WHO - Prequalification of Medicines Programme

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ipca
A dose of life
• Partnering healthcare globally in over **110 countries** & in markets as diverse as Africa, Asia, Australia, Europe & the US

• Ipca is a vertically-integrated pharmaceutical company manufacturing over **350 formulations & 80 APIs** for various therapeutic segments

• **7 formulation** manufacturing sites with 14 Bln Tablet/Capsule manufacturing capacity & **7 API** manufacturing sites

• Amongst the top 10 Pharma Exporters from India, with an employee strength of **10,000+**

• **4 Anti-malarial Formulations & 3 APIs** pre-qualified by WHO
• One of the world’s largest manufacturers of Artemisinin based APIs & Formulations

• India’s market leader in Antimalarials for over 3 decades

• Antimalarials constitute around 24% of Ipca’s annual sales - US$ 115 Mln

• Ipca’s Artemether + Lumefantrine tabs tender sale in 2011 was around 60 Mln treatments

• Public listed company, with CAGR of over 20% for last 6 years

• Total income for the FY11 was US$ 485 Mln
<table>
<thead>
<tr>
<th>1.</th>
<th>Amodiaquine Base</th>
<th>8.</th>
<th>Dihydroartemisinin</th>
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</thead>
<tbody>
<tr>
<td>2.</td>
<td>Amodiaquine HCl</td>
<td>9.</td>
<td>Lumefantrine</td>
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<td>3.</td>
<td>Artesunate</td>
<td>10.</td>
<td>Piperaquine Phosphate</td>
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<td>4.</td>
<td>Artemether</td>
<td>11.</td>
<td>Primaquine Phosphate</td>
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<td>5.</td>
<td>αβ Arteether</td>
<td>12.</td>
<td>Pyrimethamine</td>
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<td>7.</td>
<td>Chloroquine Sulphate</td>
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</table>

- **Prequalified**: Green
- **APIMF**: Grey
## Anti-malarial range - Formulations

<table>
<thead>
<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Artesunate Tablets 50mg</td>
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<tr>
<td>2</td>
<td>Artesunate 50 mg + Amodiaquine 153.1mg Tablets (Co-blisters)</td>
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<td>3</td>
<td>Artemether + Lumefantrine 20+120mg Tablets</td>
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<tr>
<td>4</td>
<td>Artesunate + Amodiaquine FDC Tablets 25+ 67.5mg, 50+135mg &amp; 100+270mg</td>
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<tr>
<td>5</td>
<td>Artemether + Lumefantrine Tablets 40+240mg, 60+360mg &amp; 80+480mg</td>
</tr>
<tr>
<td>6</td>
<td>Artemether + Lumefantrine 20+120mg dispersible Tablets</td>
</tr>
<tr>
<td>7</td>
<td>Artesunate Injection 30mg, 60mg &amp; 120 mg</td>
</tr>
<tr>
<td>8</td>
<td>Artemether Injection 20mg/ml, 40mg/ml &amp; 80mg/ml</td>
</tr>
</tbody>
</table>

- **Prequalified**
- **Submission planned**
WHO Prequalification Programme

TIMELY and THOROUGH

EXPERTS

COMPREHENSIVE

Innovative Benefit Annual Reviews

SOLUTIONS

Creating a Competitive Environment

Making Complex SIMPLE

Health

Vision

Life
• WHO prequalification of medicines has leveled the playing field and created a competitive supply of quality products to meet the demand

• The list of WHO prequalified products is a vital tool for procurement agencies / organisations

• It is a synonym for quality and reliability
• Eligible to bid for UN institutions & NGOs

• Potential for increased sales due to prequalification

• No cost for participating in prequalification process

• Saves time, resources and costs in finding reliable manufacturers

• Higher brand image for the Organisation
FPP prequalification provides an assurance that millions of people living with HIV/AIDS, TB and malaria have treatment meeting international norms and standards on Quality, Safety & Efficacy at affordable rates.
Dossier

- CTD - harmonized with international standards in terms of format & content
- Single dossier can be submitted to multiple agencies
- e-copies for initial screening - No paper copies
- Pooled multi background assessors - assure Quality, Safety & Efficacy of products
- BE protocol reviews
Process

- Fewer batches required to establish the FPP shelf life (2 instead of 3)

- Process validation of pilot batches no longer required (replaced by content uniformity demonstration of the biolot)

- Reduced process validation & pharmaceutical development requirements for established generics
API PQ - Formulators perspective

- API PQ helps identify acceptable sources of quality APIs manufactured in compliance with GMP
- Reduced product dossier assessment time - PQ API supporting FPP
- FPP applicants to notify WHO only when associated Confirmation of API PQ document is revised
APIMF - Formulators Perspective

- APIMF amendment letters highlight type of variations required to be submitted by FPP applicant
- APIMF related notification form - reduces work load, regulatory burden & time
- Upcoming variation guidance classify changes in terms of specific section of CTD with reporting category
- API prequalification provides an assurance that the API concerned is of good quality and manufactured in accordance with WHO Good Manufacturing Practices (GMP)

- The prequalification guidelines are inline with the guidance of the stringent regulatory agencies
Advantages

- Harmonised CTD format
- APIMF screening - Upfront fulfillment
- Assessment / GMP inspection
- Prequalification
- Database on the Website - easy access to formulators
- Issuance of Confirmation of API Prequalification document - LOA
• Information rich & user friendly with continuous updations

• Transparency - Assessment Status, NOC, PAR, PIR

• Database - Guidance, PQ procedure, Training material, list of PQ FPPs, APIs. Information on comparator products
• Teleconference (TC), or
• Videoconference (VC) possible
• Request can be sent by email with a Meeting Request Form

Quick decisions
• Inspections - GMP / GLP / GCP

• The inspectorate pool consists of highly qualified & experienced inspectors with expertise in relevant areas
• GMP / GLP / GCP Compliance

• Data development & compilation of dossier

Trainings / Workshops
Scope for improvement

- Need for defined variation guidelines for APIs
- Wait for confirmation prior to implementation
- APIMF assessment status - not available online
- Routine control of polymorphic forms - tedious, time consuming
• e-gateway for application submissions
• Defined timelines for approval of minor & major variations
• Duplication in FPP filing, approval & Inspection by other National regulatory agencies
Thank you