RH Supplies: Insights from an INGO

Marie Stopes International

Jason Bower
Senior Pharmaceutical Advisor

Seminar on Family Planning
Medicines and Supplies
Nov 2017
Marie Stopes International – what we do

What we do
We provide sexual and reproductive healthcare to millions of under-served women around the world.

Services
- Family planning
- Maternal health
- HIV / STIs
- Safe abortion and post-abortion care

Delivery
- Clinical outreach
- Social franchising
- Centres
- Reaching the under-served

Providing choice
Our work in family planning

Going the extra mile
Providing services on outreach
Social marketing

We distribute our own brand of high quality and affordable condoms, contraceptive pills and other contraceptive products through pharmacies, community-based distributors and other private providers.
Insight #1

There are lots of poor quality RH products
Misoprostol samples % Content vs Time

Courtesy of Peter Hall / Concept Foundation / HCI Lab
Example: India public sector

Exhibit 10.37
Molecules with more than 10.02% NSQ samples (total samples ≥ 50)

- Oxytocin 41%
- Lignocaine 38%
- Ceftriaxone 25%
- etc

Source: India National Drug Survey 2014-16
Almost Half Of Pregnancy Tests Removed From Sale After Sweeping Review

The tests were producing false negative results.

24/03/2017 9:42 AM AEDT | Updated 24/03/2017 12:27 PM AEDT

Lara Pearce
Associate Editor, HuffPost Australia

Seventeen pregnancy tests have been removed from sale following an investigation by the Therapeutic Goods Administration.

An alarming 17 pregnancy test brands have ceased sale in Australia or been recalled following a sweeping review of all home pregnancy tests available.

The review, conducted by the Therapeutic Goods Administration (TGA), found that several of the common pregnancy tests available to Australian women were giving false negative results -- indicating the woman was not pregnant, when she in fact was.
Insight #2

Whilst NDRAs have strengthened standards, lower quality RH products have entered LMIC markets
Insight #3

Higher internal standards and more oversight needed for our key products
MSI Policy on Product Quality v4

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Name of Policy or Protocol: Marie Stopes International Policy on Product Quality
Version: V4.0
Applies to: All country programmes: CSOs, SMTs; Designated Leads for Clinical Quality; Procurement & Logistics Staff; Channel Leads; Providers
Ratified by: MSI Executive Committee October 2018
Issue Date: December 2010
Review Date: December 2018

Marie Stopes International
# Product categories & minimum QA standards

<table>
<thead>
<tr>
<th>PRODUCT TYPE</th>
<th>Key SRH Products</th>
<th>Key Ancillary Drugs</th>
<th>Other Ancillary Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCTS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>❖ Contraceptive devices</td>
<td>❖ Oxytocics</td>
<td>❖ Antifungals and anthelminthics</td>
</tr>
<tr>
<td></td>
<td>❖ Contraceptive medicines</td>
<td>❖ Magnesium sulphate inj</td>
<td>❖ Other supportive medicines</td>
</tr>
<tr>
<td></td>
<td>❖ Medicines for safe abortion</td>
<td>❖ Anaesthetics</td>
<td>❖ Other medical consumables such as gloves, syringes, sutures etc</td>
</tr>
<tr>
<td></td>
<td>❖ MVA equipment</td>
<td>❖ Analgesics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>❖ Pregnancy and HIV tests</td>
<td>❖ Antibacterials, antiretrovirals, antimalarials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>❖ Metal surgical instruments</td>
<td>❖ All sterile injectable products</td>
<td></td>
</tr>
<tr>
<td>MINIMUM STANDARD</td>
<td>• WHO prequalified</td>
<td>• MSI approved international wholesalers</td>
<td>• No mandatory standard</td>
</tr>
<tr>
<td></td>
<td>• UNFPA ERP 1/2</td>
<td>• Manufacturer listed in MSI List of Recommended Manufacturers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SRA approved</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>MSI QARMA</strong> approved</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ISO &amp; CE certification + tech requirements for devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GLOBAL PROCUREMENT | LOCAL PROCUREMENT | LOCAL PROCUREMENT
# My Products

List below the products which are currently in use in your programme. You can add new products, modify products you have already entered, and delete products which you are no longer using. You should include all contraceptive, misoprostol, and mifepristone products. Once you have completed entering all your products, click "Submit" to create your new submission.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Manufacturer Name</th>
<th>Manufacturer Site Address</th>
<th>Product Details</th>
<th>DFID-funded</th>
<th>WHO or SRA Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injectable - DMPA</td>
<td>Pfizer / Pharmaci</td>
<td>Rijksweg, Puurs, Belgium</td>
<td>depomedroxyprogesterone ace</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misoprostol tablets</td>
<td>ACME Formulaci</td>
<td>Roper Road, Nalagarh, Dist. Solan HP, India</td>
<td>misoprostol 200mcg tablets (Mi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant</td>
<td>Bayer Schering F</td>
<td>Turku, Finland</td>
<td>levonorgestrel 2x75mg implant</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Afghanistan**

Add new product

Save

Delete
Insight #4

WHO PQ currently covers a limited number of RH products
### MSI List of Recommended Manufacturers for Ancillary Medicines

**Note:**

1. The manufacturers listed below have undergone satisfactory GMP assessment by an approved inspection body and are considered generally acceptable for general medicines.
2. Note however that the specific products manufactured by the listed Recommended Manufacturers have not been individually assessed, so satisfactory Quality Assurance cannot be guaranteed.
3. Recommended sources also include all medicines manufactured by multinational Pharma member companies, such as GSK, Novartis, Merck, Bayer, etc., including their local manufacturing plants.
4. These lists are extracted from QUAMED Database and are confidentially for MSI programme use only.

<table>
<thead>
<tr>
<th>Manufacturer Name</th>
<th>Manufacturer Country</th>
<th>Manufacturer Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABBOTT HEALTHCARE PRIVATE LTD</td>
<td>India</td>
<td>Village Bhatauli Khurd, Sari road, Baddi, District Solan, 173 205</td>
</tr>
<tr>
<td>ABDI İbrahim İlaç San ve Tic. A.S.</td>
<td>Turkey</td>
<td>Sanayii Mahallesi Tunç Caddesi no:3-Esenyurt-Istanbul</td>
</tr>
<tr>
<td>ACCUCAPS INDUSTRIES Ltd Stratthroy</td>
<td>Canada</td>
<td>720 Wright street, Stratthroy, Ontario N7G 3H8</td>
</tr>
<tr>
<td>ACCUCAPS INDUSTRIES Ltd Windsor</td>
<td>Canada</td>
<td>2125 Ambassador Drive Windsor, Ontario N9C 3R5</td>
</tr>
<tr>
<td>ACTAVIS LTD Malta</td>
<td>Malta</td>
<td>BLB 016, BLB 026, BLB 010, Bulobel Industrial Estate, Zoýthin, ZTH3000</td>
</tr>
<tr>
<td>ACTAVIS PHARMA MANUFACTURING PVT Ltd</td>
<td>India</td>
<td>Plot Nos 16, 17, 31 &amp; 32, SIDCO Industrial Estate, (Via) Thruponur, Kancheeparam Distric, Alatrub 603 110</td>
</tr>
<tr>
<td>ACTAVIS PT. INDONESIA</td>
<td>Indonesia</td>
<td>Jalan Raya Bogor Km 28, Jakarta, 13710</td>
</tr>
</tbody>
</table>
MSI QARMA Matrix

1. Manufacturer (company) level:
   - Manufacturing process
   - Quality management system
   - Product safety
   - Configuration change
   - Change control
   - Returned product analysis
   - After sales service
   - Software validation

2. Product dossier level:
   - Product characteristics
   - Production process
   - Quality control
   - Change control
   - Returned product analysis
   - After sales service

3. MSI Product-Specific Characteristics Risk Classification Tool:
   - Key risks:
     - Sterile dosage form
     - Non-sterile dosage form
     - Key auxiliary products
     - Other auxiliary products

Product dossier quality + Product characteristics = Manufacturer quality
Insight #5

Product quality falls in a hole if you don’t have clear accountabilities
Quality is everybody’s responsibility

Product Committee

We recommend establishing, within your MAT, a small Product Committee that meets when required to review and decide on product QA matters and maintain your Standard Products List. The committee would report to the MAT. Below is an example of who this committee could include and the scope of work that they could be responsible for.

<table>
<thead>
<tr>
<th>Members of committee</th>
<th>Tasks of committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>designated lead for clinical quality (Chair)</td>
<td>developing and reviewing your Standard Products List</td>
</tr>
<tr>
<td>procurement manager</td>
<td>ensuring Q-Trak is up to date</td>
</tr>
<tr>
<td>logistics or warehouse manager</td>
<td>reviewing and managing product related incident reports</td>
</tr>
<tr>
<td>a service delivery channel manager</td>
<td>supplier assessments</td>
</tr>
<tr>
<td>another senior clinician</td>
<td>ensuring minimum quality criteria for medical goods</td>
</tr>
<tr>
<td>programme pharmacist* (where available)</td>
<td>procurement are met when evaluating bids</td>
</tr>
<tr>
<td></td>
<td>evaluation of physical samples in procurement process</td>
</tr>
<tr>
<td></td>
<td>all other matters relating to product quality</td>
</tr>
</tbody>
</table>
Module 2 – Product Quality

This Module 2 toolkit provides assistance on:
- Understanding quality and how it is assessed
- MSi Minimum Standards and Best Practice for ensuring quality products
- Maintaining quality during storage, distribution & use
- Integrating quality into procurement
- Useful tools and resources

This module is primarily intended to be used by:
- Procurement staff
- Warehouse and logistics staff
- Clinical services senior managers
- Country Directors
- Any MSi staff to understand the basics of quality assurance

Understanding Product Quality – Quality Control Testing

Quality Control testing
Quality Control testing (sometimes referred to as batch testing) is laboratory testing conducted to check if a product meets all of the specifications that it is supposed to meet. It checks whether the QA measures of the manufacturer were followed and were effective.

QC testing is routinely carried out by the manufacturer during production (the Certificate of Analysis is thus produced to demonstrate compliance – see below), but can also be carried out by the buyer after they purchase the product. This testing can be pre-shipment (before the product is sent to the buyer) or post-shipment (after the product is already in your programme).

QC testing can tell you if the product is of acceptable quality at the time it is tested, according to what was tested. It may miss impurities or contamination, degradation that may later occur, and doesn’t tell you if the sample tested is representative of the entire batch. QC on its own is not sufficient QA and must be supported by GMP and dossier assessment.

A satisfactory QC testing result is not a guarantee that a product will be acceptable until the end of its shelf life. It means that it should be acceptable now. See the real example below on pre-shipment testing of three batches of mutated, was OK, but post-shipment testing showed that the tablets were degrading quickly.
## Integrated incident reporting

### MARIE STOPES INCIDENT NOTIFICATION FORM

**Instructions:** This form requires basic information about the incident and is NOT an investigation. This form should be completed and submitted to the designated clinical quality lead following an incident. Red incidents must be reported to Support Office and escalated to Global MDT within 24 hours. Green and amber incidents must be reported to Support Office within 48 hours.

#### 1. Initial details

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of incident (dd/mm/yyyy)</strong></td>
<td><strong>Programme</strong></td>
<td><strong>Name of site or team</strong></td>
</tr>
<tr>
<td><strong>Name of site or team</strong></td>
<td><strong>Service channel</strong></td>
<td><strong>Service channel</strong></td>
</tr>
<tr>
<td>Marie Stopes UK centre</td>
<td>MD Obstetric centre</td>
<td>Social franchise</td>
</tr>
<tr>
<td>Marie Stopes UK centre</td>
<td>Obstetrics SF</td>
<td>Outreach Team</td>
</tr>
<tr>
<td>Service channel</td>
<td>MD Obstetric centre</td>
<td>Obstetrics SF</td>
</tr>
<tr>
<td>Social franchise</td>
<td>Outreach Team</td>
<td>OBGYN, Voucher, Gynaec, Agency</td>
</tr>
<tr>
<td>With Midwife</td>
<td>Other</td>
<td>Other</td>
</tr>
</tbody>
</table>

If "other" for service channel, please describe here:

#### 2. Client details

<table>
<thead>
<tr>
<th>INITIALS of client and their client record number</th>
<th>Gender</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Obstetrics Client Type**

- Antenatal client
- Client for delivery
- Postnatal client

If Obstetrics, booked/unbooked client?

**Eventual outcome (for adult)**

- No fatality
- No fatality
- Unknown
- Unrelated

**Eventual outcome for neonate (if applicable)**

<table>
<thead>
<tr>
<th><strong>No fatality</strong></th>
<th><strong>No fatality</strong></th>
<th><strong>Unknown</strong></th>
<th><strong>Unrelated</strong></th>
</tr>
</thead>
</table>

---

### PRODUCT RELATED INCIDENT FORM

**Instructions:** Please complete this form for product-related incidents. Please note that if you have also completed the "1. INF Form" tab, clicking the "Complete PRIF" button at the bottom of the notification form will autopopulate the PRIF fields below.

#### 1. Initial details

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of incident (dd/mm/yyyy)</strong></td>
<td><strong>Programme</strong></td>
<td><strong>Name of site or team</strong></td>
</tr>
<tr>
<td><strong>Programme</strong></td>
<td><strong>Service channel</strong></td>
<td><strong>Service channel</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Type of incident</strong></td>
<td><strong>Type of incident</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 2. Client information

**Initials AND client record #**

**Gender**

**Age**

**Weight (kg)**

**Gestational age in weeks (if applicable)**

**Breastfeeding at time of incident?**

**Other relevant medical history**

**Other clinical services or medications**

---

#### 3. Suspected product information

<table>
<thead>
<tr>
<th><strong>Product description</strong></th>
<th><strong>Special attribute</strong></th>
<th><strong>Generic name</strong></th>
</tr>
</thead>
</table>

**Manufacturer**

**Batch/Lot #**

**Expiry date**

**Indication**

**Dosing/administration details**

**Date started/inserted** (dd/mm/yyyy)

**Problems during administration**

**Date stopped** (dd/mm/yyyy)

**Other medicines taken at time of incident**

**Other medicines taken at time of incident**

---

#### 4. Risk Rating (If also a clinical incident)

**Service**

**Brief Description (2-3 sentences)**

**Additional information and incident**
Insight #6

Supply planning & monitoring is critical to improve access
# Programme Standard Products Lists including approved products

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Category</th>
<th>Product name</th>
<th>Unit</th>
<th>Therapeutic Category (WHO)</th>
<th>IUD</th>
<th>Implant Insertion</th>
<th>Injectable</th>
<th>STI</th>
<th>STI plus</th>
<th>MEM int</th>
<th>ANC</th>
<th>MSP</th>
<th>General Med</th>
<th>OR Class</th>
<th>Centre Class</th>
<th>Centre Extended</th>
<th>Social Marketing</th>
<th>Approved Manufacturer/Wholesaler/Product</th>
<th>Quality Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCODE_AC1 T200</td>
<td>2MED</td>
<td>aciclovir 200mg tab</td>
<td>tablet</td>
<td>06.4 Antivirals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MSI Approved List</td>
<td>Key ancillary</td>
</tr>
<tr>
<td>EADPPC7</td>
<td>5EQPT</td>
<td>adaptor double valve 7mm pcs</td>
<td>pieces</td>
<td>33. Diagnostic Equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MSI GSC</td>
<td>KeySRH</td>
</tr>
<tr>
<td>EADPPC8</td>
<td>5EQPT</td>
<td>adaptor double valve 8mm pcs</td>
<td>pieces</td>
<td>34. Medical Equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MSI GSC</td>
<td>KeySRH</td>
</tr>
<tr>
<td>MADRU1</td>
<td>2MED</td>
<td>adrenaline 1:1000 amp</td>
<td>ampoule</td>
<td>03. Analgesics &amp; Analphetics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>per MSI Approved List</td>
<td>Key ancillary</td>
</tr>
<tr>
<td>TCODE_AM X500</td>
<td>2MED</td>
<td>amoxicillin 500mg cap</td>
<td>capsule</td>
<td>06.2 Antibiotics</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>per MSI Approved List</td>
<td>Key ancillary</td>
</tr>
<tr>
<td>MATRI05</td>
<td>2MED</td>
<td>atropine 0.5-0.6mg/ml amp</td>
<td>ampoule</td>
<td>04. Antidotes &amp; Used in Poisonings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>per MSI Approved List</td>
<td>Key ancillary</td>
</tr>
<tr>
<td>TCODE_AZ M500</td>
<td>2MED</td>
<td>azithromycin 500mg tab</td>
<td>tablet</td>
<td>06.2 Antibiotics</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>per MSI Approved List</td>
<td>Key ancillary</td>
</tr>
<tr>
<td>TCODE_BZT I24</td>
<td>2MED</td>
<td>benzathine pen 2.4MIU vial</td>
<td>vial</td>
<td>06.2 Antibiotics</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>per MSI Approved List</td>
<td>Key ancillary</td>
</tr>
<tr>
<td>ECNLP4</td>
<td>5EQPT</td>
<td>cannula no 4 pcs</td>
<td>pieces</td>
<td>34. Medical Equipment</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MSI GSC</td>
<td>KeySRH</td>
</tr>
<tr>
<td>ECNLP5</td>
<td>5EQPT</td>
<td>cannula no 6 pcs</td>
<td>pieces</td>
<td>34. Medical Equipment</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MSI GSC</td>
<td>KeySRH</td>
</tr>
<tr>
<td>ECNLP6</td>
<td>5EQPT</td>
<td>cannula no 7 pcs</td>
<td>pieces</td>
<td>34. Medical Equipment</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MSI GSC</td>
<td>KeySRH</td>
</tr>
<tr>
<td>TCODE_CFX T200</td>
<td>2MED</td>
<td>cefixime 200mg tab</td>
<td>tablet</td>
<td>06.2 Antibiotics</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>per MSI Approved List</td>
<td>Key ancillary</td>
</tr>
</tbody>
</table>
Other measures to improve access

• Development of supply plans
  o annual planning of allocated supplies versus needs
  o quarterly stock status reporting and review against plans

• Donor engagement to increase donated commodities available

• Introduction of stock-out indicators

• Working closely with MoH on planning, allocations, and supply
THANK YOU!