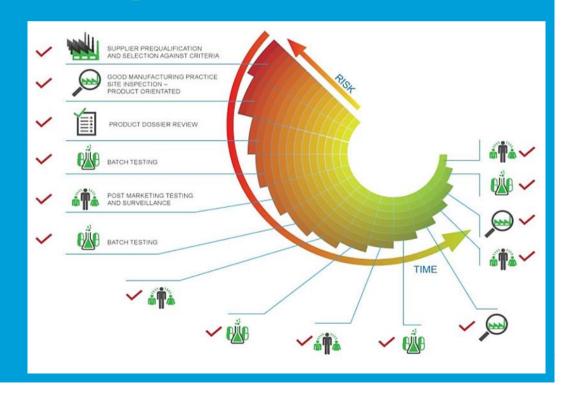


# RH Supplies: Insights from an INGO

# 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

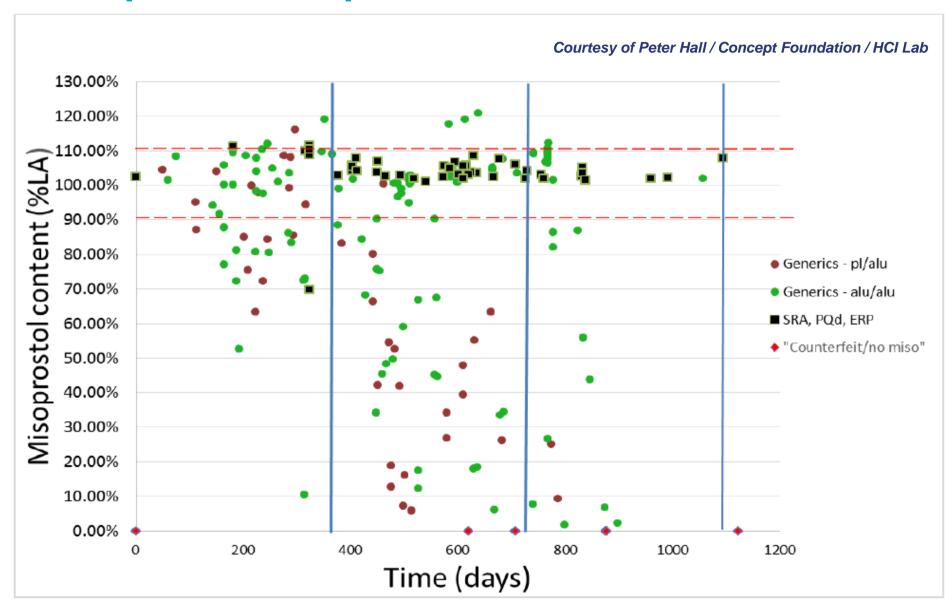
We distribute our own brand of high quality and affordable condoms, contraceptive pills and other contraceptive products through pharmacies, community-based distributors and other private providers.



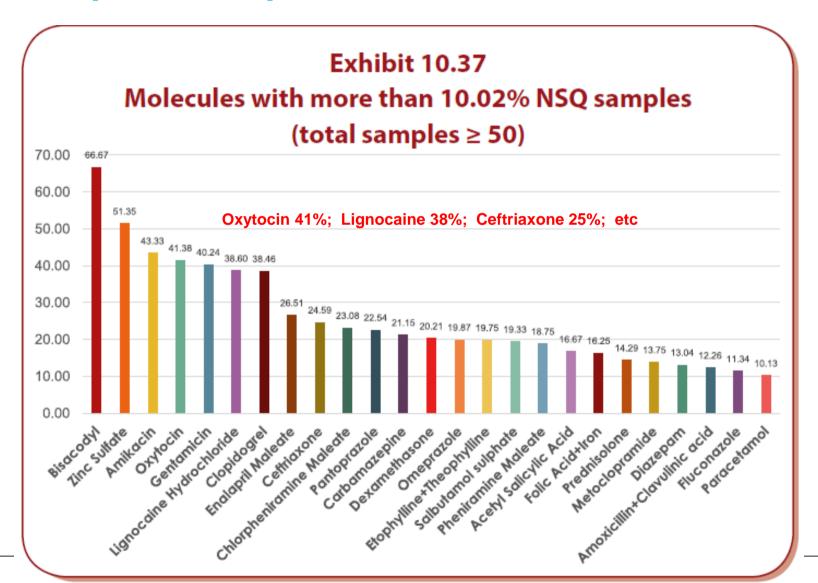


There are lots of poor quality RH products

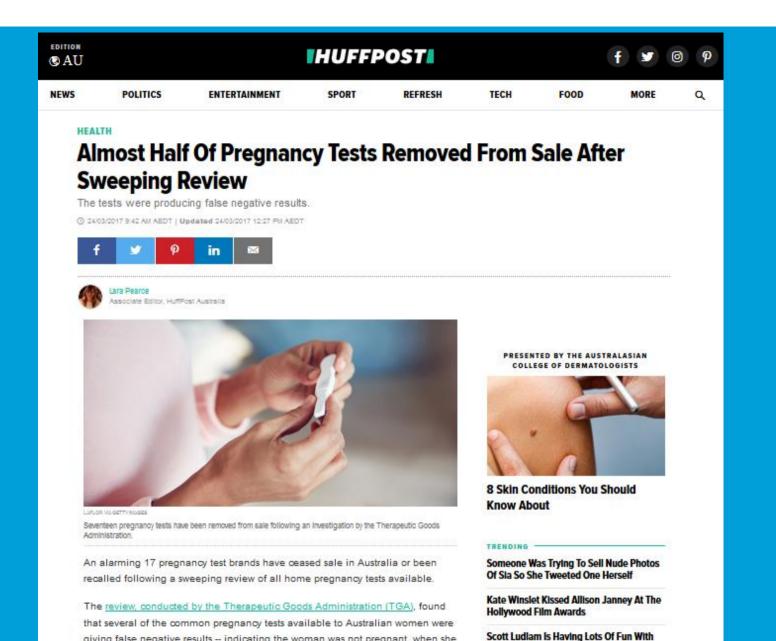
## Misoprostol samples % Content vs Time



## **Example: India public sector**



Source: India National Drug Survey 2014-16



The Citizenship Crisis

giving false negative results -- indicating the woman was not pregnant, when she

in fact was.

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

Higher internal standards and more oversight needed for our key products

# MSI Policy on Product Quality v4

### MSI Policy on Product Quality

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| Name of Policy or Protocol: Marie Stopes International Policy on Product Quality |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|
| Version:   | V4.0   |  |  |  |  |  |  |
|  | grammes: CDs; SMTs; Designated Leads for Clinical Quality; Procurement &<br>Channel Leads; Providers |  |  |  |  |  |  |
| Ratified by:   | MSI Executive Committee October 2016   |  |  |  |  |  |  |
| Issue Date:  | December 2016  |  |  |  |  |  |  |
| Review Date:   | December 2018  |  |  |  |  |  |  |

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16 17 21

# **Product categories & minimum QA standards**

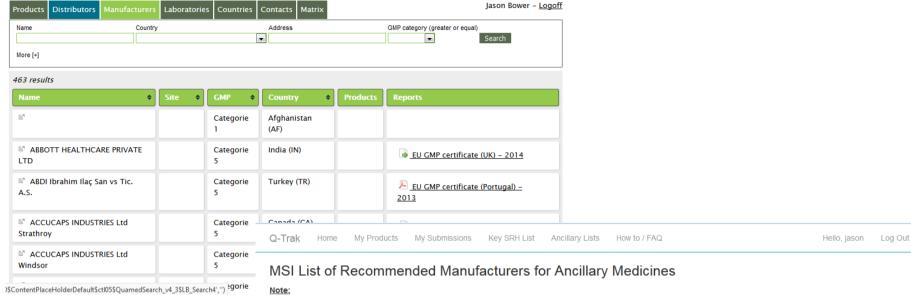
| PRODUCT<br>TYPE  | Key SRH Products  | Key Ancillary Drugs  | Other Ancillary Products  |
|------------------|---|--|---|
| PRODUCTS         | <ul> <li>Contraceptive devices</li> <li>Contraceptive medicines</li> <li>Medicines for safe abortion</li> <li>MVA equipment</li> <li>Pregnancy and HIV tests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

### **Q-Trak tool**

Q-Trak Home My Products My Submissions Key SRH List Ancillary Lists How to / FAQ Hello, jason Log Out 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. Afghanistan Add new product Product Details Product Type Manufacturer Name Manufacturer Site Address Injectable - DMPA Pfizer / Pharmaci ▼ + Rijksweg, Puurs, Belgium depomedroxyprogesterone ace ▼ + Save DFID-funded Your Product Name Supplied By Comments (optional) Delete WHO or SRA Approved Depo Provera MSI GP&L #6 Product Type Manufacturer Name Manufacturer Site Address Product Details Misoprostol tablets ACME Formulatic ▼ + Ropar Road, Nalagarh, Dist. Solan HP, India 🔻 + misoprostol 200mcg tablets (Mi ▼ + Save DFID-funded Your Product Name Supplied By Comments (optional) Delete WHO or SRA Approved MISOCLEAR MSI GP&L Product Type Manufacturer Name Manufacturer Site Address Product Details Turku, Finland Implant Bayer Schering F ▼ + levonorgestrel 2x75mg implant ▼ + Save Your Product Name Supplied By DFID-funded Comments (optional) Delete WHO or SRA Approved Jadelle Govt: non-donor ▼

# WHO PQ currently covers a limited number of RH products





- 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 can not
- 3. Recommended sources also include all medicines manufactured by multinational PhRMA 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

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| Search                               | QC                   |   |
|--------------------------------------|----------------------|---|
| Manufacturer Name                    | Manufacturer Country | Manufacturer Address  |
| ABBOTT HEALTHCARE PRIVATE LTD        | India                | Village Bhatauli Khurd, Sai road, Baddi, District Solan, 173 205  |
| ABDI Ibrahim Ilaç San vs Tic. A.S.   | Turkey               | Sanayi Mahallesi Tunç Caddesi n°3-Esenyurt,Istanbul   |
| ACCUCAPS INDUSTRIES Ltd Strathroy    | Canada               | 720 Wright street, Strathroy, Ontario N7G 3H8   |
| ACCUCAPS INDUSTRIES Ltd Windsor      | Canada               | 2125 Ambassador Drive Windsor, Ontario N9C 3R5  |
| ACTAVIS LTD Maita                    | Malta                | BLB 016, BLB 026, BLB 010, Bulebel Industrial Estate, Zejutn, ZTN3000                                       |
| ACTAVIS PHARMA MANUFACTURING PVT Ltd | India                | Plot Nos 16, 17, 31 & 32, SIDCO Industrial Estate, (Via) Thiruporur, Kancheepuram District, Alathur 603 110 |
| ACTAVIS PT. INDONESIA                | Indonesia            | Jalan Raya Bogor Km 28, Jakarta, 13710  |
|                                      |                      |   |

## **MSI QARMA Matrix**



|             | Site / Topic<br>Classification<br>Interpretation   | Site licensing  | QA & Compliance<br>History   | Sanitation & hygiene   | Validation  | Complaints &<br>Recalls  | Contracts  | Self Inspection  | Personnel and<br>training  |
|-------------|--|---|--|--|---|--|--|--|--|
| 4<br>SLIENT | Excellent GMP level is<br>established and<br>compliance<br>demonstrated<br>through fine analysis<br>of all documentations<br>and observations        | The site is authorized and inspected by the NMRA (reports available that do not contain major observations)                 | QA system is<br>developped and<br>continously adapted.<br>All required reports<br>are timely available<br>e.g. PQR   | s B. H program is quite<br>correctly<br>implemented and no<br>finding on cleanliness<br>from the auditor | The VMP is updated<br>and completed : all<br>the validation reports<br>are available and<br>approved  | Full periodic reviews<br>are performed on the<br>handling of<br>complaints and,<br>where needed, of<br>recalls with their<br>approved reports  | A SOP exists that<br>organise the<br>management of the<br>contracted<br>relationships, 100% of<br>the requested<br>agreements are signed   | A detailed SOP,<br>including "for-cause"<br>self-inspections exist.<br>All self-inspections are<br>performed and<br>reported with the<br>corresponding CAPAs | Organogram, job description and training program exist and are updated. The training realization is > 90% and assessed |
| 3           | Good GMF<br>Compliance is<br>established through<br>the existing systems<br>and documentation<br>but some weaknesses<br>are remaining                | The site is authorized and inspected by the NMRA (report available with some observations few major observations)           | QA system is<br>developed and<br>studes as modern<br>quisity to an eclaring<br>PQ as away as a<br>SQ as an borning   | S.E. H program<br>reinforced with<br>OPF-<br>clessing of all pasts of<br>the lite                        | The VMF is updated and completed daning that all daning that all personned Horizontal to the state portion of the | SOP for complaints and recalls handing is complete and to A hierts are 60 men and and white heads feel of the first are 60 men and and white heads feel of the first are 60 men and and the first are first ar | A SOP exists that organize the management of the control of the co | Detailed SOP exists<br>together with a<br>program and with a<br>template for reports.<br>Some self-inspections<br>planned are not<br>performed.              | Organogram, job description and training program exist and are updated. The training realization is > 20%              |
| 2<br>AIR    | Documentation<br>collected provides<br>some indication of<br>GMP understanding<br>but some basic pieces<br>are wrong or missing                      | The site is authorized<br>by the NMMA (valid<br>copy of official<br>document available<br>but reports are not<br>disclosed) | QA system exists and includes some other tools like CC and QRM. However corresponding reports can be missing.  | S & H program exists<br>general spie b<br>acce spire b<br>house reging<br>insufficient                   | A VMP exists and is maintain to me ve sation have be portured he are less to an progress  | SOF is evaluable for<br>constructional recent<br>and ig while labing<br>clearly eath (id an<br>east equality leaf,<br>for macker salts   | A SOP exists that<br>organize the<br>management of the<br>contracted<br>relationships. Less<br>than 50% of the<br>requested agreements<br>are signed   | Detailed 3OP exists<br>and a consistent<br>annual programme is<br>available. However<br>the plain is less than<br>80% completed.                             | Organogram, job osscription and training program exist. However the training is not fully executed (less than soft)    |
| 1<br>OR     | Assessed topic for the concerned sike shows that a number of important GMP requirements are not met or even totally missing                          | The audited site owns<br>a non-updated<br>manufacturing<br>authorization from its<br>NMRA (outdated<br>copy)                | GMP awareness is<br>poor, especially for<br>batch release. QA<br>system includes some<br>tools like IPC and<br>deviations but lack<br>modern quality tools | No S & H program and<br>general aspect and<br>housekeeping not<br>entirely satisfactory                  | Q & V are understood<br>and a simple VMP<br>exists but only some<br>processes are<br>validated or in<br>progress  | No formalized SOP for<br>handling of<br>complaints but some<br>records can be<br>presented   | Unclear description or<br>services contracted.<br>Less than 30% of the<br>requested agreements<br>are signed   | No detailed SOP on<br>self-inspections. Some<br>kind of self-<br>inspections exist but<br>poorly organized and<br>documented                                 | Organogram exists but no job descriptions. Training program exists but is not adapted to the competencies              |
| )<br>PTABLE | Available information<br>provides evidence of a<br>lack of GMP<br>understanding for the<br>corresponding topic<br>or information is not<br>available | A proof of authorization (licence) is not available   | GMP are not really<br>known. There is no<br>real QA system and<br>there are no quality<br>tools like IPC, CC or<br>deviation<br>linvestigation             | No S & H program.<br>General aspect and<br>organization very<br>weak                                     | Notions of Q.S. V are<br>poorly understood.<br>No VMP document is<br>available  | No formalized SOP for<br>handling of<br>complaints and<br>absence of a<br>complaint/recall<br>register   | Unclear description of<br>services contracted.<br>Less than 20% of the<br>requested agreements<br>are signed   | No SOP. Self<br>inspection obviously<br>not done   | No organogram. No<br>job description. No<br>recruitement based<br>on needed<br>competencies. No<br>training program    |





\*\*COMPLEX MPG PROCESS | 1 SECURITY CONTROLLARY PRODUCTS

\*\*COMPLEX MPG PROCESS | 2 SECURITY CONTROLLARY PROD

| A             | TRIX            | A: Excellent | B: Good | C: Fair | D: Poor   | E: Unacceptable |  |
|---------------|-----------------|--------------|---------|---------|-----------|-----------------|--|
|               |                 | Low          | Low     | Low     | Low       | Low             |  |
|               | A: Excellent    | Medium       | Medium  | Medium  | Medium    | Medium          |  |
|               |                 | High         | High    | High    | High      | High            |  |
| 7             |                 | Low          | Low     | Low     | Low       | Low             |  |
| QUALITY       | B: Good         | Medium       | Medium  | Medium  | Medium    | Medium          |  |
| 1 2           |                 | High         | High    | High    | High      | High            |  |
|               |                 | Low          | Low     | Low     | Low       | Low             |  |
| 2             | C: Fair         | Medium       | Medium  | Medium  | Medium    | Medium          |  |
| ΙĒ            |                 | High         | High    | High    | High      | High            |  |
| 4             |                 | Low          | Low     | Low     | Low       | Low             |  |
| MANUFACTURING | D: Poor         | Medium       | Medium  | Medium  | Medium    | Medium          |  |
| 2             |                 | High         | High    | High    | High      | High            |  |
|               |                 | Low          | Low     | Low     | Low       | Low             |  |
|               | F: Unaccentable | Marking      | Madicas | Madicas | Mandissan | Madisas         |  |

Quantifies overall latent risk of using a product, based on the three key components

PRODUCT DOSSIER QUALITY

| OVERALL RISK: Green | Very low risk of quality issues of these products   |
|---------------------|---|
| Light green         | Low risk of quality problems with these products  |
| Amber               | Medium risk of quality problems with these products. QC testing requirements would be moderate. |
| Light red           | High risk products. QC testing requirements quite extensive                                     |
| Red                 | Very high risk products and not recommended for use   |

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.

### Members of committee

- designated lead for clinical quality (Chair)
- procurement manager
- logistics or warehouse manager
- a service delivery channel manager
- another senior clinician
- programme pharmacist\* (where available)

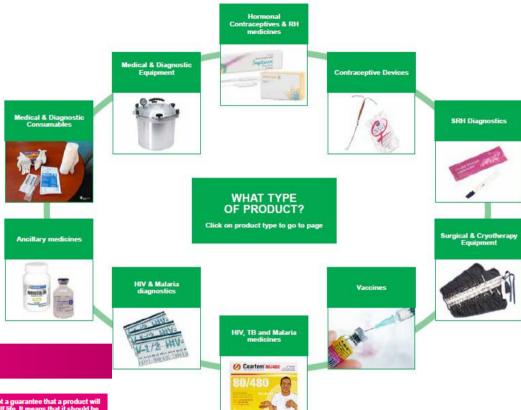
### Tasks of committee

- Developing and reviewing vour Standard Products List
- Ensuring Q-Trak is up to date Reviewing and managing product related incident reports
- Supplier assessments
- Ensuring minimum quality criteria for medical goods procurement are met when evaluating bids
- Evaluation of physical samples in procurement process
- All other matters relating to product quality

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### MARIE STOPES 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 sourcing quality products Maintaining quality during storage, distribution & use · Integrating quality into procurement · Useful tools and resources Stock Management Module 1 Procurement & Purchasing Module 2 **Product Quality** This module is primarily intended to be used by: Contract Procurement staff Warehouse and logistics staff Clinical Services senior managers Supplier Approval Any MSI staff to understand the basics

### **Product Quality Toolkit**



### **Understanding Product Quality – Quality Control Testing**

#### **Quality Control testing**

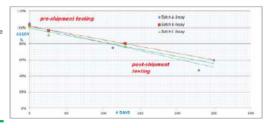
Quality Control testing (sometimes referred to as batch testing) is laboratory testing conducted to check if a product meets all of the specifications that it is supposed to meet. It checks whether the QA measures of the manufacturer were followed and were effective.

QC testing is routinely carried out by the manufacturer during production (the Certificate of Analysis is then 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) where pre-shipment testing of 3 batches of Misoolear was OK, but post-shipment testing showed that the tablets were degrading quickly.

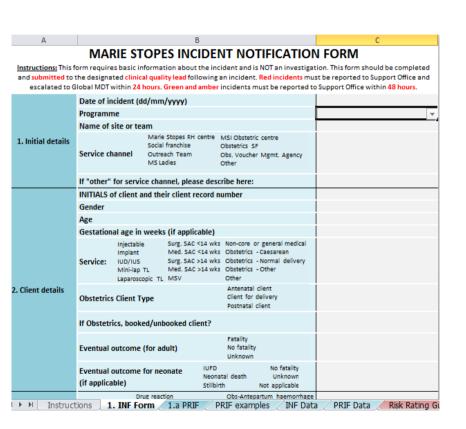
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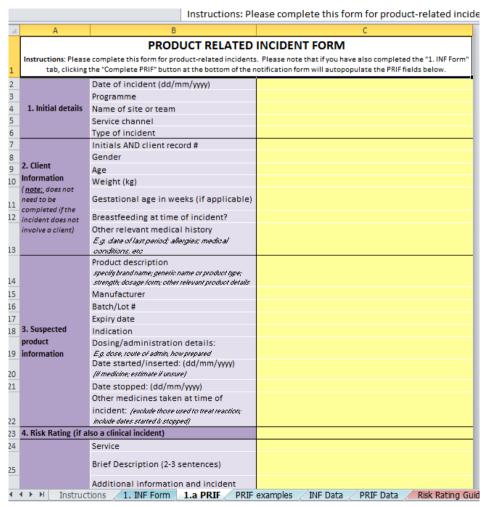


QC Testing Parameters for a tablet

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## Integrated incident reporting





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Supply planning & monitoring is critical to improve access

# Programme Standard Products Lists including approved products

| A1 • Standard Products List: Myanmar v2016 |                   |             |                                 |              |                                       |         |                              |                 |         |             |            |          |       |                 |       |         |          |         |          |  |               |
|--|-------------------|-------------|---------------------------------|--------------|---------------------------------------|---------|------------------------------|-----------------|---------|-------------|------------|----------|-------|-----------------|-------|---------|----------|---------|----------|--|---------------|
|  | А                 | В           | E                               | F            | Н                                     | L       | M                            | 0               | R       | S           | U          | X        | AC    | AD              | AF    | АН      | AJ       | AL      | AM       | AN   | AP            |
| 1  | Standar           | d Produ     | ıcts List: Myanmar v201         | .6           |                                       |         |                              |                 |         |             |            |          |       |                 |       |         |          |         |          |  |               |
| 2 DATA PRODUCT DETAILS                     |                   |             | THERAPEUTIC                     | SERVICES     |                                       |         |                              |                 |         |             |            | CHANN    | ELS   |                 |       | QUALITY |          |         |          |  |               |
|  |                   |             | Product name                    | Unit         | Therapeutic<br>Category (WHO)         | IUD     | Impla<br>nt<br>Inserti<br>on | Inject-<br>able | STI     | STI<br>plus | MEM<br>int | ANC      |       | Gener<br>al Med | IP    |         |          | Centre  |          |  |               |
|  |                   | Product     |                                 |              |                                       |         |                              |                 |         |             |            |          |       |                 |       | OR      |          |         |          | Approved Manufacturer                        |               |
| _  | TCODE ACI         | Catego ~    | aciclovir 200mg tab             | tablet       | 06.4 Antivirals                       | ~       | ~                            | _               | *       | 7           |            | ~        | ~     | ~               | *     | Clas: ▼ | Clas: 🔻  | aea 🕶   | ting     | / Wholesaler/Product  per MSIM Approved List | Category ,T   |
|  | T200              | ZIVIED      | aciciovii zoonig tab            | tablet       | 00.4 Antivirais                       |         |                              |                 |         | Х           |            |          |       |                 |       | Х       |          | X       |          | per ivisiivi Approved List                   | Key ancillary |
| 5  | EADPPC7           | 5EQPT       | adaptor double valve 7mm pcs    | pieces       | 33. Diagnostic<br>Equipment           |         |                              |                 |         |             |            |          | х     |                 |       |         |          | X       |          | MSI GSC                                      | KeySRH        |
| 6  | EADPPC8           | 5EQPT       | adaptor double valve 8mm pcs    | pieces       | 34. Medical<br>Equipment              |         |                              |                 |         |             |            |          | X     |                 |       |         |          | X       |          | MSI GSC                                      | KeySRH        |
| 7  | MADRIJ1           | 2MED        | adrenaline 1:1000 amp           | ampoule      | 03. Antiallergics &<br>Anaphylaxis    |         |                              |                 |         |             | X          |          |       |                 |       | X       | X        | X       |          | per MSIM Approved List                       | Key ancillary |
|  | TCODE_AM<br>XC500 | 2MED        | amoxicillin 500mg cap           | capsule      | 06.2 Antibacterials                   |         |                              |                 |         |             |            |          |       |                 |       | Х       | X        | X       |          | per MSIM Approved List                       | Key ancillary |
| 12   | MATRI05           | 2MED        | atropine 0.5-0.6mg/ml amp       | ampoule      | 04. Antidotes & used<br>in Poisonings |         |                              |                 |         |             | X          |          |       |                 |       | X       | X        | Х       |          | per MSIM Approved List                       | Key ancillary |
|  | TCODE_AZ<br>MT500 | 2MED        | azithromycin 500mg tab          | tablet       | 06.2 Antibacterials                   |         |                              |                 | X       |             |            |          |       |                 |       | X       | X        | X       |          | per MSIM Approved List                       | Key ancillary |
| 14   | TCODE_BZT<br>I24  | 2MED        | benzathine pen 2.4MIU vial      | vial         | 06.2 Antibacterials                   |         |                              |                 | X       |             |            |          |       |                 |       | X       | X        | X       |          | per MSIM Approved List                       | Key ancillary |
| 15   | ECNLPC4           | 5EQPT       | cannula no 4 pcs                | pieces       | 34. Medical<br>Equipment              | х       |                              |                 |         |             |            |          |       |                 |       | х       | х        | X       |          | MSI GSC                                      | KeySRH        |
| 16   | ECNLPC5           | 5EQPT       | cannula no 5 pcs                | pieces       | 34. Medical<br>Equipment              |         |                              |                 |         |             |            |          | х     |                 |       |         |          | X       |          | MSI GSC                                      | KeySRH        |
| 17   | ECNLPC6           | 5EQPT       | cannula no 6 pcs                | pieces       | 34. Medical<br>Equipment              |         |                              |                 |         |             |            |          | х     |                 |       |         |          | X       |          | MSI GSC                                      | KeySRH        |
| 18   |                   | 5EQPT       | cannula no 7 pcs                | pieces       | 34. Medical<br>Equipment              |         |                              |                 |         |             |            |          | х     |                 |       |         |          | X       |          | MSI GSC                                      | KeySRH        |
| 19   | TCODE_CFX<br>T200 | 2MED        | cefixime 200mg tab              | tablet       | 06.2 Antibacterials                   |         |                              |                 | X       |             |            |          |       | х               |       | х       | х        | X       |          | per MSIM Approved List                       | Key ancillary |
| 14 4                                       | ▶ ▶I tracke       | er / guidar | nce master list service by char | nnel / IUD / | / Impl Ins // Impl Ren                | n 🔏 Inj | ectable ,                    | OC & I          | EC / Co | ondom       | /STI/      | STI plus | ✓ MEN | M Basic ∡       | MEM i | nt 🔏 La | b test 🔏 | Child H | lealth _ | ANC / Cryo & HPV / VIA                       | GBV / PAC     |

## 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

