Access to Quality Medicines and Other Technologies Task Force
Regulation of Anti-Malarial Commodities with a focus on Artemisinin-Combination Therapy in Asia and Pacific

Sydney, March 12, 2014

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Dean and Director
Empower School of Health
New Delhi, India

With support from
Andy Barraclough, Empower School of Health
Jody Tate, HRF
Input from: Dr Alasdair Breckenridge (former Chair, MHRA, UK)
Presentation Overview

• Focus of research
• Background information to inform options for regulatory interventions
  – Global Malaria Action Plan (GMAP)
  – ACT-related challenges in Asia-Pacific
  – Regulatory strategy and challenges in Asia-Pacific
• Options for Regulatory Interventions
  – Ensuring product quality in Asia-Pacific
  – Wipe-out sub-standard and counterfeits
  – Strengthen private sector industry
  – Phase-out oral artemisinin-based monotherapies
• Options for Policies and & Next Steps
Focus of Research

Commodity Focus
- Antimalarial commodities - medicines, diagnostics, medical supplies, insecticides & bednets
- Focus area - Oral Artemisinin based combination therapy (ACTs)

Regulatory Focus
- Regulatory challenges and strategy to promote access to quality-assured ACTs
- Health systems strengthening focus (benefits antimalarial drugs, and ALL other products)
Background for regulatory interventions and policies for promoting access to quality-assured ACTs
Global Malaria Action Plan

• Provides a *global framework for action* around which partners can coordinate their efforts
• Outlines the vision for a substantial and sustained *reduction and eventual eradication* in the burden of malaria
• Highlights *anti-malarial drug resistance* as a major public health challenge

WHO (2013)
Asia-Pacific Context and Challenges

Resistance to oral artemisinin-based combination therapies

High-prevalence of substandard and counterfeit antimalarial drugs (SSFFCs)

Weak health care service delivery for hard-to-reach and mobile populations

Lack of provider and consumer knowledge regarding the disease and rational use of medicines
Asia-Pacific Context and Challenges

- Resistance to oral artemisinin-based combination therapies
- High-prevalence of substandard and counterfeit antimalarial drugs (SSFFCs)
- Weak health care service delivery for hard-to-reach and mobile populations
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Asia-Pacific Context and Challenges

- Increasing resistance to oral artemisinin-based combination therapies
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Asia-Pacific Context and Challenges

Increasing resistance to oral artemisinin-based combination therapies

High-prevalence of substandard and counterfeit antimalarial drugs (SSFFCs)

Weak health care service delivery for hard-to-reach and mobile populations

Lack of provider and consumer knowledge regarding the disease and rational use of medicines
Regulatory Strategy and Challenges
“Drug regulation is a public policy response to the perceived problems or perceived needs of society. Consequently, drug laws need to be updated to keep pace with changes and new challenges in their environment”.

Effective drug regulation: A multicountry study by WHO
National Drug Regulatory Authority Framework
# National Drug Regulatory Authority Framework

## Pharmaceutical Regulatory Framework

<table>
<thead>
<tr>
<th>Policy</th>
<th>Strategy</th>
<th>Guidelines</th>
<th>Manuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product-focused</td>
<td>Strategy-focused</td>
<td>Consumer-focused</td>
<td></td>
</tr>
</tbody>
</table>

### Key Regulatory Activities

- **Product-focused**
  - Clinical Trial
  - Product Registration
  - Pre-Market
  - Post-Market
- **Price Negotiation**
- **Quality Control**

### Critical Supporting Structures

- Management Information System
- Financial Management
- Human Resource Management
- Coordination
# National Drug Regulatory Authority Framework

## Pharmaceutical Regulatory Framework

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### Key Regulatory Activities

<table>
<thead>
<tr>
<th>Product Focused</th>
<th>Stakeholder Focused</th>
<th>Consumer Focused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial</td>
<td>Manufacturing License &amp; Inspection</td>
<td>Monitoring of Drug Utilization</td>
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<tr>
<td>Product Registration</td>
<td>Import License</td>
<td>Control of Drug Promotion</td>
</tr>
<tr>
<td>Pre-Market</td>
<td>Distributor License</td>
<td>Targeted Programs (Counterfeits)</td>
</tr>
<tr>
<td>Post-Market</td>
<td>Retailer License</td>
<td></td>
</tr>
<tr>
<td>Price Negotiation</td>
<td>Health Professionals</td>
<td>Pharmaceutical Vigilance</td>
</tr>
<tr>
<td>Quality Control</td>
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</tr>
</tbody>
</table>

### Critical Supporting Structures

- Management Information System
- Financial Management
- Human Resource Management
- Coordination
### Relative Capacity for Quality Assurance

<table>
<thead>
<tr>
<th>More Stringent</th>
<th>Less Stringent</th>
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</thead>
<tbody>
<tr>
<td><strong>SRA Countries</strong></td>
<td><strong>PIC/S Countries</strong></td>
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<tr>
<td><img src="images" alt="Logos" /></td>
<td>• 44 member countries</td>
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Prequalification
### Capacity for Quality Assurance in the Asia Pacific region

#### More Stringent

<table>
<thead>
<tr>
<th>SRA Countries</th>
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<tbody>
<tr>
<td>Japan</td>
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<tr>
<td>Australia</td>
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<table>
<thead>
<tr>
<th>PIC/S Countries</th>
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<tbody>
<tr>
<td>Indonesia</td>
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<td>Malaysia</td>
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<td>Singapore</td>
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<td>New Zealand</td>
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<td>Taiwan</td>
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</table>

#### Less Stringent

<table>
<thead>
<tr>
<th>Other Countries</th>
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<tbody>
<tr>
<td>Cambodia</td>
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<tr>
<td>Myanmar</td>
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<tr>
<td>Vietnam</td>
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<tr>
<td>Lao</td>
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</tbody>
</table>

日本是ICH的成员，澳大利亚是安交协成员国。
Regulatory gaps resulting in increasing resistance to ACTs

- Weak National Drug Regulatory Authorities (NDRAs)
- Lack of post-market surveillance
- Lack of drug quality testing due to weak National Laboratory infrastructure
- Lack of consumer awareness and education
- Weak coordination among NDRAs in the region

7. Phanouvong, S. (2013b) Presentation at the WHO Bi-regional Meeting on Healthy Borders in the GMS, August 2013, Bangkok
Options for Interventions
(focus on regionally-based interventions)
Options for Interventions (focus on regionally-based interventions)

- Ensure product quality in Asia-Pacific
- Wipe out Counterfeit antimalarial medicines
- Strengthen private sector
- Phase out oral artemisinin monotherapies
Intervention 1
Ensure product quality in Asia-Pacific

• Reviews the marketing applications using its normal standards for authorization
• Issues “Tentative approval” in place of “full” approval- if product has marketing protection in the U.S
• USAID allows purchase of "full" or "tentative" FDA approved products

• Article 58 of Regulation, operates in co-operation with the WHO to review product registration.
• This review is for markets outside of the EU
• Mechanism applied to 2 ACTs already:
  • Pyramax®, (pyronaridine-artesunate)
  • Eurartesim® (dihydroartemisinin-piperaquine)
Intervention 1
Ensure product quality in Asia-Pacific

Australia and Japan? Singapore? Malaysia? Indonesia? New Zealand?

Could Asia Pacific provide additional capacity to the work being conducted by WHO’s Prequalification program? By USFDA? By EMA?

Only ICH members, observer and associate countries? PIC/S countries also?
Intervention 2
Wipe-out the widespread distribution of sub-standard and counterfeit pharmaceutical products

STRATEGIES

Build consumer awareness
Catalyze Consumer involvement
Build NDRA capacity
Catalyze Consumer involvement

Build consumer awareness

Build NDRA capacity

STRATEGIES
Build Consumer Awareness
Build Consumer Awareness

Heat Index

Relative humidity (%)

| Air Temperature (°F) | 0  | 5  | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 45 | 50 | 55 | 60 | 65 | 70 | 75 | 80 | 85 | 90 | 95 | 100 |
|----------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 140                  |    |    | 125|    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 135                  |    | 120| 128|    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 130                  |    | 117| 122| 131|    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 125                  |    | 111| 116| 123| 131| 141|    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 120                  |    | 107| 111| 116| 123| 130| 139| 148|    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| 115                  |    | 103| 107| 111| 115| 120| 127| 135| 143| 151|    |    |    |    |    |    |    |    |    |    |    |    |
| 110                  |    | 99 | 102| 105| 108| 112| 117| 123| 130| 137| 143| 150|    |    |    |    |    |    |    |    |    |    |
| 105                  |    | 95 | 97 | 100| 102| 105| 109| 113| 118| 123| 129| 135| 142| 149|    |    |    |    |    |    |    |    |
| 100                  |    | 91 | 93 | 95 | 97 | 99 | 101| 104| 107| 110| 115| 120| 126| 132| 138| 144|    |    |    |    |    |    |
| 95                   |    | 87 | 88 | 90 | 91 | 93 | 94 | 96 | 98 | 101| 104| 107| 110| 114| 119| 124| 130| 136|    |    |    |
| 90                   |    | 83 | 84 | 85 | 86 | 87 | 88 | 90 | 91 | 93 | 95 | 96 | 98 | 100| 102| 106| 109| 113| 117| 122|    |
| 85                   |    | 78 | 79 | 80 | 81 | 82 | 83 | 84 | 85 | 86 | 87 | 88 | 89 | 90 | 91 | 93 | 95 | 97 | 99 | 102| 105| 108|
| 80                   |    | 73 | 74 | 75 | 76 | 77 | 77 | 78 | 79 | 79 | 80 | 81 | 81 | 82 | 83 | 85 | 86 | 86 | 87 | 88 | 89 | 91 |
| 75                   |    | 69 | 69 | 70 | 71 | 72 | 72 | 73 | 73 | 74 | 74 | 75 | 75 | 76 | 76 | 77 | 77 | 78 | 78 | 79 | 79 | 80 |
Build Consumer Awareness

Heat Index

Pollution Index
Build Consumer Awareness

PM25 AQI
22:00:00 01/14/12

PM25 - AQI 105
AQI Index 105
Unhealthy For Sensitive Groups
Build Consumer Awareness

Heat Index

Pollution Index

Drug Quality Index
Build Consumer Awareness

Drug Quality Index

- Extreme Danger
- Danger
- Caution
- Excellent

All Drugs
- Public sector
- Private sector (formal)
- Private sector (informal)

Anti-malarials
- Public sector
- Private sector (formal)
- Private sector (informal)
Catalyze Consumer Involvement

**Social media**
- Facebook / Twitter
- NDRA Websites
- Healthcare blogs

**TV-media**
- TV advertisement
- Live PMS activity

**Print media**
- Notices about counterfeit drugs
- Blacklisted manufacturers/products

**NDRA**
Build Consumer involvement: NDRA Websites
Consumer Involvement

Social media

Healthcare Blogs
NDRA's using Facebook
Consumer Involvement

TV-media
Consumer Involvement

Print media

The Possible Dangers of Buying Medicines Over the Internet

COUNTERFEIT DRUGS KILL!

THE AUSTRALIAN

GLOBAL EPIDEMIC:
COUNTERFEITERS TARGET CHRONICALLY ILL
National Drug Regulatory Authority Framework

Policy

Strategy

Guidelines

Manuals

Key Regulatory Activities

Product-focused

- Clinical Trial
- Product Registration
- Pre-Market
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- Quality Control

Stakeholder-focused

- Manufacturing License
- Import License
- Distributor License
- Health Professionals

Consumer-focused

- Monitoring
- Drug Utilization
- Targeted Programs (Counterfeits)
- Pharmacovigilance

Critical Supporting Structures

Management Information System

Financial Management

Human Resource Management

Coordination
Intervention 3
Strengthen private sector industry to attain higher quality manufacturing standards

Strengthen Private Sector
Through provision of technical assistance

Catalyze Self Regulation
Through involvement of industry associations
Strengthen private sector industry to attain higher quality manufacturing standards

Strengthen private sector

- Through provision of technical assistance

Catalyze self regulation

- Through involvement of industry associations
India case study – Building Capacity

There are more than 10,000 manufacturing sites in India.
India case study – Building Capacity

There are more than 10,000 manufacturing sites in India

1,500 sites

State Level Approved (GMP – Schedule M) (8000-9000 units)

WHO and SRA Approved sites
PIC/S country approved
Certified by international procurement agent
Certified by various NDRAs
Approved by central and state Drug Regulatory Authority (WHO cGMP)
US-FDA inspected facilities for Finished Pharmaceutical Products and Active Pharmaceutical Ingredients (outside USA)

USFDA inspected sites

- China, 606
- India, 559
- Rest of the world, 2145

Source: Pharmexcil data 2012
Intervention 4
Phase-out oral artemisinin-based monotherapies
(as part of ‘Emergency Response to Artemisinin Resistance’)

**PHARMACEUTICAL REGULATORY FRAMEWORK**

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<td>IMPORT LICENSE</td>
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<tr>
<td>PRE-MARKET</td>
<td>DISTRIBUTOR LICENSE</td>
<td>RETAILER LICENSE</td>
<td></td>
</tr>
<tr>
<td>POST-MARKET</td>
<td>HEALTH PROFESSIONALS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRICE NEGOTIATION</td>
<td>QUALITY CONTROL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MANAGEMENT INFORMATION SYSTEM</td>
<td>FINANCIAL MANAGEMENT</td>
<td>HUMAN RESOURCE MANAGEMENT</td>
<td>COORDINATION</td>
</tr>
</tbody>
</table>

**CRITICAL SUPPORTING STRUCTURES**
Intervention 4
Phase-out oral artemisinin-based monotherapies (as part of ‘Emergency Response to Artemisinin Resistance’)

Policy
Halt all new AMT registration

Manufacturing/Import/Distributor/Retail
Revoke license

Monitoring/control/Pharmacovigilance
• Wipe out AMTs from illegal market
• Post Marketing Surveillance

Human Resource Management
Create taskforce of inspectors

Coordination
Share results with countries in the region
Intervention 4
Phase-out oral artemisinin-based monotherapies (as part of ‘Emergency Response to Artemisinin Resistance’)

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Human Resource Management
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Coordination
Share results with countries in the region
Options for Policies and Next Steps
Allocate an appropriate level funding for effective operations of NDRA

Make consumers the epicentre of the fight

Regional Center of Excellence for Regulatory Sciences

Ensure product quality in Asia-Pacific Drugs, Diagnostics, Devices, Labs...
Next steps

• Exhaustive inventory of all regional/global regulatory-linked ongoing activities
• Analyze potential for scale up

• Convene a technical consultation
• Create portfolio of activities best suited for the challenges faced by region

• Create a roadmap for:
  • Regional/national strategies
  • Detailed workplans/budget
Empower School of Health area of expertise is the area of ‘Access to Medicines’ including procurement, supply chain, pharmaceutical management, regulatory and quality-assurance. Empower focuses on research, capacity building and developing tools for Ministries of Health, NGOs, National Drug Authorities, and more. Empower School of Health works across 30 countries, has 7 offices across India with more than 200 staff and 50 independent consultants globally.

Prof. Paul S. Lalvani is the Dean & Director, Empower School of Health; former Head of Global Fund’s Department of Procurement and Supply Chain Management; co-chair, Procurement and Supply Chain Management-Working Group, Roll Back Malaria Partnership, Geneva; advisor to RBM Partnership for their India strategy; former member of the AMFm task force; Senior Advisor to Swiss Tropical Public Health School; and various UN agencies and MoH.
Background Slides
Resistance to oral artemisinin-based combination therapies

- Resistance to ACTs detected in Cambodia, Myanmar, Thailand and Vietnam
- Greater-Mekong Subregion has history of anti-malarial resistance
- No other alternative to ACTs that is safe, effective and quality-assured
- Emergency response to artemisinin resistance in the Greater Mekong subregion: Regional framework for action 2013–2015, released by WHO
High-prevalence of substandard and counterfeit antimalarial drugs

- 38 – 52 % Artesunate blister packs do not contain any active ingredient in mainland South-East Asia\(^4\)
- 12 % failure rate of antimalarial medicines – Study of Thai-Cambodia border\(^5\)
- 60 % failure rate of AMTs
- 12.5-35 % failure rate of other oral artemisinin-based drugs

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5. Phanouvong, S. 2013
Weak health care service delivery for hard-to-reach and mobile populations

• Coverage of rational diagnosis and treatment for malaria very low in remote areas, case study results of Cambodia\(^8\)
• Hard-to-reach mobile populations access health services from the predominately low-cost, poor quality, informal sector
• These populations form the ‘hot-spots’ of drug resistance
• Existence of unregulated private retail outlets- major source of sub-standard anti-malarial medicines in Laos, Cambodia, Myanmar
• Private sector- first point of contact for 70% of population seeking malaria treatment

Predominant use of the informal private sector for malaria services

Lack of provider and consumer knowledge regarding the disease and rational use of medicines

- High degree of self-medication by a population:
  - generally not well informed (especially in remote areas)
  - which accesses low-cost, irrational, poor-quality antimalarials from the informal private sector
- Drug-use surveys have reported a high rate of malaria self-medication in many parts of the GMS (53%, in a Lao PDR survey)\(^9\)
- No access to public sector health facilities
- Often receive a ‘cocktail’ of drugs

\(^9\) WHO (2010) Malaria in the greater mekong subregion: Regional and country profiles
## NDRA-linked characteristics of three focus-countries: A comparison

<table>
<thead>
<tr>
<th>Comparative measures</th>
<th>Myanmar(^1)</th>
<th>Thailand(^2)</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>GDP per capita (nominal) (US$) (2011)</td>
<td>1,144</td>
<td>5,775</td>
<td>1,516</td>
</tr>
<tr>
<td>Pharma market size (domestic) (US$ billions) (2012)</td>
<td>0.25</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Population (million) (2011)</td>
<td>53</td>
<td>67</td>
<td>1,237</td>
</tr>
<tr>
<td>Pharmaceutical consumption (US$) per capita</td>
<td>5</td>
<td>60</td>
<td>13</td>
</tr>
<tr>
<td>Technical staff at NDRA (central level)</td>
<td>42</td>
<td>96</td>
<td>119</td>
</tr>
<tr>
<td>Market size per technical staff (US$ million)</td>
<td>6</td>
<td>40</td>
<td>220</td>
</tr>
<tr>
<td>Number of drug samples tested (per year)</td>
<td>1,980</td>
<td>2,500</td>
<td>8,000</td>
</tr>
<tr>
<td>Market size per test conducted</td>
<td>$126,000</td>
<td>$1,600,000</td>
<td>$2,000,000</td>
</tr>
<tr>
<td>Percentage of drug products which fail quality control tests</td>
<td>8-10%</td>
<td>10%</td>
<td>6%(^3)</td>
</tr>
</tbody>
</table>

3 CDSCO (2009) Report on countrywide survey on spurious drugs
## Therapeutic category as per WHO EML

<table>
<thead>
<tr>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthetics</td>
</tr>
<tr>
<td>Analgesics, antipyretics, NSAIMs</td>
</tr>
<tr>
<td>Antiallergics</td>
</tr>
<tr>
<td>Antidotes used in poisonings</td>
</tr>
<tr>
<td>Anticonvulsants</td>
</tr>
<tr>
<td>Anti-infective medicines</td>
</tr>
<tr>
<td>Antimigraine medicines</td>
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<tr>
<td>Anti-neoplastic medicines</td>
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<tr>
<td>Anti-parkinsonism medicines</td>
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<tr>
<td>Medicines affecting the blood</td>
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<tr>
<td>Cardiovascular medicines</td>
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<tr>
<td>Dermatological medicines</td>
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<tr>
<td>Disinfectants and antiseptics</td>
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<tr>
<td>Diuretics</td>
</tr>
<tr>
<td>Gastrointestinal medicines</td>
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<tr>
<td>Hormones and contraceptives</td>
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<td>Immunologicals</td>
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<tr>
<td>Muscle relaxants</td>
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<tr>
<td>Ophthalmological preparations</td>
</tr>
<tr>
<td>Oxytocics and antioxytocics</td>
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<tr>
<td>Peritoneal dialysis solution</td>
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<tr>
<td>Medicines for mental and behavioral disorders</td>
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<tr>
<td>Medicines acting on respiratory tract</td>
</tr>
<tr>
<td>Solution correcting water, electrolyte balance</td>
</tr>
<tr>
<td>Vitamins and minerals</td>
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<tr>
<td>Ear, nose and throat conditions in children</td>
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<tr>
<td>Medicines for neonatal care</td>
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### Prequalification

#### Finished Pharmaceutical Products

<table>
<thead>
<tr>
<th>Therapeutic category as per WHO EML</th>
<th>WHO-Prequalified sub-category</th>
<th>Number of prequalified products</th>
<th>Number of products under assessment</th>
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<tbody>
<tr>
<td><strong>Anesthetics</strong></td>
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<tr>
<td><strong>Anti-infective medicines</strong></td>
<td>HIV, TB, Malaria, Influenza and neglected diseases</td>
<td>261</td>
<td>122</td>
</tr>
<tr>
<td><strong>Antimigraine medicines</strong></td>
<td></td>
<td></td>
<td></td>
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<td>Anti-neoplastic medicines</td>
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<tr>
<td>Disinfectants and antiseptics</td>
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<td><strong>Diuretics</strong></td>
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<td><strong>Gastrointestinal medicines</strong></td>
<td>Diarrhoea</td>
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<tr>
<td><strong>Hormones and contraceptives</strong></td>
<td>Reproductive health</td>
<td>17</td>
<td>6</td>
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<tr>
<td>Immunologica<strong>l</strong></td>
<td>Vaccines</td>
<td>37</td>
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<td>Muscle relaxants</td>
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<td>Ophthalmological preparations</td>
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<td>Oxytocics and antioxytocics</td>
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<td>Peritoneal dialysis solution</td>
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<td>Medicines for mental and behavioral disorders</td>
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<tr>
<td>Medicines acting on respiratory tract</td>
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<td>Solution correcting water, electrolyte balance</td>
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<td>Vitamins and minerals</td>
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<td>Ear, nose and throat conditions in children</td>
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<tr>
<td>Medicines for neonatal care</td>
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</tbody>
</table>

**Total Products**  362  131
Intervention 1
Ensuring product quality in Asia-Pacific

• What is WHO Prequalification?
  – The Prequalification Programme, set up in 2001, is a service provided by the World Health Organization (WHO) to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria, tuberculosis and other essential health commodities

• What is the importance of WHO Prequalification?
  – WHO prequalification has become the gold-standard for quality for donor agencies, procurement organizations and various country organizations. It confirms the quality of product produced by the manufacturer and establishes confidence among the buyers

• What is the scope of WHO Prequalification?
  – See next slide
Global Fund SRA policy

- List of countries considered as Stringent Regulatory Authorities (SRA) from 1st July 2009.
- The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority (SRA) as per the Global Fund Quality Assurance Policy for Pharmaceutical Products from July 1, 2009. For details on ICH, please look at www.ich.org. Please find below the list of countries which are members, observers and associates of ICH.
- **MEMBERS:**
- **European Union member States** (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, and United Kingdom)
- **Japan**
- **United States**
- **Observers:** European Free Trade Association (EFTA) represented by Swiss Medic of Switzerland, and Health Canada (as may be updated from time to time).
- **Associates** through mutual recognition agreements: Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).
- For medicines used exclusively outside the ICH region, positive opinions or tentative approval under any of the following three special regulatory schemes are recognized as **stringent approval**:
  - Article 58 of European Union Regulation (EC) No. 726/2004
  - Canada S.C. 2004, c. 23 (Bill C-9) procedure
  - United States FDA tentative approval (for antiretrovirals under the PEPFAR programme)