

RH Supplies: Insights from an INGO

Marie Stopes International

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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



<u>Source</u>: India National Drug Survey 2014-16

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HEALTH

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





Associate Editor, HuffPost Australia



LARLOR VISIGETTY RISSIES

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.

PRESENTED BY THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS



8 Skin Conditions You Should Know About

TRENDING

Someone Was Trying To Sell Nude Photos Of Sia So She Tweeted One Herself

Kate Winslet Kissed Allison Janney At The Hollywood Film Awards

Scott Ludiam is Having Lots Of Fun With The Citizenship Crisis



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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Version:	V4.0
	ntry programmes: CDs; SMTs; Designated Leads for Clinical Quality; Procurement & s Staff; Channel Leads; Providers
Ratified by:	MSI Executive Committee October 2016
Issue Date:	December 2016
Review Date:	December 2018

Product categories & minimum QA standards

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



Q-Trak	Home	My Products	My Submissions Key SRF	List Ancillary Lists How to / FAQ		Hello, jas	on Log Out
	he product: g. You shou	s which are curre		You can add new products, modify product fepristone products. Once you have comp			
	le - DMPA oduct Nam	• Ie	Manufacturer Name Pfizer / Pharmaci + Supplied By MSI GP&L •	Manufacturer Site Address Rijksweg, Puurs, Belgium Comments (optional)	* +	Product Details depomedroxyprogesterone ace - DFID-funded WHO or SRA Approved	+ Save Delete
	ostol tablets oduct Nam		Manufacturer Name ACME Formulatic • + Supplied By MSI GP&L •	Manufacturer Site Address Ropar Road, Nalagarh, Dist. Solan HP, Comments (optional)	India 👻 +	Product Details misoprostol 200mcg tablets (Mi - DFID-funded WHO or SRA Approved	+ Save Delete
Product Implant Your Pro		• Ie	Manufacturer Name Bayer Schering F → + Supplied By Govt: non-donor →	Manufacturer Site Address Turku, Finland Comments (optional)	* +	Product Details levonorgestrel 2x75mg implant - DFID-funded WHO or SRA Approved	+ Save Delete



WHO PQ currently covers a limited number of RH products



Products	Distributors Manu		Laboratories	Countrie	es Co	ontacts Matri	ix		Jason Bower – <u>Lo</u>
Name		Country	(Address			GMP category (greater or equal)
More [+]][
463 result	's								
Name	-	\$	Site ¢	GMP	\$	Country	¢	Products	Reports
E,				Categorie		Afghanistan (AF)			
	TT HEALTHCARE PRI	WATE		Categorie		India (IN)			
LTD	TT HEALTHCARE FRI	VATE		5		nula (IN)			EU GMP certificate (UK) - 2014
ABDI A.S.	Ibrahim Ilaç San vs 1	Гic.		Categorie 5	e .	Turkey (TR)			🔑 EU GMP certificate (Portugal) –
A.J.				, 					2013
In ACCU Strathroy	ICAPS INDUSTRIES Lt	d		Categorie 5	-	Canada (CA)			
						Q-Trak	Home	e My Prod	ucts My Submissions Key SRH List
Windsor	ICAPS INDUSTRIES Lt	a		Categorie 5		MSI List	t of	Recom	mended Manufacturers for
							. 01	1,0000111	

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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 can not be guaranteed
- 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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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 Malta	Malta	BLB 016, BLB 026, BLB 010, Bulebel Industrial Estate, Zejutn, ZTN3000
ACTAVIS PHARMA MANUFACTURING PVT	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



1. Manufacture	r GMP Rating Tool	* Summarises ratings o	GMP compliance of a man	efecturer across all of the i	ey WHO GMP areas *				
	Site / Topic Classification Interpretation	Site licensing	QA & Compliance History	Sanitation & hygiene	Validation	Complaints & Recalls	Contracts	Self Inspection	Personnel and training
4 EXCELLENT	Excellent GMP level is established and compliance demonstrated through fine analysis of all documentations and observations	The site is authorized and inspected by the NMRA (reports available that do not contain major observations)	QA system is developped and continously adapted. All required reports are timely available e.g. PQR	S & H program is quite correctly implemented and no finding on cleanliness from the auditor	The VMP is updated and completed : all the validation reports are available and approved	Full periodic reviews are performed on the handling of complaints and, where needed, of recalls with their approved reports	A SOP exists that organize the management of the contracted relationships. 100% of the requested agreements are signed	A detailed SDP, including "for-cause" self-inspections exist. All self-inspections are performed and reported with the corresponding CAPAs	Organogram, job description and training program exist and are updated. The training realization is > 50% and assessed
3 6000	Good GMP Compliance is estabilished through the existing systems and documentation but some vestinesses are remaining	The site is authorized and inspected by the NMRA (report available with some observations : few major observations)	QA system is developed and success of modern of sity of noclaring PA is due of s SO with the milling.	5 & H program reinforces with cop pr cisting of the prisof the tre	The VMP is updated and completed set of completed set of the set period set of the period set of the period set of the period set of the period set of the period set of the period set of the period set of the period set of the period set of the period set of the period set of the period set of the p	SOP for complaints and receits handling is conjuste and life of A hierts are do menud and where adde recei are god	A SOP exists that organize the management of the common of station bizzon we office the recognite present of biggs	Detailed SOP exists together with a program and with a template for reports. Some self-inspectione planned are not performed.	Organogram, job description and training program exist and are updated. The training realization is > 80%
2 FAIR	Documentation collected provides some indication of GMM understanding but some basic pieces are wrong or missing	The site is authorized by the NMRA (valid copy of official document available but reports are not disclosed)	QA system exists and includes some other tools like CC and QRM. However corresponding reports can be missing.	S & H program exists genere usper 5 accel able 5 house easing insummer	A VMP exists and is maintain the same ye abon have ex- p de taking in progress	SOP is evaluable for one light and results and is we taking clearly estimated resp. gashit e.g. for macking alls	A SOP exists that organize the management of the contracted relationships. Less than SOA of the requested agreements are signed	Detailed SOP exists and a consistent annual programme is evailable. However the plan is less than BO% completed.	Organogram, job description and training program exist. However the training is not fully executed (was than soft)
1 POOR	Assessed topic for the concerned site shows that a number of important GMP requirements are not met or even totally missing	The audited site owns a non-updated manufacturing authorization from its NMMR (outdated copy)	GMP awareness is poor, especially for batch release. QA system includes some tools like IPC and deviations but lack modern quality tools	No 5 & H program and general aspect and housekeeping not entirely satisfactory	Q & V are understood and a simple VMP exists but only some processes are validated or in progress	No formalized SOP for handling of completints but some records can be presented	Unclear description of services contracted. Less than 30% of the requested agreements are signed	No detailed SOP on self-inspections. Some kind of self- inspections exist but poorly organized and documented	Organogram exists but no joo descriptions. Training program exists but is not adapted to the competencies
0 UNACCEPTABLE	Available information provides evidence of a lack of GMP understanding for the corresponding topic or information is not available	A proof of authorization (licence) is not available	GMP are not really known. There is no real QA system and there are no quality tools like IPC, CC or deviation linvestigation	No S & H program. General aspect and organization very weak	Notions of Q. & V are poorly understood. No VMP document is available	No formalized SOP for bandling of complaints and absence of a complaint/recall register	Unclear description of services contracted. Less than 20% of the requested agreements are signed	No SOP. Self inspection obviouly not done	No organogram. No job description. No recruitement based on needed competencies. No training program



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

	STERILE DOSAGE FORM	8	COMPLEX MEG PROCESS	4	SENSITIVE ACTIVE SUBSTANCE		OA REQUIREMENTS	128	HIGH
	STERILE DOSAGE FORM	•	COMPLEX MED TROOLSS	4	SENSITIVE ACTIVE SUBSTANCE	2	QA REQUIREMENTS	64	HIGH
			STANDARD MEG PROCESS	2	SENSITIVE ACTIVE SUBSTANCE		DA REQUIREMENTS	64	HIGH
				-	STANDARD ACTIVE SUBSTANCE	2		32	MED
KEY SRH PRODUCTS	NON STERILE DOSAGE FORM	4	COMPLEX MFG PROCESS	4	SENSITIVE ACTIVE SUBSTANCE	4	OA REQUIREMENTS	64	HIGH
					STANDARD ACTIVE SUBSTANCE	2	OA REQUIREMENTS	32	MED
			STANDARD MFG PROCESS	2	SENSITIVE ACTIVE SUBSTANCE	4	QA REQUIREMENTS	32	MED
					STANDARD ACTIVE SUBSTANCE	2	QA REQUIREMENTS	16	MED
	STERILE DOS CORM	4	COMPLEX MFG PROCESS	4	SENSITIVE ACTIVE SUBSTANCE		QA REQUIREMENTS	64	HIGH
					STANDARD ACTIVE SUBSTANCE	2		32	MED
			S A DARL ME 3 PR CL SS	- 2	SENSITIVE ACTIVE SUBSTANCE	4	GA REQUIREMENTS	32	MED
EY ANCILLARY PRODUCTS		-	JUUC		STANDARD ACTIVE SUBSTANCE	2	GA REQUIREMENTS	16	MED
	NON STERILE DOSAGE FORM	2	COMPLEX MFG PROCESS	4	SENSITIVE ACTIVE SUBSTANCE	4	OA REQUIREMENTS	32	MED
					STANDARD ACTIVE SUBSTANCE	2		16	MED
			STANDARD MFG PROCESS	2	SENSITIVE ACTIVE SUBSTANCE	4		16	MED
		-	at a vi		STAL DARD ACTIVE SUBSTANCE	2	OA REQUIREMENTS	8	LOW
				5	· · · · · ·				
	STELLE JUS SE ORT	Æ	COMPLEX IFG PROLESS	4	EN TIV A TVE SUBSTAN	4	OA REQUIREMENTS	32	MED
			STANDARD MEG PROCESS	-	STANDARD ACTIVE SUBSTINUCE	2	OA REQUIREMENTS	16	MED
			STANDARD MEG PROCESS	2	SENSITIVE ACTIVE SUBSTANCE	4	QA REQUIREMENTS	16	MED
OTHER ANCILLARY PRODUCTS	NON STERILE DOSAGE FORM	-	COMPLEX MEG PROCESS	2	STANDARD ACTIVE SUBSTANCE SENSITIVE ACTIVE SUBSTANCE	2	QA REQUIREMENTS	8	LOW
	NON STENCE DUSAGE FORM	1	COMPLEX MPO PROCESS	2	SENSITIVE ACTIVE SUBSTANCE STANDARD ACTIVE SUBSTANCE	4	QA REQUIREMENTS	8	LOW
			STANDARD MEG PROCESS	1	SENSITIVE ACTIVE SUBSTANCE	4	QA REQUIREMENTS	4	LOW
			on the area and though	1.1	SENSITIVE ACTIVE SUBSTANCE STANDARD ACTIVE SUBSTANCE		QA REQUIREMENTS	2	LOW
					STANDARD ADTINE SUBSTANCE	4	UN REVUNEMENTS	- 4	2014
TERILE DOSAGE	COMPLEX PROCESS		SENSITIVE ACTIVE SUBSTANC	F	1				
niectable products	Fixed-dose combination		Narrow therapeutic index	-					
	Modified release products		Polymorphism						
	Aseptic manufacturing		Low stability		1				
	Very low dosage formulations				1				
1									

ATRIX			PR	ODUCT DOSSIER QUAL	TY ²	
A_	JEIA	A: Excellent	B: Good	C: Fair	D: Poor	E: Unacceptabl
		Low	Low	Low	Low	Low
	A: Excellent	Medium	Medium	Medium	Medium	Medium
		High	High	High	High	High
۲,		Low	Low	Low	Low	Low
QUALITY ¹	B: Good	Medium	Medium	Medium	Medium	Medium
2		High	High	High	High	High
		Low	Low	Low	Low	Low
RIN	C: Fair	Medium	Medium	Medium	Medium	Medium
MAMUFACTURING		High	High	High	High	High
IFA		Low	Low	Low	Low	Low
3	D: Poor	Medium	Medium	Medium	Medium	Medium
ž		High	High	High	High	High
		Low	Low	Low	Low	Low
	E: Unacceptable	Medium	Medium	Medium	Medium	Medium
		High	High	High	High	High

Light green Amber

Light red

Low risk of quality problems with these products

Medium risk of quality problems with these products. QC testing requirements would be moderate.

High risk products. QC testing requirements quite extensive

Very high risk products and not recommended for use

Insight #5

Product quality falls in a hole if you don't have clear accountabilities



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	Tasks 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) 	 Developing and reviewing your 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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Integrated incident reporting

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. Date of incident (dd/mm/yyyy) Programme Name of site or team Marie Stopes RH centre MSI Obstetric centre 1. Initial details Social franchise Obstetrics SF Service channel Outreach Team Obs. Voucher Mgmt. Agency MS Ladies Other If "other" for service channel, please describe here: INITIALS of client and their client record number Gender Age Gestational age in weeks (if applicable) Injectable Surg. SAC <14 wks Non-core or general medical Med. SAC <14 wks Obstetrics - Caesarean Implant Service: IUD/IUS Surg. SAC >14 wks Obstetrics - Normal delivery Med. SAC >14 wks Obstetrics - Other Mini-lap TL Laparoscopic TL MSV Other Antenatal client 2. Client details Client for delivery **Obstetrics Client Type** Postnatal client If Obstetrics, booked/unbooked client? Fatality No fatality Eventual outcome (for adult) Unknown IUFD No fatality Eventual outcome for neonate Neonatal death Unknown (if applicable) Stillbirth Not applicable Drug reaction Obs-Antepartum haemorrhage INF Form 1.a PRIF PRIF examples / INF Data PRIF Data 🧹 Risk Rating G

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MARIE STOPES INCIDENT NOTIFICATION FORM

Instructions: Please complete this form for product-related incide

PRODUCT RELATED INCIDENT FORM

В

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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.

2		Date of incident (dd/mm/yyyy)									
3		Programme									
4	1. Initial details	Name of site or team									
5		Service channel									
6		Type of incident									
7		Initials AND client record #									
8		Gender									
9	2. Client	Age									
10	Information	Weight (kg)									
11	(<u>note:</u> does not need to be completed if the	Gestational age in weeks (if applicable)									
12	incident does not	Breastfeeding at time of incident?									
	involve a client)	Other relevant medical history									
		E.g. date of last period; allergies; medical									
13		conditions, etc									
		Product description									
14		specify brand name; generic name or product type; strength; dosage form; other relevant product details									
15		Manufacturer									
16		Batch/Lot #									
17		Expiry date									
18	3. Suspected	Indication									
	product	Dosing/administration details:									
19	information	E.g. dose, route of admin, how prepared									
		Date started/inserted: (dd/mm/yyyy)									
20		(if medicine; estimate if unsure)									
21		Date stopped: (dd/mm/yyyy)									
		Other medicines taken at time of									
		incident: (evolute those used to treat reaction; include dates started & stopped)									
22	A Rick Pating (if a)	Include dates started & stopped/ Iso a clinical incident)									
23	4. NISK NAUIIg (II a										
24		Service									
25		Brief Description (2-3 sentences)									
		Additional information and incident									
- ا	Instructions 1. INF Form 1.a PRIF PRIF examples INF Data PRIF Data Risk Rating Guid										

Insight #6

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	М	0	R	S	U	X	AC	AD	AF	AH	AJ	AL	AM	AN	AP
1	1 Standard Products List: Myanmar v2016																				
2	DATA PRODUCT DETAILS			THERAPEUTIC	SERVICES										CHANN	ELS			QUALITY		
	Product	Product	Product name	Unit	Therapeutic Category (WHO)	IUD	Impla nt Inserti on	Inject- able	STI	STI plus	MEM int	ANC		Gener al Med	IP		Centre		Marke	Approved Manufacturer	
3		Catego 🗸				-	-	-			-	-	-			Clas: 👻	Clas: 👻	ded 👻	ting 👻	/ Wholesaler/Product 👻	Category 🖵
4	TCODE_ACI T200	2MED	aciclovir 200mg tab	tablet	06.4 Antivirals					х						х		x		per MSIM Approved List	Key ancillary
5	EADPPC7	5EQPT	adaptor double valve 7mm pcs	pieces	33. Diagnostic Equipment								х					x		MSI GSC	KeySRH
6	EADPPC8	5EQPT	adaptor double valve 8mm pcs	pieces	34. Medical Equipment								х					x		MSI GSC	KeySRH
7	MADRIJ1	2MED	adrenaline 1:1000 amp	ampoule	03. Antiallergics & Anaphylaxis						х					х	x	х		per MSIM Approved List	Key ancillary
11	TCODE_AM XC500	2MED	amoxicillin 500mg cap	capsule	06.2 Antibacterials											х	х	х		per MSIM Approved List	Key ancillary
12	MATRI05	2MED	atropine 0.5-0.6mg/ml amp	ampoule	04. Antidotes & used in Poisonings						х					х	х	х		per MSIM Approved List	Key ancillary
13	TCODE_AZ MT500	2MED	azithromycin 500mg tab	tablet	06.2 Antibacterials				x							х	x	x		per MSIM Approved List	Key ancillary
14	TCODE_BZT I24	2MED	benzathine pen 2.4MIU vial	vial	06.2 Antibacterials				x							х	x	x		per MSIM Approved List	Key ancillary
15	ECNLPC4	5EQPT	cannula no 4 pcs	pieces	34. Medical Equipment	x										х	x	x		MSI GSC	KeySRH
16	ECNLPC5	5EQPT	cannula no 5 pcs	pieces	34. Medical Equipment								x					x		MSI GSC	KeySRH
17	ECNLPC6	5EQPT	cannula no 6 pcs	pieces	34. Medical Equipment								x					x		MSI GSC	KeySRH
18	ECNLPC7	5EQPT	cannula no 7 pcs	pieces	34. Medical Equipment								х					x		MSI GSC	KeySRH
	TCODE_CFX T200	2MED	cefixime 200mg tab	tablet	06.2 Antibacterials				x					x		х	x	x		per MSIM Approved List	Key ancillary
I4 4	H 🔹 🕨 tracker / guidance] master list / service by channel / IUD / Impl Ins / Impl Rem / Injectable / OC & EC / Condom / STI / STI plus / MEM Basic / MEM int / Lab test / Child Health / ANC / Cryo & HPV / VIA / GBV / PAC /																				

Other measures to improve access

- Development of supply plans

 annual planning of allocated supplies versus needs
 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

