WHO – Prequalification of Medicines Programme

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ipca
A dose of life

Overview

- 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

Overview

- One of the world's largest manufacturers of Artemesinin 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

Anti-malarial range - APIs

1	Amodiaquine Base	8	Dihydroartemesinin
2	Amodiaquine HCl	9	Lumefantrine
3	Artesunate	10	Piperaquine Phosphate
4	Artemether	11	Primaquine Phosphate
5	αß Arteether	12	Pyrimethamine
6	Chloroquine Phosphate	13	Sulphadoxine
7	Chloroquine Sulphate		

Prequalified

APIMF

Anti-malarial range - Formulations

1	Artesunate Tablets 50mg
2	Artesunate 50 mg + Amodiaquine 153.1mg Tablets (Co-blisters)
3	Artemether + Lumefantrine 20+120mg Tablets
4	Artesunate + Amodiaqine FDC Tablets 25+ 67.5mg, 50+135mg & 100+270mg
5	Artemether + Lumefantrine Tablets 40+240mg, 60+360mg & 80+480mg
6	Artemether + Lumefantrine 20+120mg dispersible Tablets
7	Artesunate Injection 30mg, 60mg & 120 mg
8	Artemether Injection 20mg/ml, 40mg/ml & 80mg/ml

Prequalified

Submission planned


TIMELY and THOROUGH
EXPERTS
COMPREHENSIVE
Health
Innovative Benefit
Annual Reviews
SOLUTIONS
Vision
Creating a Competitive Environment
Life
Making Complex
SIMPLE

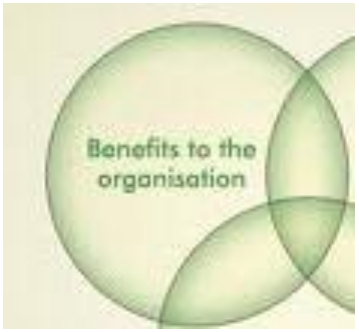
WHO Prequalification Programme

- 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 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

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

- 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

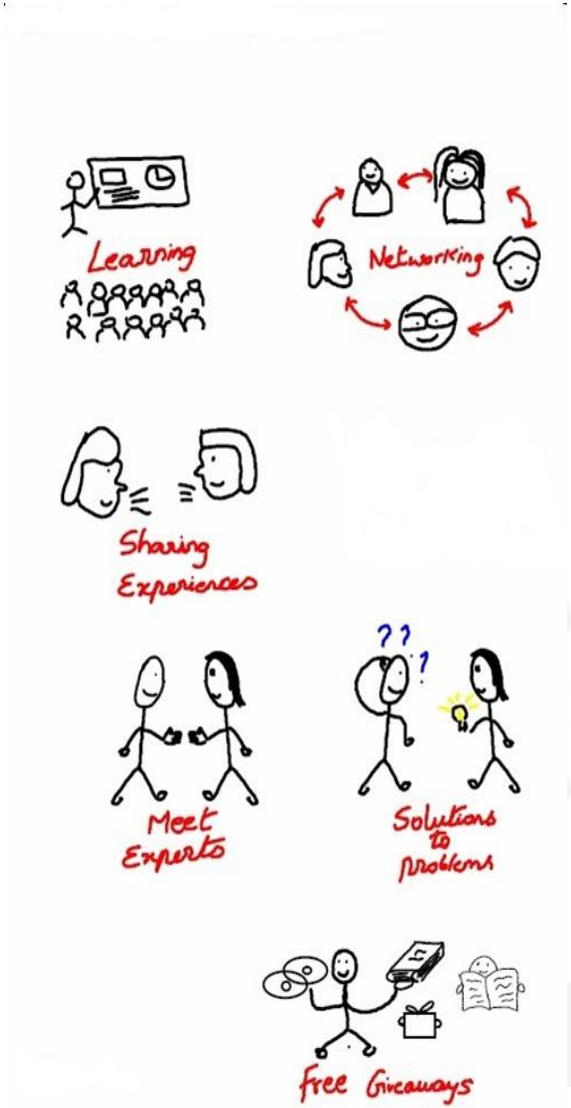
Advantages

- 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

Website

- 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

Tech Savvy



- Teleconference (TC), or
- Videoconference (VC) possible
- Request can be sent by email with a Meeting Request Form

Quick decisions

Inspections

- Inspections – GMP/ GLP / GCP
- The inspectorate pool consists of highly qualified & experienced inspectors with expertise in relevant areas

Technical Assistance

- 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

Scope for improvement

- 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