Quality Reproductive Health Medicines & Contraceptive Devices: 2018 Annual Meeting of Procurers
I. INTRODUCTION

The annual meeting of procurers is a unique global forum driving the agenda of quality-assured reproductive health (RH) medicines and contraceptive devices. 2018 marked the seventh year the group has met, with discussions ranging from the financial challenges of investing in quality RH commodities to procedures for reporting, tracking and resolving quality complaints, to building a culture of quality that ensures quality along the entire life-cycle of a product, from production to distribution, storage, and use.

Since the group first met in 2010, the number of quality-assured reproductive health (RH) commodities on procurement lists has grown steadily, and practical, collaborative efforts are being taken to harmonize quality assurance policies, promote the procurement of generic products, and tackle the challenges generic manufacturers face in bringing affordable quality products to new markets.

As in past years, global funding for contraceptive supplies and other RH products is under strain while the need for these commodities in low- and middle-income countries remains high. Procurers and donors were once again faced with the need to identify effective — and cost-effective — ways to close the supply gap and make high-quality products available to all.

Meeting overview

In his welcome remarks, Eric Dupont, Chief, Procurement Services Branch UNFPA, commended the group for its long-standing commitment to quality and harmonizing quality policies, and pledged UNFPA's continued support for hosting this forum and working as a partner to improve quality-assured RH commodities, harmonize quality policies, and increase uptake of generic medicines—a priority for UNFPA.

The meeting began with a report on the progress on 2017 action items, including efforts to share information on the procurement of maternal health medicines (Concept Foundation), improving communication on quality issues (UNFPA), providing regulatory support to FP2020 priority countries (WHO, UNFPA, USAID), and sharing information to support generics (USAID). More detail on these efforts are provided in the following pages.

Participants heard updates on the WHO Prequalification Programme for RH medicines and the UNFPA Prequalification Programme for Condoms and IUDs, which continue to build capacity for the manufacture and registration of RH commodities. UNFPA and USAID reported on efforts to scale up access and uptake of more affordable generic medicines, and UNICEF and Médicins sans Frontières (MSF) described the challenges quality assurance (QA) teams face in balancing quality and price.

A highlight of the meeting was hearing the results of innovative research and initiatives that are ushering important new RH products into the market, providing insights into the effects of temperature fluctuations on condom quality during shipment and storage, and introducing a more efficient and cost-effective risk-based approach to monitoring condom quality. One of the most positive updates was of the WHO CHAMPION clinical trial of heat-stable carbetocin for the prevention of post-partum hemorrhage (PPH), which would provide an alternative to shipping oxytocin in the cold chain. The product is now on the path to WHO Prequalification and may become available in low- and middle-income countries by 2020.

This report captures the progress made on 2017 action items, presents the findings of recent research, spotlights new initiatives and innovations, and details the nine action items that will be pursued over the next year.
II. PROGRESS ON 2017 ACTION ITEMS

1. Improving communication on quality issues (UNFPA)

Progress
At the last meeting, UNFPA committed to hold monthly virtual meetings with QA experts from various organizations. Although just one virtual meeting was held, there has been regular monthly communication on quality issues and harmonization efforts.

Progress has been made with discussions on quality alerts, oxytocin and the supply chain (it was agreed that oxytocin should be shipped through the cold chain regardless of the price difference), and the removal of Bayer’s Levonorgestrel 0.15mg + Ethinylestradiol 0.03mg with ferrous fumarate, Microgynon®, from the WHO Prequalification list, which generated intense debate on the availability and access of a generic product, but it was decided that the product should be removed from the UNFPA product catalogue once it is no longer WHO prequalified. UNFPA is working with Bayer in the transition phase to avoid sending mixed messages on quality.

The group also addressed the lack of clear quality policies among donors. Without a clear quality policy, a donor’s primary concern becomes value for money, with quantity trumping quality. This year the group worked to raise awareness that donors either need to adopt another organization’s quality assurance policy or create their own. A questionnaire on quality policies was sent to donors and global procurers, and the group promoted the quality message at the Maternal Health Caucus (tech team) and hopes to gain traction with the Interagency Pharmaceutical Cooperation Group (IPC) this year on the quality versus price debate.

2. Sharing information to support generics (USAID)

Progress
Over the last year, USAID has made a concerted effort to work with generic manufacturers, strengthen collaboration and communication on generics, and add more generic products to its product catalogue, including PCs, oral contraceptives, and the Levo implant. To avoid duplication, it has worked closely with UNFPA on approved vendors for IUDs (it will adopt this list as its supplier base), piggybacked on WHO’s testing for implants, and shared its technical review questionnaire for personal lubricants with UNFPA.

Challenges
As USAID has engaged more with generic manufacturers, it has had some difficulty getting samples for testing and communication has not always been fluid. However, this is improving as relationships with new vendors develop and they learn the quality requirements.

Progress by the numbers
Generics are delivering value for money
In the last 4 years, UNFPA has saved over $2.4 million, with the biggest savings in 2017.

These savings have the potential to provide an additional 800,000 women with generic combined low-dose oral contraceptives for 1 year (9.6 million cycles).
3. Collaboration to provide regulatory support to FP2020 priority countries
(WHO, UNFPA, USAID)

**Progress:** Over the last year, the WHO has supported several regional economic groups with joint assessments and the Collaborative Registration Procedure (CP). Work continues with the East African Community (EAC) and ZaZiBoNa, and traction is expected in the Economic Community of West African States (ECOWAS), where work began in October 2017.

**Challenges:** When manufacturers respond to tenders, it is not known where the product is needed, making it difficult to prioritize which products to register and where. Once the tender is won, timelines for delivery may not support quick registration. UNFPA, WHO, and USAID all collect and share registration information with manufacturers, but this is a fluid process and it is not known which registrations have expired or are up for renewal.

It was agreed that WHO, procurement agencies, regulators and manufacturers need to work together to understand the supply chain, regulatory cycle and the mechanisms that are in place to supply products (sometimes in small quantities).

**Next steps**

**A registration database?**
Creating a consolidated, standardized, joint process to submit priority products, report existing registrations, and identify country needs would help to avoid duplication, expedite registration, and allow manufacturers to better prepare for it.

Over the last year, USAID has been working on a way to close this information gap and consolidate registration data, perhaps in the form of a registration database.

The project is currently in the brainstorming stage, but USAID wanted to expand the discussion to participants at the meeting and will continue to work closely with FHI360 to determine the right platform.

*See Action Item #1, page 12*

4. Sharing information on the procurement of maternal health medicines
(Concept Foundation)

**Progress:**
At last year’s meeting, Concept Foundation encouraged participation in an institutional questionnaire to map the procurement landscape for heat-stable carbetocin. Eleven institutions responded, including UN agencies, international wholesalers, and INGOs. Since then, CF has collected information from a range of procurers to determine the role of international procurers in purchasing uterotonic and other maternal health medicines (MHMs).

**Findings & Recommendations**

**Procurement of MHMs is highly fragmented.** MHMs are procured primarily by governments in LMICs, either directly from manufacturers or public sector wholesalers.

**Purchasing by international procurers is very limited** and, in a range of countries, MHMs come primarily from four agencies.

**The quality of MHMs in LMICs needs to be improved.** International procurement agencies and wholesalers could play a bigger role.

**Market competitiveness is a major barrier for manufacturers** pursuing new markets and significant advocacy on quality is required.
Updates on the prequalification of RH commodities

Medicines

The WHO PQ Programme will stay
The WHO’s 13th General Programme of Work, 2019–23 recognizes the PQ Programme as a stamp of quality and point of reference for UN, international, regional and national procurement.

Time to PQ
Although WHO time to PQ has hovered around 200 days since 2013, manufacturer time remains high. To speed up the process, WHO has made pre-submission meetings mandatory for all new applicants, introduced strict response timelines (30, 60, 90 days), provided additional guidance on common deficiencies in FPP dossiers, and delivered training for manufacturers.

Better support for RH manufacturers
Reduced stability data requirements have been removed at submission.

New SRA definition
Expert committee has replaced ‘SRA’ with ‘WHO-Listed Authority’, which will be grandfathered in.

Good response to new fee structure
More than 95 percent of fees have been received and there has been no apparent impact on the number of applications received.

Prequalification of RH Medicines

43 The number of PQ RH medicines has risen from 8 in 2009 to 43 in May 2018.

The Collaborative Registration Procedure is working
299 registrations
35+ countries
85 days to registration (median timeline)

Condoms & IUDs

New Male Latex Condom Specification
UNFPA has removed the procurement guidelines so it is now a stand-alone technical specifications document.

Quality complaints
One quality alert was published on the UNFPA website and the manufacturer was removed from PQ list. The complaint has since been addressed and the manufacturer reinstated.

PQ funding after 2020
With funding ending in 2020, manufacturers have been identified as a source of funding and will gradually contribute to 100 percent of costs.
Traditionally, international procurement agencies have relied on pre-shipment testing to monitor the quality of condoms, but at a time when resources are shrinking and products often need to be shipped quickly to avoid stockouts, is it adding value?

UNFPA and USAID have been trying a different approach. With the assistance of Bill Potter from Stapleford Scientific Service, Ltd., they have been working to implement a risk-based, private industry-style approach to managing condom quality. Under this system, manufacturers with a proven quality record can test smaller sample sizes from every lot and test a random selection of lots (skip lot testing) except FFH and those with visible defects.

Manufacturers are assessed at three levels: Approved, Qualified, and Certified, each of which carries minimum requirements, such as years of PQ status and number of lots shipped. USAID has approved all its suppliers at the Qualified level and is now working to approve manufacturers at the Certified level.

Qualified manufacturers must maintain the following quality and delivery levels:

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<thead>
<tr>
<th></th>
<th>Freedom from Holes</th>
<th>Freedom from Visible Defects</th>
<th>Burst Properties</th>
<th>Package Integrity</th>
<th>Dimensions, Packaging &amp; Lubricant Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Permitted Process Average (%)</td>
<td>0.1</td>
<td>0.2</td>
<td>0.5</td>
<td>1.0</td>
<td>0.07</td>
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</table>

Certified manufacturers must maintain the following quality and delivery levels:

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<tr>
<th></th>
<th>Freedom from Holes</th>
<th>Freedom from Visible Defects</th>
<th>Burst Properties</th>
<th>Package Integrity</th>
<th>Dimensions, Packaging &amp; Lubricant and quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Permitted Process Average (%)</td>
<td>0.02</td>
<td>0.1</td>
<td>0.3</td>
<td>0.2</td>
<td>0.1</td>
</tr>
</tbody>
</table>

A risk-based approach can deliver big benefits, such as faster response time, greater flexibility to respond to changes in demand, and a cost savings of 20 to 30 percent from reduced testing. It also provides an incentive for manufacturers to maintain and improve quality as they can ship products faster, reduce inventory and keep storage costs low.

Deusedit Mubangizi of WHO committed to promote this guidance and offered strong support for this risk-based approach:

“This is a strong incentive for people to work toward quality, which is good for all of us in the long run. It should be popularized, driven by data.”

Next steps

UNFPA and USAID are working to roll out this system as soon as possible to organizations like PSI, in-country labs, and Ministries of Health, but need to address some final issues to ensure the system is extremely robust.

A technical report series is planned, which will include technical specifications for manufacturers as well as plain language and advocacy documents.
2. Temperature monitoring of condom shipments (UNFPA)

One potential risk to the quality of RH commodities is exposure to extreme temperature conditions during shipping and customs clearance, particularly when products are being shipped between manufacturers and destination sites in countries with hot climates.

Condoms stored outdoors in shipping containers are particularly vulnerable, as the temperatures inside can be substantially above ambient temperatures, resulting in faster deterioration. Collecting condom shipment temperature data can help to avert this risk and minimize the losses incurred by the receipt of damaged goods.

Methodology

Five countries in climatic zones III and IV were targeted for the study: Uganda, Nigeria, Kenya, Zimbabwe, and Ethiopia. Temperature conditions of condom shipments were electronically monitored from the supplier’s warehouse to the final destinations, in this case in Uganda and Nigeria.

The temperature loggers were activated at the manufacturing site, where they were placed in cartons and on the top, middle, and bottom of containers. A reading was taken every 15 minutes. When the shipment arrived, the recipient (regulators or others) sent the data to UNFPA. The acceptable mean kinetic temperature (MKT) range is 28 to 35 degrees, within which condom quality would probably not be affected, but more information is needed.

Findings

In Uganda, there were temperature spikes at ports (40 to 45 degrees Celsius) and more stable temperatures at sea (25 to 30 degrees Celsius) and when the shipment arrived at warehouses (20 to 25 degrees Celsius).

The impact of temperature excursions on the properties of some products can be difficult to assess without additional testing. With male condoms, for example, temperature excursions may cause unexpected increases in hole levels or changes in burst volumes. Storage time in containers should therefore be minimized.

Next steps

Countries will be informed of the test results and the data will be presented to the ISO TC 157 Committee in September 2018. Follow-up testing may be conducted on selected lots to assess the impact of shipping conditions on the products. Unfortunately, the follow-up study was not approved for funding, but UNFPA will look for cost-effective ways to continue the research and share the results. It is hoped that the temperature monitoring project will ultimately extend to other RH commodities as well.
3. WHO CHAMPION trial of heat-stable carbetocin  
(WHO, Merck for Mothers, Ferring Pharmaceuticals, Concept Foundation)

In 2013, Ferring Pharmaceuticals, WHO, and MSD for Mothers established a collaboration to improve maternal health. Carbetocin was identified as having the potential to fulfil the unmet medical need in low- and middle-income (LIC/LMIC) countries of a heat-stable uterotonic for the prevention of PPH. A Phase 3 trial has been conducted in 10 countries with 29,655 women to assess the effectiveness and safety of heat-stable carbetocin versus oxytocin, which must be shipped through the cold chain.

Results
Stability data was encouraging and the formulation was not sensitive to freezing or light in its primary container.

The expected label claim for Carbetocin Ferring for LIC/LMIC countries is to store below 30°C and a shelf life of at least 36 months.

Next steps
1. Ferring will obtain WHO Prequalification and register carbetocin in an agreed list of LIC/LMIC countries with a high burden of maternal mortality.
2. WHO will consider inclusion of heat-stable carbetocin in its PPH prevention clinical recommendation and EML on the basis of the CHAMPION results.
3. The partners will work together to make the medicine available in the public sector of LIC/LMIC countries at an affordable and sustainable price.
4. The objective is to begin introducing carbetocin in LIC/LMIC countries in 2020.

CHAMPION partners will work together to make an affordable and sustainably priced heat-stable carbetocin available in low- and middle-income countries in 2020.

4. Brand Recognition Study (USAID)

In 2017, McKinsey conducted a multi-country study for USAID that found there was minimal disruption in the public health sector in the shift from Bayer to a generic product.

A presentation of the research findings is ready and will be shared with the procurers group.

The shift from a well-known brand to a generic product was found to cause minimal disruption in the public health sector.
Building a culture of quality

From poor manufacturing conditions and counterfeit products to inadequate transportation, distribution, and storage, low-quality medicines and medical devices are finding their way into many markets.

This can have a terrible cost: 116,000 additional deaths from malaria in Sub-Saharan Africa could be caused each year by low-quality anti-malarials, and the effects of defective, unsterile, or poor quality IV catheters or diagnostic tests can cause problems ranging from patient discomfort to life-threatening conditions. Ultimately, cheaper RH commodities end up being more expensive in the long run.

How do we build quality into products and our organizational cultures?

Regulatory systems are being strengthened, but more needs to be done, namely:

- Improving the quality and production of medicines and medical devices;
- Facilitating access to affordable quality commodities;
- Ensuring procurement decisions are guided by a robust quality assurance policy; and
- Having clearly defined procedures in place that separate decisions about quality from commercial considerations.

“You have to build quality into a product, not test for it.”

– Aiteno Ojoo, UNICEF
IV. NEW PARTNERSHIPS & RESOURCES

Afro-Condom Network
UNFPA has established a network of national laboratories and regulators in Sub-Saharan Africa modelled on the African Vaccines Regulatory Forum (AVAREF) to discuss technical issues and share information. Where possible, UNFPA will facilitate information sharing and experiential learning across national regulatory agencies (NRAs). It is just getting started, but Zimbabwe, Zambia, Nigeria, Uganda, Ghana, and Ethiopia are already onboard.

Engaging the Private Sector
The Reproductive Health Supplies Coalition (RHSC) has a new Manufacturers Group that has met once in person and is now meeting virtually on a quarterly basis. The Private Sector Condom Group (PSCG) participated in the Condom Working Group Meeting organized by the Gates Foundation in May 2018 and will meet at the next meeting of the 20 by 20 initiative in September 2018 in Bangkok.

Global Contraceptive Commodity Gap Analysis
Updated in 2018, the new version projects growth in contraceptive use over the next three years, providing new information on the volume and cost of contraceptive supplies that will be needed in LMICs. It projects there will be 493 million users of contraception by 2020, 337 million of whom will live in the 69 FP2020 countries, and that supply volumes will increase nearly four times, creating a significant funding gap.

“Buy Quality Oxytocin, Keep it Cold!”
This new RHSC Maternal Health Caucus publication provides advocacy messages for purchasing high-quality oxytocin and shipping it within the cold chain. UNFPA has taken on this messaging and promoted it through a new infographic.

Next Annual Meeting of Procurers

The 2019 procurers meeting will be held in Copenhagen, either before or after the ISO/TC157 meeting. In 2020, the meeting may be held in conjunction with the ISO/TC157 meeting in Bangkok.

## V. ACTION ITEMS for 2018–19

<table>
<thead>
<tr>
<th>ACTION ITEM</th>
<th>RESPONSIBLE</th>
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<tbody>
<tr>
<td><strong>1. Create a consolidated registration database</strong></td>
<td>USAID</td>
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<tr>
<td>Registration requirements are driven by individual countries. UNFPA, USAID, and other agencies already collect information on national legal and technical requirements and which products are registered in which countries, but this information is fragmented and often outdated. Bringing this information together into one registration database and making it visible to procurers and manufacturers will help them understand the gaps and opportunities in different markets and lower barriers to access. <strong>Next steps:</strong> USAID has already begun work on a registration database and will engage with meeting participants to continue the process and determine the right platform.</td>
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<tr>
<td><strong>2. Promote harmonized registration</strong></td>
<td>WHO with support from Reproductive Health Supplies Coalition (RHSC)</td>
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<tr>
<td>Regional economic authorities are driving efforts to harmonize, and WHO has been working closely with the EAC, SADC, and WAEMU to simplify and harmonize registration requirements. Africa is moving toward establishing a single medicines agency, which would ultimately consolidate registration requirements. A draft treaty will be discussed at the upcoming World Health Assembly.</td>
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<tr>
<td><strong>3. Identify registered products</strong></td>
<td>WHO with support from UNFPA, PSI &amp; USAID</td>
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<tr>
<td>Identify which products are registered in which countries to engage with national regulatory authorities and respond to specific country challenges and needs.</td>
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<td><strong>4. Expand WHO guidance on transport and storage of vaccines to pharmaceuticals</strong></td>
<td>WHO with support from UNFPA &amp; USAID</td>
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<td>Although WHO has guidelines for the transport and storage of time- and temperature-sensitive vaccines, there are not similar guidelines for pharmaceuticals like oxytocin, which must be shipped in the cold chain (at 2 to 8 degrees regardless of labelling). <strong>Next steps:</strong> WHO will take this recommendation back to update the guidance. UNFPA will assist with the guidance and advocate for it at the next Interagency Pharmaceutical Cooperation Group meeting. USAID has a draft internal guidance document on temperature excursions, shelf life, and mitigation options that it is willing to share.</td>
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<td><strong>5. Move oxytocin into the EPI cold chain</strong></td>
<td>Led by WHO in collaboration with UNFPA &amp; UNICEF</td>
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<td>There are currently two separate cold chain systems: one for vaccines and another for products like oxytocin. UNFPA, WHO, and UNICEF are working on a joint statement that would help countries consider using the secured Expanded Program for Immunization (EPI) Supply Chain, but this has stalled because WHO must first develop guidelines for how oxytocin would be put into the vaccine EPI (see Action Item 4). <strong>Next steps:</strong> This is a long-term effort that will require buy-in from a range of stakeholders. Deus Mubangizi from WHO will check on the status of these efforts and who is leading it and report back.</td>
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<td>6. Change ERP Category 3 language</td>
<td>RESPONSIBLE</td>
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<td>The term “objection” should be removed from ERP Category 3 guidance and replaced with more flexible terminology, for example, “concern” or “in the event of...”.</td>
<td>FHI360 &amp; RHSC</td>
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<td><strong>Next steps:</strong> Aida Cancel of FHI360 will submit suggestions on terminology and, once agreed, a request will be sent as a community to the ERP coordinator through RHSC.</td>
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<tr>
<th>7. Continue with ERP for DMPA, safe abortion product, mifepristone, and benzanthine benzylpenicillin</th>
<th>RESPONSIBLE</th>
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<tr>
<td>Following a discussion on the expense and value of the ERP, it was agreed there were only four products in urgent need of assessment: a safe abortion product, mifepristone, DMPA, and benzanthine benzylpenicillin. This change will be included in the next EOI.</td>
<td>UNFPA</td>
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<td><strong>Next steps:</strong> This proposal will be explored with manufacturers and UNFPA will ask if they can share their reports. UNFPA will share the EOI when it is published.</td>
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<th>8. Pilot for harmonizing condom registration requirements</th>
<th>RESPONSIBLE</th>
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<tr>
<td>For condom manufacturers and social marketing organizations, it is expensive to register multiple brands and product types (e.g. specialty condoms with different colours or scents) in every country they enter, and it is time consuming for national regulators to review products that are often identical in every respect but the artwork on the package.</td>
<td>WHO will coordinate the pilot. UNFPA, PSI &amp; USAID will bring a list of priority manufacturers to the next meeting.</td>
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<td><strong>Next steps:</strong> WHO will coordinate a pilot, perhaps in Tanzania, aimed at reducing the regulatory burden and increasing access to condoms. This may be done in collaboration with the EAC (or other regional economic community), which is beginning to harmonize registration requirements for medicines and is discussing expanding to diagnostics and medical devices. The first step will be to identify which manufacturers are ready and willing to participate. The timeline to finding a solution may be two to three years.</td>
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<th>9. Identify local in-country agents</th>
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<tr>
<td>Facilitating registrations at the country level requires identifying an in-country agent that is familiar not only with the legal and technical requirements for registration, but the commercial market. However, even if a product is won through tender, it can be challenging to identify this person, and the role of the agent can differ between countries. For example, an agent could be a lawyer who does not understand how dossiers are approved, or a technical expert who is unfamiliar with legal and commercial agreements.</td>
<td>PSI, MSI &amp; FHI360</td>
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<td>This risk needs to be migrated by compiling and sharing a list of local agents, perhaps in a registration database (see Action Item 1), and defining the criteria for a local agent (capabilities, knowledge, etc.). This will provide the ‘outside the box’ information manufacturers need, such as the challenges others have encountered with registration, whether the same products can be registered in neighbouring countries, and other issues.</td>
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<td><strong>Next steps:</strong> Since PSI has an extensive country presence and works with wholesalers and distributors, it has the greatest clarity on individual country requirements and in-country agents. Manufacturers also often have in-country agents and are most familiar with registration restrictions and requirements, so they will be approached to compile this list.</td>
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# APPENDIX 1: MEETING AGENDA

**Annual Meeting of Procurers of Quality RH Medicines and Contraceptive Devices**  
Copenhagen, Denmark, 17-18 May 2018  
UN City Copenhagen, Press Room  
Marmorvej, 51 2100 Copenhagen

## DAY 1: THURSDAY, 17 MAY 2018

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<thead>
<tr>
<th>TIME</th>
<th>SESSION</th>
<th>MODERATOR/ PRESENTER</th>
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<tbody>
<tr>
<td>8.45-9.00</td>
<td>Security and registration</td>
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<td></td>
<td><strong>WELCOME</strong></td>
<td>UNFPA</td>
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<td>9.00-9.10</td>
<td>Welcome, introductions, meeting objectives, expected outcomes</td>
<td>Eric Dupont, UNFPA PSB</td>
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<td></td>
<td><strong>SESSION 1</strong></td>
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<td>9.10-9.30</td>
<td>Sharing information on procurement of maternal health medicines</td>
<td>Concept Foundation</td>
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<td>9.30-9.40</td>
<td>Improving communication on quality issues</td>
<td>UNFPA</td>
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<td>9.40-10.00</td>
<td>Collaborative efforts to provide regulatory support to countries with</td>
<td>WHO, UNFPA, USAID</td>
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<td>focus on FP2020 priority countries</td>
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<tr>
<td>10.00-10.20</td>
<td>Sharing information to support generics</td>
<td>USAID</td>
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<td><strong>SESSION 2</strong></td>
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<td>10.20-10.45</td>
<td>Specific quality technical requirements included for RH medicines:</td>
<td>UNFPA PSB/MSI/PSI/IPPF/USAID Population and Reproductive Health</td>
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<td></td>
<td>Lessons learned and areas of improvement</td>
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<td>10.45-11.15</td>
<td>COFFEE BREAK (30 minutes)</td>
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<td><strong>SESSION 3</strong></td>
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<td>11.15-11.45</td>
<td>Post-Market Surveillance</td>
<td>MSI</td>
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<td><strong>SESSION 4</strong></td>
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<td>11.45-12.05</td>
<td>Medicines: WHO update of the last 12 months</td>
<td>WHO PQT</td>
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<tr>
<td>12.05-12.25</td>
<td>Condoms and IUDs: UNFPA update of the last 12 months</td>
<td>UNFPA PQT</td>
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<td>12.25-12.30</td>
<td>Open discussion</td>
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<td>12.30-13.30</td>
<td>LUNCH BREAK (60 minutes)</td>
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<td><strong>SESSION 5</strong></td>
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<tr>
<td>13.30-14.00</td>
<td>Updates by Partners</td>
<td>Lester Chinery, Concept Foundation</td>
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<tr>
<td>14.00-14.10</td>
<td>Quality agenda in the donors' policies: Successes and challenges</td>
<td>DFID/Gates Foundation (in absentia)</td>
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<td>14.10-14.20</td>
<td>Specific challenges after harmonization of QA policies</td>
<td>All</td>
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<tr>
<td></td>
<td><strong>SESSION 6</strong></td>
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<tr>
<td>14.20-14.40</td>
<td>Progress on scaling up access to generics</td>
<td>UNFPA</td>
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<tr>
<td>14.40-15.00</td>
<td>Challenges faced by manufacturers of generics</td>
<td>GEMS</td>
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<tr>
<td>15.00-15.30</td>
<td>COFFEE BREAK (30 minutes)</td>
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<td><strong>SESSION 7</strong></td>
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<tr>
<td>15.30-16.10</td>
<td>Update on trial for comparing carbetocin with oxytocin (prevention of</td>
<td>WHO/Merck for Mothers/Ferring Pharmaceuticals</td>
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<tr>
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<td>PPH after vaginal delivery</td>
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<tr>
<td>16.10-16.30</td>
<td>Discussions</td>
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</table>
## SESSIONS

### SESSION 8

**Time:** 9.00-9.15
**Session:** Review of Day 1: Summary of outcomes from Day 1
**Moderator/Presenter:** Deus Mubangizi, WHO PQT

**Time:** 9.15-9.35
**Session:** Financial Impact of Ensuring Quality of Products: Social Marketing Organizations
**Moderator/Presenter:** Deus Mubangizi, WHO PQT

**Time:** 9.35-9.50
**Session:** Challenges faced by QA teams in bridging the financial gap between quality and price of products
**Moderator/Presenter:** Open discussion

**Time:** 9.50-10.10
**Session:** How do we do it? Quality vs. price
**Moderator/Presenter:** MSF/UNICEF

### SESSION 9

**Time:** 10.10-10.30
**Session:** Open discussion
**Moderator/Presenter:** Deus Mubangizi, WHO

**Time:** 10.45-11.00
**Session:** USAID strategy
**Moderator/Presenter:** USAID

**Time:** 11.00-11.10
**Session:** Reports of 2017
**Moderator/Presenter:** All

**Time:** 11.00-11.40
**Session:** Discussion
**Moderator/Presenter:** All

### SESSION 10

**Time:** 11.40-11.55
**Session:** Risk-based approach to condom quality monitoring: update
**Moderator/Presenter:** UNFPA/USAID/FHI360

**Time:** 11.55-12.10
**Session:** Temperature monitoring of condom shipments
**Moderator/Presenter:** UNFPA

**Time:** 12.10-12.30
**Session:** Projects on quality monitoring of shipments (RH medicines and contraceptives)
**Moderator/Presenter:** All

**Time:** 12.30-13.30
**Session:** LUNCH BREAK (60 minutes)

### SESSION 11

**Time:** 13.30-13.55
**Session:** Oxytocin: Quality vs. Cost of Shipment
**Moderator/Presenter:** Roberto Mena, UNFPA

**Time:** 13.55-14.20
**Session:** Oxytocin: Messaging on quality and storage
**Moderator/Presenter:** Open discussion

### SESSION 12

**Time:** 14.50-15.05
**Session:** ERP for RH Medicines: Update
**Moderator/Presenter:** UNFPA

**Time:** 15.05-15.30
**Session:** Challenges for marketing authorization holders or social marketing organizations on registration
**Moderator/Presenter:** PSI/MSI

**Time:** 15.30-15.45
**Session:** Open discussion

**Time:** 15.45-16.00
**Session:** Summary of Day 1 & 2: Where do we want to go with this forum?
**Moderator/Presenter:** Eric Dupont, UNFPA

**Time:** 16.00-16.15
**Session:** Closure of the Meeting
**Moderator/Presenter:** Eric Dupont, UNFPA
## APPENDIX 2: MEETING PARTICIPANTS

<table>
<thead>
<tr>
<th></th>
<th>FIRST NAME</th>
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<th>ORGANIZATION</th>
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<tbody>
<tr>
<td>1</td>
<td>Gustavo</td>
<td>Adreoli</td>
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<tr>
<td>2</td>
<td>Chadia</td>
<td>Allaouidine</td>
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<td>Kelly</td>
<td>Catlin</td>
<td>CHAI</td>
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<td>6</td>
<td>Mario</td>
<td>Chaves</td>
<td>IPPF (International Planned Parenthood Federation)</td>
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<td>Lester</td>
<td>Chinery</td>
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<td>Vivian</td>
<td>Cintron</td>
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<td>9</td>
<td>Eric</td>
<td>Dupont</td>
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<td>10</td>
<td>Steve</td>
<td>Hamel</td>
<td>FHI360/USAID</td>
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<td>11</td>
<td>Godfrey</td>
<td>Itoro</td>
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<td>Brian</td>
<td>McKenna</td>
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<td>Metin Gulmezoglu</td>
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<td>32</td>
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<td>Widmer</td>
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**Attendees joining virtually**

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<thead>
<tr>
<th></th>
<th>Fergus</th>
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<tr>
<td>33</td>
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<td>Hurkchand</td>
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<td>Isabel</td>
<td>Lucas Manzano</td>
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<td>Mwangi</td>
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