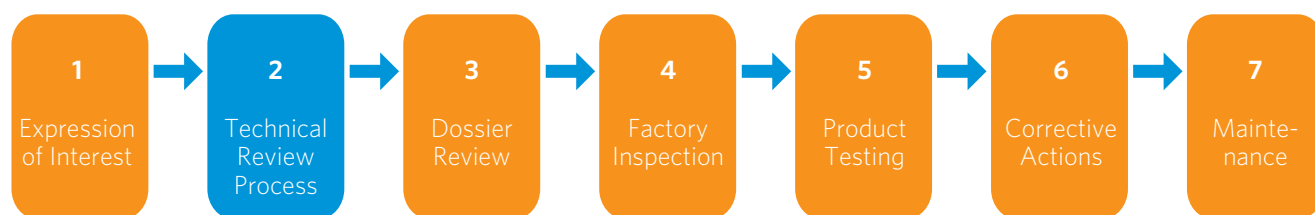


Figure 3. Female Condom Prequalification Process



For female condoms, as the design may be unique, the manufacturer must also demonstrate the acceptability, safety and efficacy of a new female condom design with clinical data from appropriate clinical investigations. The design must be approved via the technical review process by the WHO Technical Review Committee for Female Condoms.

The reviews during these processes are conducted by technical experts with experience in male and female condom manufacturing, quality management and quality control. Applicants that successfully complete the process are included on the prequalification list publically available on WHO and UNFPA websites.

For a more detailed step-by-step guide to the prequalification process for male condoms, refer to WHO/UNFPA's most recent version of: *WHO/UNFPA Male Latex Condom: Specification and Guidelines for Procurement, 2012*. For more information about the prequalification process for female condoms and the technical review process, refer to *WHO/UNFPA Female Condom: Generic Specification, Prequalification and Guidelines for Procurement, 2012*.

2.1.2 Quality Criteria for Procurement

UNFPA only procures prequalified products that are sourced from the corresponding WHO/UNFPA prequalified manufacturing site that has been evaluated.

UNFPA only procures condoms that comply with the requirements of the most recent editions of the WHO/UNFPA Specification for Male Latex Condoms and the WHO/UNFPA Female Condom Generic Specification. Eligibility to bid for Long Term Agreements with UNFPA is only open to prequalified male and female condom manufacturers. There are certain parameters that must be specified on an order by order basis, within the confines of the WHO/UNFPA specification for male condoms, for example, texture, size, colour. These guidelines are designed to provide information and tools to assist in achieving programme objectives that work towards improving the acceptability and use of male and female condoms.

2.1.3 Quality Control: Pre-shipment Inspection and Testing

Good manufacturing practice requires condom manufacturers to perform internal quality control testing on finished products prior to their release to the market. In addition, UNFPA conducts pre-shipment compliance inspection and testing on each lot of condoms it procures. Inspection and sampling for pre-shipment testing is conducted by an independent sampling and inspection agency. Male condoms are sampled in accordance with Annex B of ISO 4074³ and ISO 2859-1⁴, and are inspected for quantity, labelling, packaging materials and markings. Female condoms are sampled in accordance with ISO 2859-1. Packing and marking are also inspected to ensure compliance with the requirements specified in the UNFPA purchase order.

The sampled condoms are sent to a third-party independent laboratory for pre-shipment quality control testing. Laboratories that conduct pre-shipment testing for male and female condoms must be ISO 17025⁵ accredited for the testing of that product and are selected through an international competitive bidding process which requires evidence of expertise and experience in male condom and female condom testing.

Testing of male condoms is performed in accordance with the requirements of the WHO/UNFPA Specification for Male Latex Condoms and ISO 4074. The parameters that are being tested and required for pre-shipment include: bursting volume and pressure, freedom from holes, visible defects, shape and texture, package integrity, integral bead, colour, scents and flavouring, width, length, thickness and lubricant quantity.

For female condoms, testing is performed in accordance with ISO 25841 and/or WHO/UNFPA Female Condom Generic Specification 2012⁶ or manufacturers' specification for certain parameters where applicable. The parameters that are being tested include: burst volume and pressure, freedom from holes, visible defects, package integrity, design, colour, scents and flavouring, width, length, thickness and lubricant quantity.

The test results are received by the independent sampling agency, which then alerts UNFPA should any failures or non-conformities have been detected at the inspection or pre-shipment testing. Lots that fail to meet inspection and testing and requirements are rejected and have to be replaced by manufacturers and undergo the same procedure of sampling and testing before they are accepted. A pre-shipment test report summary issued by the testing laboratory is sent to the consignee of each condom Lot procured indicating which tests have been performed and that the condoms supplied have successfully passed them.

UNFPA conducts pre-shipment testing as opposed to post-shipment testing in order to:

1. Stop unacceptable commodities from leaving the factory and being shipped to recipient countries.
2. Eliminate delays due to shipping and clearance, allowing any necessary replacements to be provided in the minimum possible time.
3. Consolidate test results so individual results can be interpreted with the aid of the results from the same factory to facilitate early warning of problems.
4. Reduce costs in replacing Lots deemed inadequate for distribution, as this is determined before Lots are shipped.

³ ISO is the principal international standards authority and is responsible for drafting international standards based on best available evidence and practice. ISO Technical Committee 157 - Non-Systemic Contraceptives and STI Barrier Prophylactics is responsible for developing the international standard for male latex rubber condoms and female condoms.

⁴ ISO 2859-1 is the international standard for sampling procedures for inspections.

⁵ ISO 17025 is the international standard for general requirements for the competence of testing and calibration laboratories.

⁶ Should there be a discrepancy, the highest and strictest requirement will prevail.



UNFPA PSB QA team coordinates inspections at the manufacturing sites to ensure compliance with WHO/UNFPA requirements

2.1.4 Quality Monitoring: Post-shipment Inspection and Testing

UNFPA recommends that on receipt of each shipment the physical condition of the boxes and the condoms be checked and the quantity and remaining shelf-life be assured that it is in compliance with local requirements and buyer's specifications.

It is important that, on receipt of commodities, the following checks are conducted:

- Quantities and product details (e.g. name of medical device, model if relevant, manufacturer, country of origin) are checked to ensure they match the documents provided. If any discrepancies exist, these should be brought to the attention of UNFPA PSB so that they can remedy the situation with the supplier.
- Condition of the devices is checked for any damage that might have occurred during transportation, handling and storage before inspection. Any observed anomalies should be reported to UNFPA PSB as soon as they are noted.

For Lots sourced from prequalified manufacturers that have undergone pre-shipment testing from an ISO 17025 accredited laboratory, UNFPA recommends post-shipment testing only on shipments when there is evidence that condom integrity was compromised during transport due to, for example, faulty storage or shipping conditions that are outside the Zone IV climatic conditions. Research indicates that condoms stored at average temperatures in tropical climates following the storage recommendations do not deteriorate during their claimed shelf-life. In the event that post-shipment testing must be performed, it should be carried out by an ISO 17025 accredited laboratory, with male and female condom testing within the scope of its accreditation in line with WHO/UNFPA specifications and the relevant ISO standard. As part of continuous monitoring efforts, countries are encouraged to utilize their post market surveillance systems to capture any adverse events.

2.1.5 Recommendations for Storage, Customs, and Transportation

UNFPA recommends that condoms be stored in cool,

dry places away from direct sunlight. Manufacturers that supply condoms to UNFPA are required to submit evidence to verify their shelf-life claims. This evidence includes real-time studies that are conducted at a specified temperature, which is the mean kinetic temperature of the most extreme climate in climatic Zones III and IV⁷.

To avoid compromising condom quality by storing them for excessive periods of time and delaying delivery, requirements for custom clearance should be communicated at the time of order placement. Condoms should be stored according to the recommended conditions during the customs clearance process. The cardboard storage containers that condoms are packed in are vulnerable to moisture and should be stored in a dry storeroom away from walls and placed on pallets to protect against rising damp. 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. Guidelines for male and female condom storage are provided in Chapter 8 of *Male Latex Condom: Specification and Guidelines for Procurement, 2010* and Chapter 10 of *Female Condom: Generic Specification, Prequalification and Guidelines for Procurement, 2012*.

Condoms should be left in their original cartons and inner boxes until distribution, unless these have been compromised at some point in the supply chain. Cartons should be positioned so that lot number and expiry date are visible, and released on a first expiry, first out basis (FEFO). Expired condoms or those not fit for use should be quarantined and disposed of in accordance with UNFPA's guidelines on *Safe Disposal and Management of Unused, Unwanted Contraceptives*.

2.1.6 Additional Lubricants for Use with Male and Female Condoms

Male and female condoms are normally sold pre-lubricated to make condom use more comfortable. The type of lubricant used with a condom is important as not all lubricants are safe to use with latex or the

⁷ Please refer to Annex I of the WHO Working Document: http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS06_179_StabilityGuidelineSept06.pdf

different types of materials used to make condoms. The wrong type of lubricating agent can weaken and damage the condom causing it to break or tear. UNFPA PSB adheres to the recommendations in the *WHO/UNFPA/FHI360 Advisory Note: Use and Procurement of Additional Lubricants for Male and Female Condoms* when procuring additional lubricants and is continuously working on initiatives to improve the supply of safe and quality assured lubricants with condoms.

2.2 Copper-bearing Intrauterine Devices

2.2.1 Introduction

Copper-bearing IUDs are long-acting reversible contraception methods and are included on WHO's Model List of Essential Medicines. UNFPA procures and prequalifies TCu380A IUDs. Like the male and female condom prequalification programmes, WHO has transferred the implementation of prequalification for copper-bearing IUDs to UNFPA. The most recent edition of the WHO/UNFPA TCu380A guideline document for procurers and programme managers outlines the procurement and prequalification requirements and processes: *TCu380A Intrauterine Contraceptive Device (IUD): Specification, Prequalification and Guidelines for Procurement*

Prequalification

UNFPA only procures prequalified IUD products that are sourced from manufacturing facilities that have successfully completed the prequalification process. This programme mirrors the prequalification processes that are conducted for female and male latex condoms. Sections 2.1.1 and 2.1.2 of this framework provide general information regarding WHO/UNFPA prequalification processes. Please refer to Figure 4 for a summary of the IUD prequalification steps.

During the prequalification process, products are sampled for testing by laboratories that have been selected through a competitive bidding process and have been deemed compliant with technical requirements, including IUD testing within the scope of the laboratories' ISO 17025 accreditation. Testing is conducted against WHO/UNFPA specification

requirements for TCu380A IUDs and ISO 7439, the standard for copper-bearing contraceptive intrauterine devices. For more information on the tests conducted during prequalification, please contact procurement@unfpa.org.

Manufacturers that have successfully completed the process are listed on the UNFPA and WHO websites and are eligible for supply to UN agencies. These lists are recognised as a requirement for bidding not only by UNFPA but also a number of public procurement bodies.

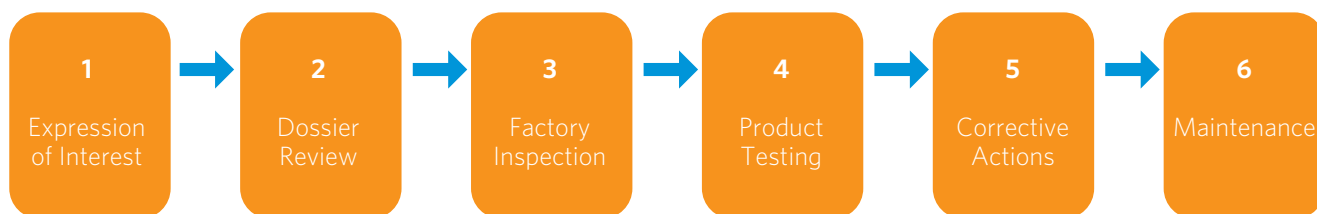
2.2.2 Quality Criteria for Procurement

UNFPA only procures IUDs that comply with the requirements of the most recent edition of the WHO/UNFPA Specification for TCu380A IUDs. This specification is developed to reflect buyer requirements for bulk procurement for the public sector. The specification is published together with a technical basis paper that provides evidence supporting specification requirements.

2.2.3 Quality Control: Pre-shipment Inspection and Testing

Good manufacturing practice requires manufacturers to perform quality control testing on products prior to release. Prior to shipment the IUDs can be inspected for compliance with the purchase specification in regards to labelling and marking as well as other purchase order requirements. Random Lots can be sampled for pre-shipment testing by laboratories that are ISO 17025 accredited with IUD testing within the scope of their accreditation. Testing shall be performed in accordance with the requirements of the WHO/UNFPA specification and includes parameters related to dimensions, performance, and packaging. It is recommended that inspection and testing be carried out in advance of the shipment to mitigate any delays and costs caused by non-compliant products.

Figure 4. IUD Prequalification Process



2.2.4 Quality Monitoring: Post-shipment Inspection

UNFPA recommends that on receipt of each shipment the physical condition of the boxes and IUDs, quantity of IUDs, and remaining shelf-life of IUDs be checked for compliance with buyer specifications.

It is important that, on receipt of commodities, the following checks are conducted:

- Quantities and product details (e.g. name of medical device, model if relevant, manufacturer, country of origin) are checked to ensure they match the documents provided. If any discrepancies exist, these should be brought to the attention of UNFPA PSB so that they can remedy the situation with the supplier.
- Condition of the devices is checked for any damage that might have occurred during transportation, handling and storage before inspection. Any observed anomalies should be reported to UNFPA PSB as soon as they are noted.

As part of continuous monitoring efforts, countries are encouraged to utilize their post market surveillance systems to capture any adverse events.

2.2.5 Recommendations for Storage, Customs and Transportation

Copper-bearing intrauterine devices are sterile commodities that should be properly stored to avoid contamination. IUDs should be stored in cool, dry places where they are protected against heat, sunlight, water and mechanical shocks. A requirement of prequalification is that manufacturers conduct stability testing to establish shelf-life that factor in high and low range temperatures that products may experience prior to use. The commodities should be stored in a manner in which the latest insertion dates are clearly visible. IUDs should be released from storage on a first expiry, first out basis. IUDs that have exceeded their 'latest insertion date' or those not fit for use should be quarantined and disposed of in accordance with UNFPA's guidelines on *Safe Disposal and Management of Unused, Unwanted Contraceptives*. While copper tarnishing does not affect the performance of IUDs, UNFPA only procures polymer film packaged IUDs to reduce the risk of tarnishing during storage.

2.3 Hormonal Contraceptives and Essential Reproductive Health Medicines

2.3.1 Introduction

UNFPA supports procurement of hormonal contraceptives and other pharmaceuticals included in the WHO Model List of Essential Medicines and in the National Essential Drugs Lists. The hormonal contraceptives procured by UNFPA are: oral hormonal contraceptives (including combined oral contraceptives, low-dose contraceptives and emergency contraceptives), injectable contraceptives and contraceptive implants. Other pharmaceuticals procured by UNFPA include medicines used for and to support sexual, reproductive and maternal health.

2.3.2 Quality Assurance Policy for RH Medicines and Quality Criteria for Procurement

Since the approval of the UNFPA QA Policy for RH medicines in April 2011, UNFPA has been following the stringent requirements stated in this policy. UNFPA QA Policy for RH medicines differentiates between the medicines that are invited to be assessed by the WHO prequalification programme, i.e. hormonal contraceptives; uterotonics and the rest of medicines that are not currently assessed by the WHO prequalification programme, and hence different evaluation procedures must be applied. Please refer to Annex I in this document for the complete list of RH medicines that are covered by the WHO Prequalification Programme. For all other medicines that are not eligible for WHO prequalification an internal QA system based on the Model QA system for procurers is implemented.

i. Assessment Process for Hormonal Contraceptives and Uterotonics

Please find below specific procedures applicable according to this classification:

UNFPA will only procure hormonal contraceptives that have

- Stringent Regulatory Authority (SRA) approval or
- WHO prequalified status or
- have been reviewed by the WHO Expert Review Panel for Reproductive Health Medicines (ERP/RHM) and listed as acceptable for procurement.

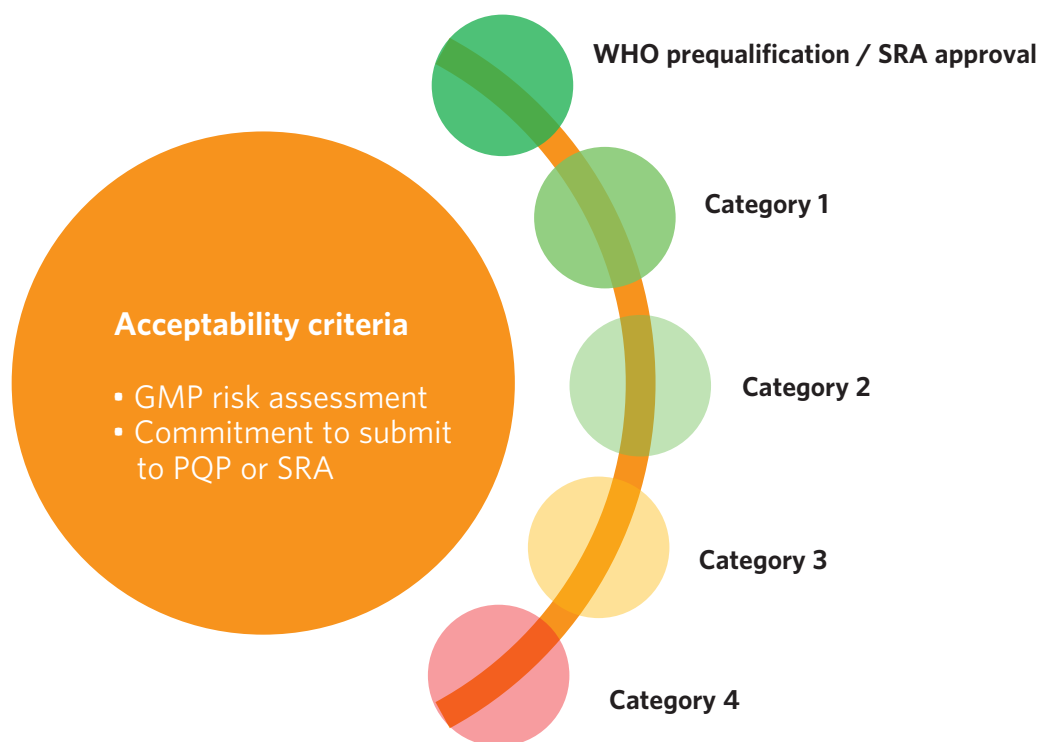
This QA criteria applies to hormonal contraceptives and other essential reproductive health medicines, i.e. oxytocin, misoprostol, mifepristone and magnesium sulphate.

The WHO Prequalification Programme for Medicines⁸ is a well-established process that has been in place for RH medicines since 2006, when the first expression of interest was published inviting manufacturers of these commodities to participate. It aims to make quality priority medicines available through its evaluation and inspection activities, in addition to building capacity for sustainable manufacturing and monitoring. The list of prequalified medicines has become a key tool for bulk procurement organisations, including UNFPA, at both country and international level. More information can be found in WHO's Prequalification Programme website: <http://apps.who.int/prequal/>.

The ERP/RHM is an independent technical body composed of external experts and hosted by WHO's Department of Essential Medicines and Health Products Quality and Safety of Medicines unit (WHO/QSM). The ERP/RHM mechanism has been designed as an interim mechanism that allows procurement of a product after having conducted a comprehensive assessment of its safety, efficacy and quality. The acceptability criteria for procurement as well as the different ERP risk categories are detailed in Figure 5. It is a risk assessment. There is a time limit for procuring medicines that receive risk category 1, 2 or 3 rating. After this period of time, the product can be considered for an extension for 12 months based on whether it has made substantial

⁸ For more information on the PQP of RH medicines see briefing "Who Prequalification of Medicines for RH", from 17 April 2012: http://apps.who.int/prequal/info_press/documents/RH_briefing-note_April2012.pdf

Figure 5. Expert Review Panel criteria and results



progress in relation to the PQP or SRA approval process. Medicines that have receive risk category 4 rating are never procured.

ii. Other Reproductive Health Support Medicines

In addition to the previously described contraceptives and essential reproductive health medicines, UNFPA procures a wide range of medicines aimed at supporting reproductive health-related interventions. These medicines include different categories, such as anaesthetics, analgesics, antiseptics, intra venous solutions and etc.

Medicines not included in the EOI for the WHO Prequalification of Medicines Programme will be assessed by a technical review process conducted by UNFPA. Manufacturers will be requested to submit information in the form of the Interagency Pharmaceutical Questionnaire, which includes information related to the following fields:

- Stability data
- Good manufacturing practice status⁹
- Pharmacopeia reference
- Quality assurance regarding the active pharmaceutical ingredient (API)
- Bio-equivalence
- Registration status/manufacturing site certifications
- Packaging/labelling

The information provided is evaluated based on a risk assessment system. In addition to this assessment, additional GMP inspections are conducted where deemed necessary to complement the information provided by the manufacturer.

⁹ For more information, refer to WHO Technical Report Series No. 961 Annex 3: http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex3.pdf.

2.3.3 Quality Control: Pre-shipment Inspection and Testing

Good manufacturing practices requires manufacturers to perform internal quality control testing on finished products prior to their release to the market. UNFPA conducts pre-shipment inspections of RH medicines through independent inspecting agents.

These pre-shipment inspections are conducted on randomly selected shipments.

Specifically for ERP recommended medicines, a quality control testing is conducted by an independent, WHO prequalified quality control laboratory. This pre-shipment testing assures that the product does comply with the standards applied by UNFPA. An independent inspection agency is in charge of collecting the samples that are sent for testing to an independent prequalified laboratory. This process is in addition to the manufacturer's own quality control testing and is conducted prior to the release of the medicines from the manufacturer's facilities.

2.3.4 Quality Control: Post-shipment Inspection and Testing

Recipients may conduct post-shipment testing as part of their regulatory requirements. UNFPA encourages recipients to engage the services of a WHO Prequalified Laboratory or an ISO 17025 certified laboratory for analysis of medicines.

UNFPA has processes in place to manage potential non-conformances and deviations to ensure that any non-conformities are documented and, where applicable investigated and tracked. The information from the tracking report is then used to guide continuous improvement on the part of UNFPA and the suppliers.

2.3.5 Recommendations for Storage, Customs and Transportation¹⁰

Medicines are very sensitive commodities that need to be carefully handled in order to avoid changes in the

quality, safety and/or efficacy of the final product that is administered to/consumed by the public.

Regarding transportation and storage – and unless dealing with special condition items in terms of temperature – all pharmaceuticals must be kept under 25°C and a relative humidity of no more than 60%. Special conditions must apply in case stability has been proven, assessed and found acceptable for other conditions.

¹⁰ For more information, refer to WHO Technical Report Series No. 908 Annex 9: http://apps.who.int/prequal/info_general/documents/TRS908/WHO_TRS_908-Annex9.pdf.

2.4 Medical Devices – Medical Equipment, Consumables and Kits

2.4.1 Introduction

A medical device¹¹ is defined as: an article, instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article intended by the manufacturer to be used alone or in combination, for human beings for one or more of the specific medical purposes of diagnosis, prevention, monitoring or treatment of illness or disease or for control of conception, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. The purpose of the medical device is not achieved by pharmacological, immunological or metabolic means.

Medical equipment¹² is defined as: medical devices that require calibration, maintenance, repair, user training and decommissioning. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

UNFPA procures medical devices and equipment, including consumables or supplies, for RH procedures.

In support of reproductive health and maternal health programmes and services, UNFPA procures medical devices and medical equipment in the following categories: medical and surgical instruments; diagnostic; laboratory; medical electrical; anaesthetic; sterilisation; medical renewable supplies; medical attire; and medical utensils. A full list of commodities can be found in the [UNFPA catalogue](#). In collaboration with partners, UNFPA has developed Inter-agency Reproductive Health Kits for use in crisis situations. These kits have been designed to facilitate the provision of priority reproductive health services to displaced populations

¹¹ As defined by the Global Harmonization Task Force, 2012 (http://www.ghtf.org/documents/sg1/sg1final_n071.pdf)

¹² As defined in the WHO Medical Device Technical Series 2011.

without medical facilities, or where medical facilities are disrupted during a crisis. They contain essential medical equipment and supplies and medicines to be used for a limited period of time and a specific number of people. The full list of the various kits is provided in Annex II of this document.

In addition, UNFPA, following input from health care professionals and other experts, has compiled a number of standardised surgical sets for sexual and reproductive health procedures. Because quality is crucial to UNFPA, efforts are made to ensure, that the medical devices provided to relevant countries are safe and of good quality in line with international standards and WHO guidelines. For details of the technical requirements, refer to the UNFPA technical requirements for medical devices.

2.4.2 Quality Criteria for Procurement

To ensure safety and technical performance, UNFPA adheres to a set of technical requirements and processes that are in line with international quality standards for medical devices. The following guiding principles are in effect:

- Medical devices that are included in the UNFPA catalogue must have successfully undergone a competitive bidding process, which includes a technical evaluation with specifications and a review of all documents referred to in the technical requirements outlined below. UNFPA may request that samples of devices be sent for evaluation or such devices may be inspected at suppliers' facilities.
- Commodities should be sought from experienced suppliers who meet the technical requirements and other contractual considerations for medical devices.
- UNFPA follows WHO guidelines and recommendations on management of medical devices, and requirements and standards recommended by the Global Harmonization Task Force (GHTF, now under the International Medical Device Regulatory Framework: www.imdrf.org); manufacturers and products must, therefore, meet these requirements. These requirements cover safety, performance, quality, packaging and labelling.

The following technical requirements apply and are assessed during the bid evaluation process:

- Valid manufacturing licences.
- Quality management systems that conform to ISO 9001 and/or ISO 13485. These should be supported with valid copies of certificates.
- Complete technical specifications for the product that meet UNFPA's specifications. These should be accompanied by product data sheets or detailed specifications.
- Declaration of conformity to the relevant product specific standards, if relevant.
- Proof of product specific approvals and certifications, e.g. CE mark or equivalent, relevant ISO certifications.
- Operating manuals, installation guides and maintenance manuals should be provided in three languages (English, French and Spanish).
- Product samples sent to UNFPA for review or reviewed on site should be labelled and packaged in the same form as they will be supplied to end users.
- Certain types of medical devices will be sent by UNFPA for laboratory testing. The test results will be included in the overall outcome of the evaluation process.

2.4.3 Quality Control: Pre-shipment Inspection and Testing

All purchase orders for medical devices currently undergo pre-shipment inspection by an independent inspection agency that has been contracted by UNFPA. Pre-shipment inspection involves:

- Visual inspection of shipping cartons and product packaging and labelling to ensure that they are in accordance with requirements agreed with the supplier.
- Verification that medical devices are being supplied from the approved manufacturers.
- Verification that quantities are accurate and the products meet the agreed specifications as per the established LTA and purchase order.

2.4.4 Quality Monitoring: Post-shipment Inspection and Testing

It is important that, on receipt of commodities, the following checks are conducted:

- Quantities and product details (e.g. name of medical device, model if relevant, manufacturer, country of origin) are checked to ensure they match the documents provided. If any discrepancies exist, these should be brought to the attention of UNFPA PSB so that they can remedy the situation with the supplier.
- Condition of the devices is checked for any damage that might have occurred during transportation, handling and storage before inspection. Any observed anomalies should be reported to UNFPA PSB as soon as they are noted.
- As part of continuous quality monitoring, PSB encourages recipients to report any quality related issues using the medical device feedback form in Annex III.

2.4.5 Recommendations for Storage, Customs and Transportation

Poor storage conditions can adversely affect medical devices. Manufacturers' recommendations on storage and handling during transportation should always be followed. The following conditions should be upheld through transportation, storage and usage of medical devices:

- Avoid wet or dirty storage conditions or direct exposure to climatic elements.
- Avoid temperature or humidity that is outside the ranges indicated by the manufacturer or the relevant international standard.
- Prevent and refrain from poor stacking that may cause physical damage.
- Clearly mark storage areas to prevent mixing of contaminated, damaged, recalled or for disposal devices.
- Establish a system for sorting of sterile items so that 'Use by' or 'sterilisation' dates are not exceeded.

2.5 Considerations for Customs Clearance

Requirements for custom clearance should be communicated at the time of order placement. The UNFPA procurement team ensures that all documentation needed to clear customs according to national requirements is available when a shipment arrives.

It is advised that customs clearance be expedited in a timely manner to prevent unnecessary exposure of RH Commodities to unsuitable storage, handling and management conditions. This also prevents escalating costs resulting from port storage charges, container demurrage and possible loss due to theft. Customs clearance regulations differ from country to country and UNFPA works with relevant countries to ensure compliance. UNFPA encourages local parties to inform UNFPA of any changes in customs requirements to facilitate a smooth supply chain process that enables the public to have access to quality medicines at the right time. Each shipment from UNFPA will be dispatched with the following documents to facilitate customs clearance:

- Bill of lading for sea freight or air way bill for air freight
- Invoice including freight invoice
- Packing list or delivery note
- Certificate of origin
- Cargo tracking note
- Certificate of Analysis if applicable

Part Three: Additional Information and Resources

The screenshot shows the top navigation bar of the AccessRH website. It includes links for CONTACT, NEWS, SEARCH, and language options (English, Francais, Español). There are also buttons for LOG IN and REGISTER. Below this is the AccessRH logo and a secondary navigation bar with links for About us, Products, Plan, Order, and RHInterchange. The main content area features a banner titled "Access to Reproductive Health Supplies Starts Here" with two sections: "RHInterchange" and "Access Supplies".

Access to Reproductive Health Supplies Starts Here

RHInterchange The most comprehensive source of information on contraceptive orders for more than 140 countries around the world.

Review historical and current orders for your country or region
Données des livraisons vers votre pays ou région
Aquí puede **revisar** los envíos para su país o región

Access Supplies Tools, documents and instructions for ordering reproductive health products.

Plan for your supply needs
View the interactive AccessRH product catalog.
Order direct from UNFPA

3.1 Ordering RH Commodities through UNFPA

UNFPA Procurement Services Branch provides procurement services for clients such as governments and ministries, NGOs and UN agencies, through AccessRH. AccessRH is a service that offers easy access to UNFPA quality assured commodities. The online catalogue has products that have been quality assured and prices that have been pre-negotiated. It also has access to updated information for planning and tracking orders. <http://www.MyAccessRH.org/products>

3.2 Guidelines and Further Reading

Below is a selection of readings and guidelines that have been useful in developing this framework.

The guidelines also provide recommendations on appropriate quality assurance measures that can be integrated within existing procurement practices for RH commodities.

3.3 Complaints

Complaints concerning products procured through UNFPA will be investigated accordingly.

For answers to any questions about the Quality Assurance Framework or complaints on any quality related issues, please email: procurement@unfpa.org

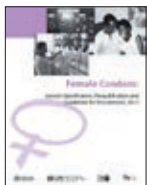
Please include the UNFPA Purchase Order number and Batch number, if applicable.

Resources



Title: *Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010 – Revised April 2013*

Summary: Describes the key elements of male condom quality assurance including the prequalification process and operational guidance for manufacturers on applying for prequalification. The guidelines are also available in Spanish and French.



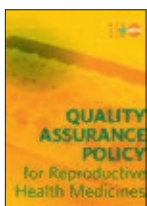
Title: *Female Condom: Generic Specification, Prequalification and Guidelines for Procurement, 2012*

Summary: Details the WHO/UNFPA scientific and technical requirements for the prequalification of female condoms for bulk procurement, including the clinical investigation requirement that female condom designs be approved for technical review.



Title: *TCu380A Intrauterine Contraceptive Device (IUD): Specification, Prequalification and Guidelines for Procurement, 2010*

Summary: Describes the key elements of Copper T 380A intrauterine device quality assurance, including the prequalification process and operational guidance for manufacturers on applying for prequalification.



Title: *Quality Assurance Policy for Reproductive Health Medicines*

Summary: Following international quality standards and supported by WHO and other organisations, UNFPA has developed a quality assurance policy for hormonal contraceptives and other medicines wherein the prequalification process is of greatest importance.



Title: *Post-Shipment Testing of Male Condoms*

Summary: Statement on UNFPA's policy on post-shipment testing. Describes pre-shipment and post-shipment testing and identifies the disadvantages of implementing post-shipment testing of condoms procured by UNFPA.



Title: *Safe Disposal and Management of Unused, Unwanted Contraceptives*

Summary: Provides recommendations on policies and procedures for the responsible management and safe disposal of unusable and unwanted condoms, copper-bearing IUDs and hormonal contraceptives.



Title: *UNFPA Green Procurement Strategy*

Summary: Specific environment goals are described in this strategy. It outlines the environmental focus areas for which UNFPA would like to set up requirements.

Please visit the Quality Assurance section on UNFPA's website to access the most recent version of the above documents.

Link: <http://www.unfpa.org/public/home/procurement/pid/10863>

3.4 Glossary

Lot

Also referred to as a 'batch', a quantity of a single grade, class, size and composition, manufactured under essentially the same conditions. The word "Lot" is capitalized to emphasize that it is the technical term for a batch of condoms and to distinguish it from " a lot" meaning "many".

Post Market Surveillance

A broad term that covers monitoring activities, including the vigilance system for medical device in use

Prequalification

Steps taken by the buyer to verify a manufacturer's suitability to provide products of the required quality. The WHO/UNFPA Prequalification Programmes include periodic assessment of manufacturing dossiers, testing of samples and factory inspection. Prequalification enables a manufacturer and their product to be eligible to bid for a UN contract, but does not guarantee a contract

Shelf-life

The period of time after manufacture that the product is considered acceptable for use

Specification

A detailed statement of a product's requirements as established by the requester. Usually, a specification is based on an established standard

Standard

A detailed statement of the minimum acceptance requirements, as established by a national or international regulatory authority

Stringent Regulatory Authority

Stringent regulatory authority (SRA): a regulatory authority which is: (a) a member of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (as specified on www.ich.org); or (b) an ICH observer, being the European Free Trade Association (EFTA), as represented by Swissmedic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time).

Annex I: List of Medicines Included Under the Hormonal Contraceptives and RH Medicines EOI for WHO PQP

The list of medicines included under hormonal contraceptives and reproductive health medicines referred to in this framework are as follows. These medicines are included in the WHO Prequalification Programme based on public health needs and the ERP/RHM process.

1. Oral hormonal contraceptives

- Ethinylestradiol + desogestrel, tablet 30 mg + 150 mg
- Ethinylestradiol + levonorgestrel, tablet 30 mg + 150 mg
- Levonorgestrel, tablet 30 mg
- Levonorgestrel, tablet 750 mg (pack of two); 1.5 mg (pack of one)
- Norethisterone, tablet 350 mg
- Norgestrel, tablet 75 mg

2. Injectable hormonal contraceptives

- Medroxyprogesterone acetate, depot injection 150 mg/ml, in 1-ml vial
- Medroxyprogesterone acetate + estradiol cypionate, injection 25 mg + 5 mg

- Norethisterone enanthate, injection 200 mg
- Norethisterone enanthate + estradiol valerate, injection 50 mg + 5 mg

3. Implantable contraceptives

- Two-rod levonorgestrel-releasing implant, each rod containing 75 mg of levonorgestrel (150 mg in total)
- Etonogestrel, implant, 68 mg of etonogestrel

4. Oxytocics

- Oxytocin, injection 10 IU, 1 ml
- Mifepristone 200 mg tablet (only to be used in combination with misoprostol)
- Misoprostol 200 mg tablet

5. Prevention and treatment of eclampsia

- Magnesium sulphate, injection 500 mg/ml, in 2-ml and 10 ml ampoule

Annex II: List of Emergency Reproductive Health Kits

For more information about the contents of these kits, please refer to the **Inter-Agency Reproductive Health Kits for Use in Crisis Situation Manual**

http://www.unfpa.org/webdav/site/global/shared/procurement/06_for_customers/02_gccp-erhkits/RH%20Kits%20Manual%202011.pdf

| | | Colour code |
|--------|--|-------------------|
| Kit 0 | Administration/training supplies | Orange |
| Kit 1 | Condoms (A and B) | Red |
| Kit 2 | Clean delivery, individual (A and B) | Dark Blue |
| Kit 3 | Post-rape treatment | Pink |
| Kit 4 | Oral and injectable contraception | White |
| Kit 5 | Treatment of sexually transmitted infections | Turquoise |
| Kit 6 | Clinical delivery assistance (A and B) | Brown |
| Kit 7 | Intrauterine devices (IUDs) | Black |
| Kit 8 | Management of miscarriage and complications of abortion | Yellow |
| Kit 9 | Suture of tears (cervical and vaginal) and vaginal examination | Purple |
| Kit 10 | Vacuum extraction delivery | Grey |
| Kit 11 | Referral level kit for reproductive health (A and B) | Fluorescent green |
| Kit 12 | Blood transfusion kit | Dark green |

Note: Kits include medical devices, renewable consumables and medicines.

Annex III: Medical Device Feedback Form

This form is to provide feedback to UNFPA on the type, functionality, performance, condition and quality of medical devices UNFPA has provided to you in order to improve on the type and quality of next supplies.

Please provide the following either for a particular product or group of products you have recently received from UNFPA and have some feedback based on your experience during use or receipt of the medical device(s) in the past 12 months.

Type of product:..... or Product group

Product name: or Model (if applicable)

Batch/Serial/Batch no. (if applicable).....

Manufacturer or supplier (if known)

Date received or year received:..... PO number(if known)

1. Was product received in good condition: Yes No
If No, please give details.....

2. Was it the correct medical device requested: Yes No

3. Was installation/assembly required: Yes No

4. If installation/assembly was required, was sufficient and appropriate information provided to enable safe installation/assembly? Yes No

If No, please explain:
.....
.....

5. Any problems during use: Yes No
If Yes, please explain:

6. Was training provided to use the equipment: Yes No N/A

7. Any support required with maintenance: Yes No N/A

8. Any quality related problems: Yes No

If Yes, please explain and include all information that will improve on better quality:
.....
.....

9. Suggestions for improvement on medical device(s) being provided by UNFPA (specifications, maintenance, spare parts, training etc):
.....
.....
.....



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