If change is the only constant, here is a beautiful one!
Ipca is continuously evolving. Our brand identity has evolved too.

The **butterfly** represents life at its energetic best. At its heart is a molecular structure endorsing Ipca’s pharmaceutical bent of purpose. The butterfly is in flight, matching the soaring aspirations of the company.

As our work mirrors life, the tagline ‘**A dose of life**’ expresses what Ipca lives by. Of touching all aspects of human life and helping it bounce back to health; much like the butterfly’s nature of flitting from flower to flower.
• 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 manufacturer of Artemisinin based APIs & Formulations

• India’s largest market leader in Antimalarial over 3 decades

• Antimalarial constitutes around 24% of Ipca’s annual sale - US$ 115 Mln

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

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

• Total income for the FY11 was US$ 485 Mln
## Anti-malarial range - APIs

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<tbody>
<tr>
<td>1</td>
<td>Amodiaquine Base</td>
<td>8</td>
<td>Dihydroartemisinin</td>
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<tr>
<td>2</td>
<td>Amodiaquine HCl</td>
<td>9</td>
<td>Lumefantrine</td>
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<tr>
<td>3</td>
<td>Artesunate</td>
<td>10</td>
<td>Piperaquine Phosphate</td>
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<tr>
<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>6</td>
<td>Chloroquine Phosphate</td>
<td>13</td>
<td>Sulphadoxine</td>
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<td>7</td>
<td>Chloroquine Sulphate</td>
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- **Prequalified**: Green
- **APIMF**: Light grey
<table>
<thead>
<tr>
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<th>Formulation</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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<tr>
<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>
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<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

Health

Vision

Life

TIMELY and THOROUGH

EXPERTS

COMPREHENSIVE

Innovative Benefit

Annual Reviews

SOLUTIONS

Creating a Competitive Environment

Making Complex

SIMPLE
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.
Business benefits of PQP

• Eligible to bid for UNFPA procurement & nongovernment organizations (NGOs)

• Potential for increased sales due to requirement of prequalification

• No cost for participating in prequalification process

• Saves time, resources and costs in finding reliable manufacturers

• High quality, affordable medicines
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 medicines.
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
Advantages

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
• 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