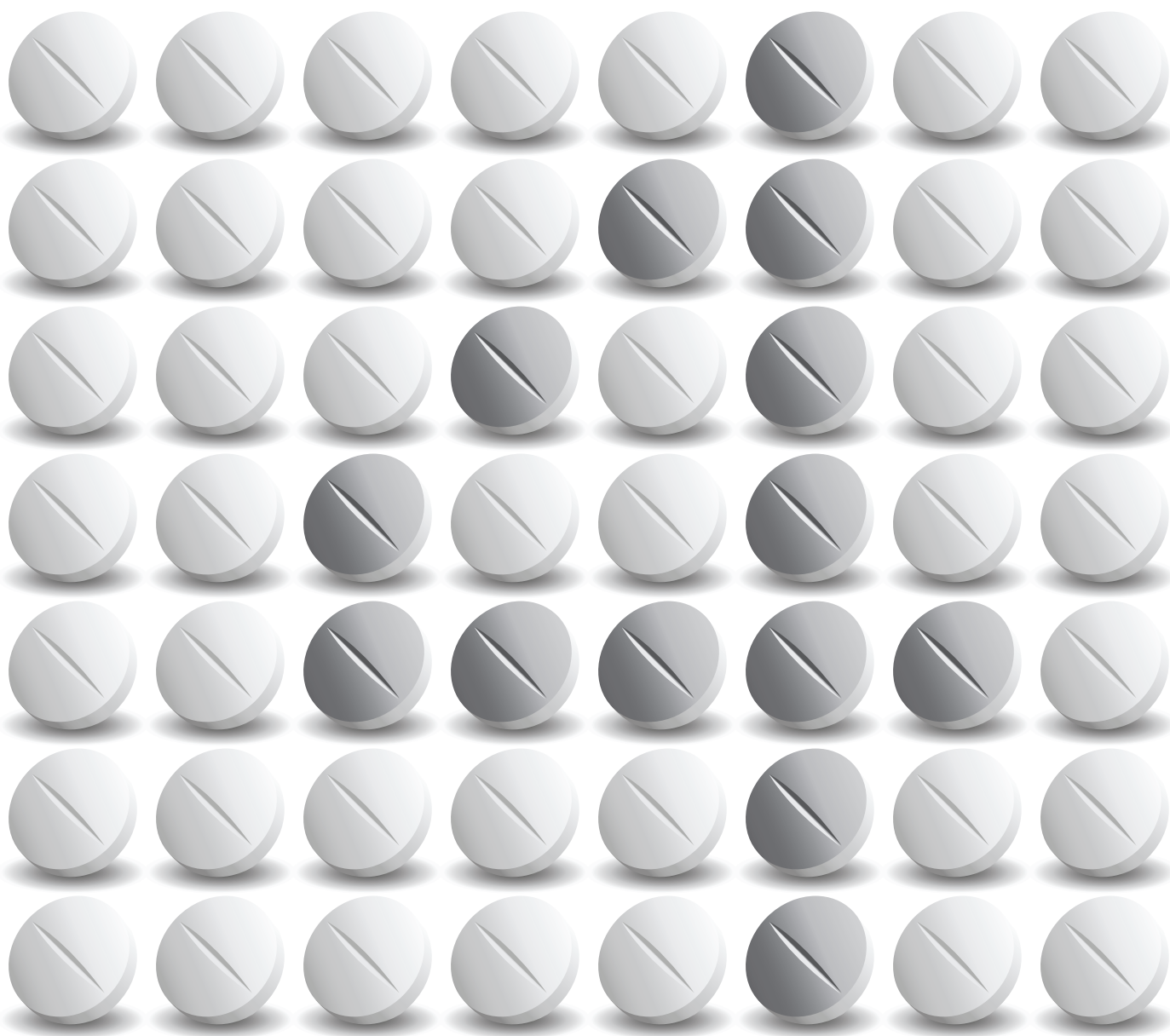


QUARTERLY REPORT

QUALITY ASSURANCE & LONG-TERM AGREEMENTS WITH SUPPLIERS

Quarter 4 / 2011



ABOUT THIS REPORT

This report includes the current quality assurance status of products supplied by GDF, as well as the long-term agreements (LTAs) for procurement that are in place.

Products in this report are listed according to the following categories:

WHO PQP	Green	Products are recommended for procurement.
SRA Authorized	Green	Products are recommended for procurement.
ERP Category 1 and 2	Green	Products may be considered for time-limited procurement.
ERP Category 3	Orange	Products may be considered for procurement only if there is no other option and the risk of not treating the disease is higher than the risk of using the product.
ERP Category 4	Red	Products may not be considered for procurement under any circumstances.

- **WHO PQP: World Health Organization Pre-qualification of Medicines Programme**
(<http://apps.who.int/prequal/>)
- **SRA Authorized: Stringent Regulatory Authority authorized products** are products approved or authorized for use in the country by a stringent regulatory authority (a member, observer or associate of ICH (<http://www.ich.org/>))
- **Expert Review Panel (ERP)** is a group of regulatory experts convened by World Health Organization/Essential Medicines Policy/Quality Safety of Medicines to conduct quality risk assessment of finished pharmaceutical products (FPP) for which there is less than 3 WHO pre-qualified and/or Stringent Regulatory Authority authorized sources and recommended for procurement for limited period of time. The ERP classifies the FPPs reviewed into 4 categories.

TABLE OF CONTENTS

FIRST LINE ANTI-TB MEDICINES	3 - 7
1. Oral Solid Dosage Forms: Fixed Dosed Combinations for Adults	
2. Oral Solid Dosage Forms: Single Dose Formulations for Adults	
3. Oral Solid Dosage Forms: Fixed Dosed Combinations for Children	
4. Oral Solid Dosage Forms: Single Dose Formulations for Children	
5. Parenteral Injectables	
6. Medical Devices	
7. STOP TB Kits	
SECOND LINE ANTI-TB MEDICINES	8 - 11
1. Oral Solid Dosage Forms: Fluoroquinolones	
2. Oral Solid Dosage Forms: Bacteriostatics Second Line Drugs	
3. Parenteral Injectables	
THIRD LINE ANTI-TB MEDICINES	12
FIRST LINE ANTI-TB DRUGS USED AGAINST DRUG-RESISTANT TB	12

For further information, please, see **GDF's Quality Assurance Policy** at:
http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp

FIRST LINE ANTI-TB MEDICINES

1. Oral Solid Dosage Forms: Fixed Dosed Combinations for Adults

4FDC/RHZE¹/150/75/400/75 mg tablet - (blister) – High demand product

MACLEODS	LUPIN	SANDOZ/STRIDES	STRIDES ARCOLAB	SVIZERA
WHO PQ	WHO PQ	SRA authorized	ERP Category 3	ERP category 4

Comments: As this is a high demand product, multiple Long Term Agreements (LTA's) implemented with Sandoz/Strides, Lupin and Macleods, from 1/7/11 to 30/6/12.

4FDC/ RHZE/150/75/400/75 mg tablet - (loose) – Low demand product

MACLEODS	LUPIN	STRIDES ARCOLAB	SVIZERA
WHO PQ	WHO PQ	ERP Category 3	ERP category 4

Comments: As this is a low demand product, LTA implemented with only 1 supplier - Lupin from 1/7/11 to 30/6/12.

3FDC/ RHE/150/75/75 mg tablet - (blister) – Medium demand product

MACLEODS	LUPIN
WHO PQ	ERP Category 3

Comments: LTA's implemented with Lupin and Macleods from 1/7/11 to 30/6/12.

3FDC/ RHE/150/75/75 mg tablet - (loose) – Low demand product

MACLEODS	LUPIN
WHO PQ	ERP Category 3

Comments: LTA's implemented with Lupin and Macleods from 1/7/11 to 30/6/12.

2FDC/ RH/150/75mg tablet - (blister) – High demand product

MACLEODS	LUPIN	SANDOZ/STRIDES	STRIDES ARCOLAB	SVIZERA
WHO PQ	WHO PQ	SRA authorized	ERP Category 3	ERP category 3

Comments: As this is a high demand product, LTA's implemented with Sandoz/Strides, Lupin and Macleods from 1/7/11 to 30/6/12.

2FDC/RH/150/75 mg tablet - (loose) – Low demand product

MACLEODS	LUPIN	SANDOZ/STRIDES	STRIDES ARCOLAB	SVIZERA
WHO PQ	WHO PQ	SRA authorized	ERP Category 3	ERP category 3

Comments: LTA implemented with Lupin from 1/7/11 to 30/6/12.

¹ R: Rifampicin; H: Isoniazid; Z: Pyrazinamide; E: Ethambutol

2FDC/RH/150/150 mg tablet - (blister) – Low demand product

No qualified supplier

Comments: There are two producers of this medicine - Lupin and Svizera. Both submitted dossiers to the ERP for review and were categorized 4 in April 2011. GDF is working with the Global Fund and WHO PQP to endeavour to ensure that a quality assured product can be sourced within the next 6 months. It is noted that the product is in low demand.

2FDC/RH/150/150 mg tablet - (loose) – Low demand product

No qualified supplier

Comments: There are two producers of this medicine - Lupin and Svizera. Both submitted dossiers to the ERP for review and were categorized 4 in April 2011. GDF is working with the Global Fund and WHO PQP to endeavour to ensure that a quality assured product can be sourced within the next 6 months. It is noted that the product is in low demand.

2FDC/EH/400/150 mg tablet - (blister) – Medium demand product

MACLEODS	CADILA	LUPIN	SVIZERA
WHO PQ	WHO PQ	ERP Category 3	ERP category 3

Comments: LTA implemented with Cadila from 1/7/11 to 30/6/12.

2. Oral Solid Dosage Forms: Single Dose Formulations for Adults

Ethambutol (E) 400mg tablet - (blister) – Low demand product

MACLEODS	CADILA	LUPIN	SVIZERA
WHO PQ	WHO PQ	WHO PQ	ERP Category 2 (15/07/2012)

Comments: LTA implemented with Cadila from 1/7/11 to 30/6/12.

Isoniazid (H) 300 mg tablet - (blister) – Medium demand product

MACLEODS	SVIZERA
WHO PQ	ERP Category 3

Comments: The enormous price increase in Macleods pricing as submitted in June 20011, is not acceptable because Macleods have not been able to justify the price. No LTA will therefore be implemented for this product at this time and orders will be consolidated for spot bidding.

Pyrazinamide (Z) 400 mg tablet - (blister) – Low demand product

MACLEODS	CADILA	SVIZERA
WHO PQ	WHO PQ	ERP Category 4

Comments: LTA implemented with Cadila from 1/7/11 to 30/6/12.

3. Oral Solid Dosage Forms: Fixed Dosed Combinations for Children

3FDC/RHZ/60/30/150 mg tablet - (blister) – High demand product

MACLEODS	LUPIN	STRIDES ARCOLAB	SVIZERA
WHO PQ	ERP Category 3	ERP Category 3	ERP category 4

Comments: LTA's implemented with Lupin and Macleods from 1/7/11 to 30/6/12. GDF is concerned about high pricing from Macleods and will consolidate orders for spot bidding.

2FDC/RH/60/60 mg tablet - (blister) – Low demand product

MACLEODS	SANDOZ	SVIZERA
WHO PQ	ERP Category 3	ERP category 4

Comments: LTA implemented with Macleods from 1/7/11 to 30/6/12.

2FDC/RH/60/30 mg tablet - (blister) – High demand product

MACLEODS	LUPIN	STRIDES ARCOLAB	SVIZERA
WHO PQ	ERP Category 3	ERP Category 3	ERP category 4

Comments: LTA's implemented with Lupin and Macleods from 1/7/11 to 30/6/12. GDF is concerned about high pricing from Macleods and will consolidate orders for spot bidding.

4. Oral Solid Dosage Forms: Single Dose Formulations for Children

Isoniazid (H) 100 mg tablet - (blister) – High demand product

MACLEODS	FATOL
WHO PQ	SRA authorized

Comments: LTA implemented with Macleods from 1/7/11 to 30/6/12. At the moment, there are no additional manufacturers in the pipeline². GDF is very concerned about this and is working with partners further.

Ethambutol (E) 100 mg tablet - (blister) – Low demand product

MACLEODS	FATOL
WHO PQ	SRA authorized

Comments: LTA implemented with Macleods from 1/7/11 to 30/6/12.

² Manufacturers in the pipeline mean that the drug dossier has been submitted and is under assessment either by WHO PQP or an SRA or by the ERP.

5. Parenteral Injectables

Streptomycin 1 g powder for injection - (vial) – High demand product

REIG JOFRE	PANPHARMA	MACLEODS
SRA authorized	Renewal submitted to the French regulatory authorities in June 2011. Under review.	Dossier submitted to ERP in September 2011. Under review.

Comments: LTA implemented with Reig Jofre from 1/7/11 to 30/6/12. In addition to the two producers in the pipeline (Panpharma and Macleods), other companies from India, Ukraine and Thailand are working on product development, site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM³. The time estimated to prequalification is +24 months.

Water for injection 5 ml - (ampoules) – High demand product

B BRAUN	LABESFAL
SRA authorized	SRA authorized

Comments: LTA implemented with Labesfal from 1/7/11 to 30/6/12.

6. Medical Devices

Auto disable syringes and needles 5ml - 21G – Medium demand product

HINDUSTAN
WHO PQS ⁴

Comments: LTA implemented with Hindustan from 1/7/11 to 30/6/12.

Auto disable syringes and needles 5ml - 23G – Medium demand product

HINDUSTAN
WHO PQS

Safety disposal box – Unknown demand as this is a new product in 2011

HINDUSTAN
NA

Comments: LTA implemented with Hindustan from 1/7/11 to 30/6/12.

³ United States Pharmacopoeia/Promoting Quality of Medicines: <http://www.usp.org/worldwide/>

⁴ PQS: Performance, Quality and Safety: http://www.who.int/immunization_standards/vaccine_quality/pqs/en/index.html

7. STOP TB Kits

CAT I & III KIT A: 4 FDC and 2 FDC (RH 150/75) tablets – Medium demand product

MACLEODS	STRIDES/SANDOZ	LUPIN	SVIZERA
Component products compliant with QA criteria	Component products compliant with QA criteria	Component products compliant with QA criteria	Component products not compliant with QA criteria

Comments: LTA's implemented with Strides/Sandoz and Lupin from 1/7/11 to 30/6/12.

CAT I & III KIT B: 4 FDC and 2 FDC (EH 400/150) tablets – Medium demand product

MACLEODS	LUPIN	SVIZERA	CADILA
Component products compliant with QA criteria	4 FDC component product compliant with QA criteria	Component products not compliant with QA criteria	Component products not compliant with QA criteria

Comments: LTA's implemented with Macleods and Lupin from 1/7/11 to 30/6/12.

CAT I & III KIT C: 4 FDC and 2 FDC (RH 150/150) – Medium demand product

No qualified supplier

Comments: The only two manufacturers and bidders are Lupin and Svizera which are not approved as offering quality-assured products (i.e RH 150/150). GDF is working with the Global Fund and WHO PQP to endeavour to ensure that a quality assured product can be sourced within the next 6 months.

CAT II KIT A1: 4 FDC, 3 FDC, S and water for injection – Low demand product

No qualified supplier

Comments: The only bidder was Svizera which is not approved as offering quality-assured kit products. GDF is working with the Global Fund and WHO PQP to endeavour to ensure that a quality assured product can be sourced within the next 6 months. It is noted that the product is in low demand.

CAT I & III KIT B1: 4 FDC, 2 FDC, E 400, S, water for injection – Low demand product

No qualified supplier

Comments: The only bidder was Svizera which is not approved as offering quality-assured kit products. GDF is working with the Global Fund and WHO PQP to endeavour to ensure that a quality assured product can be sourced within the next 6 months. It is noted that the product is in low demand.

SECOND LINE ANTI-TB MEDICINES

1. Oral Solid Dosage Forms: Fluoroquinolones

Ofloxacin 200mg tablet - (blister) – Low demand product

MACLEODS	CIPLA
ERP Category 3	ERP Category 2 (31/03/2012)*

*ERP validity period

Comments: LTA implemented with Cipla from 15/10/11 to 14/10/12.

Ofloxacin 400mg tablet - (blister) – Low demand product

CIPLA
ERP Category 2 (31/03/2012)

Comments: LTA implemented with Cipla from 15/10/11 to 14/10/12.

Levofloxacin 250mg tablet - (blister) – High demand product

MACLEODS	CIPLA
ERP Category 1 (31/01/2012)	ERP Category 1(15/07/2012)

Comments: LTA's implemented with Macleods and Cipla from 15/10/11 to 14/10/12. One additional company from India has submitted the dossier for ERP review in September 2011.

Levofloxacin 500mg tablet - (blister) – High demand product

MACLEODS	CIPLA
ERP Category 2 (15/07/2012)	ERP Category 2 (15/07/2012)

Comments: LTA's implemented with Macleods and Cipla from 15/10/11 to 14/10/12. One additional company from India has submitted the dossier for ERP review in September 2011. Other companies from Brazil, India, Indonesia, Nepal, Philippines and Thailand are working on product development (both strengths 250 and 500 mg), site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM⁵. The time estimated to prequalification is +24 months.

Moxifloxacin 400mg tablet - (blister) – Medium demand product

BAYER	CIPLA	MACLEODS
SRA-authorized	WHO PQP	ERP Category 2 (15/07/2012)

Comments: Bayer signed an agreement with WHO in August 2011 to provide a quota of moxifloxacin at a concessional price. LTA's implemented with Cipla and Macleods from 15/10/11 to 14/10/12. A company from Nepal is working on product development, site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM. The time estimated to prequalification is +24 months.

⁵ United States Pharmacopoeia/Promoting Quality of Medicines: <http://www.usp.org/worldwide/>

2. Oral Solid Dosage Forms: Bacteriostatics Second Line Drugs

Ethionamide 250mg tablet - (blister) – High demand product

MACLEODS	LUPIN	CIPLA
WHO PQP	ERP Category 1 (15/07/2012)	ERP Category 1 (31/01/2012)

Comments: LTA's implemented with Macleods, Lupin and Cipla from 15/10/11 to 14/10/12. One additional company from India has submitted the drug dossier for ERP review in September 2011. Another company from India is working on product development, site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM. The time estimated to prequalification is +24 months.

Prothionamide 250mg tablet - (blister) – High demand product

FATOL
SRA-authorized

Comments: LTA implemented with Fatol from 15/10/11 to 14/10/12. Two companies from India have submitted the drug dossiers for ERP review in September 2011. One additional company from India is working on product development, site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM. The time estimated to prequalification is +24 months.

Prothionamide 250mg tablet - (loose) – High demand product

LUPIN	OLAINFARM
ERP Category 1 (15/07/2012)	SRA authorized

Comments: LTA implemented with Lupin from 15/10/11 to 14/10/12. Lupin and another company from India have submitted the drug dossiers in blister packing for ERP review in September 2011. OlainFarm was approved in September 2011 and will be invited to future bids.

Cycloserine 250mg capsules - (strips) – High demand product

MACLEODS
WHO PQP

Comments: LTA implemented with Macleods from 15/10/11 to 14/10/12. One company from Russia and one company from India have submitted drug dossiers for ERP review in September 2011. Additional companies from India and Nepal are working on product development, site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM. The time estimated to prequalification is +24 months.

Cycloserine 250mg capsules - (loose – 100 caps) – Low demand product

ASPEN
WHO PQP

Comments: Aspen has offered a product with very short shelf life of just 18 months and long delivery of 26 weeks. In addition to this, it is more expensive than the blister packed product, which has a 24 month shelf life and 8-10 week delivery period. Procurement of this product is on a case by case basis if countries specifically request loose as opposed to blister packaging.

Cycloserine 250mg capsules - (loose – 40 caps) – Low demand product

CHAO CENTRE
SRA-authorized

Comments: The fact that the loose product is more expensive than blister packing means that GDF only procures this product on a case by case basis if countries specifically request as opposed to more common packing of 100 capsules.

PAS Acid enteric coated granules - (sachets) – High demand product

JACOBUS

SRA-authorized

Comments: LTA implemented with Jacobus from 15/10/11 to 14/10/12.

PAS Sodium powder for oral solution - (sachets) – Medium demand product

OLAINFARM

WHO PQP

Comments: LTA implemented with OlainFarm from 15/10/11 to 14/10/12.

PAS Sodium enteric coated granules - (container) – Medium demand product

MACLEODS

WHO PQP

Comments: LTA implemented with Macleods from 15/10/11 to 14/10/12.

PAS Sodium enteric coated granules - (sachets) – Medium demand product

MACLEODS

WHO PQP

Comments: LTA implemented with Macleods from 15/10/11 to 14/10/12. Overall, there are 3 qualified manufacturers for the p-aminosalicylic, both formulations acid and sodium. At the moment, there are no additional manufacturers in the pipeline.

Terizidone 250mg capsules - (blister) – No demand in previous years (All countries had requested cycloserine instead.)

FATOL

SRA-authorized

Comments: LTA implemented with Fatol from 15/10/11 to 14/10/12.

3. Parenteral Injectables

Capreomycin 1g inj powder for injection - (vial) – High demand product

AKORN	VIANEX	MACLEODS
SRA authorized	Dossier submitted to the Spanish regulatory authorities in Q4/2010. Under review.	Dossier submitted to WHO PQP and ERP in September 2011. Under review.

Comments: LTA implemented with Akorn from 15/10/11 to 14/10/12. In addition to the two producers in the pipeline (Vianex and Macleods), other companies from India, South Africa and Ukraine are working on product development, site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM. The time estimated to prequalification is between 12 and 24 months.

Kanamycin 1g powder for injection - (vial) – High demand product

No qualified supplier

PANPHARMA	MACLEODS
Renewal /variations submitted to the Baltic regulatory authorities in Q3-Q4/2010. Under review.	Dossier submitted to WHO PQP and ERP in September 2011. Under review

Comments: In addition to the two producers in the pipeline (Vianex and Macleods), other companies from Russia, India and Ukraine are working on product development, site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM. The time estimated to prequalification is between 12 and 24 months.

Kanamycin 0.5g powder for injection - (vial) – Low demand product

No qualified supplier

Comments: This packaging has been requested specifically by India due to low patient weights and perceived product wastage.

MACLEODS
Dossier submitted to WHO PQP and ERP in September 2011. Under review.

Kanamycin 1g solution for injection - (ampoule) – High demand product

MEIJI
SRA-authorized

Comments: LTA implemented with Meiji from 15/10/11 to 14/10/12. At the moment, there are no additional manufacturers in the pipeline for kanamycin *solution for injection*.

Amikacin 500mg powder for injection - (vial) – High demand product

MYLAN
SRA-authorized

Comments: Mylan did not submit a bid and therefore it has not been possible to implement an LTA for this product. Orders will be consolidated for spot bidding.

Companies from Thailand and the Philippines are working on amikacin 1 g development, site and dossier preparations in line with WHO PQP requirements with the technical assistance of USP/PQM. The time estimated to prequalification is + 24 months.

Amikacin 500mg solution for injection - (ampoule) – High demand product

MEDOCHEMIE	CIPLA
SRA-authorized	WHO PQ

Comments: LTA's implemented with Medochemie and Cipla from 15/10/11 to 14/10/12. At the moment, there are no additional manufacturers in the pipeline for amikacin *solution for injection*.

THIRD LINE ANTI-TB MEDICINES

1. Oral Solid Dosage Forms

Amoxicillin clavunate 875mg + 125mg tablet - (blister) – Low demand product

MEDOCHEMIE

SRA-authorized

Comments: LTA implemented with Medochemie from 15/10/11 to 14/10/12.

Clarithromycin 500 mg tablet - (blister) – Low demand product

REMEDICA

SRA-authorized

Comments: Remedica was approved as supplier in September 2011. The company will be invited to future bids.

One company from India submitted a **linezolid** dossier for ERP review in September 2011.

FIRST LINE ANTI-TB DRUGS USED IN DRTB

Pyrazinamide (Z) 500 mg tablet - (blister) – Low demand product globally, product mostly supplied to India DRTB programme

MACLEODS

ERP Category 3

Comments: No LTA to be implemented at this time. This product was also included in the ITB for SLD for India with specific quantity requirements.

Pyrazinamide (Z) 750 mg tablet - (blister) – Low demand product globally, product mostly supplied to India DRTB programme

MACLEODS

ERP Category 3

Comments: No LTA to be implemented at this time. This product was also included in the ITB for SLD for India with specific quantity requirements.

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