Cipla Introduction

• Established: 1935
• Founder: Dr. K.A. Hamied (1898-1972)
• Corporate office: Cipla Ltd., Mumbai Central, Mumbai 400 008, India.
• Chairman and Managing Director: Dr. Y.K. Hamied
• Employees: >20000
• Ranked No. 1 company in India
• Turnover: >USD 1.8 Billion
• Stock Exchange listing: BSE, NSE & LUXEMBOURG SE
• Market Capitalization: >$ 5 Bn
• Facilities: 39 facilities in India
• Tablets and caps capacity: 170 bn per annum
Anti Malaria

- Cipla has more than 30 wide range of anti malarial products.
- Cipla’s Malarial products are pre-qualified by WHO. Few others are under development stage.
- Cipla is also into the manufacturing of anti-malaria API’s.
- Global Fund Partners under AMFm.
Anti-Malarial APIs currently being manufactured:

1. Artesunate
2. Artemether
3. Lumefantrine
4. DHA
5. Piperaquine
**Anti Malarial Product Range-1 (we don’t market monotherapies)**

<table>
<thead>
<tr>
<th>Sr.No</th>
<th>Product</th>
<th>Pack size</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Artesunate 50mg + Amodiquine 153mg</td>
<td>3+3, 6+6, 12+12</td>
<td>(kit)</td>
</tr>
<tr>
<td>2</td>
<td>Artesunate 100mg + Amodiquine 300mg</td>
<td>3+3, 6+6</td>
<td>(Kit)</td>
</tr>
<tr>
<td>3</td>
<td>Artemether 20mg + Lumefantrine 120mg</td>
<td>24’s, 18’s, 12’s, 6’s</td>
<td>(FDC)</td>
</tr>
<tr>
<td>5</td>
<td>Artesunate 50mg + Sulfadoxine 500mg / Pyrimethamine 25mg</td>
<td>12+3, 6+2, 3+1</td>
<td>(kit)</td>
</tr>
<tr>
<td>6</td>
<td>Artesunate 100mg + Sulfadoxine 500mg / Pyrimethamine 25mg</td>
<td>6+3, 3+2</td>
<td>(Kit)</td>
</tr>
</tbody>
</table>
# Anti Malarial Product Range-2

<table>
<thead>
<tr>
<th>Sr.No</th>
<th>Product</th>
<th>Pack Size</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Artesunate 25mg + Mefloquine 55mg</td>
<td>6’s</td>
<td>(BL)</td>
</tr>
<tr>
<td>8</td>
<td>Artesunate 100mg + Mefloquine 220mg</td>
<td>6’s</td>
<td>(BL)</td>
</tr>
<tr>
<td>9</td>
<td>Artesunate 200mg + Mefloquine 250</td>
<td>3 + 3</td>
<td>(kit)</td>
</tr>
<tr>
<td>10</td>
<td>Atorvaquone 250mg + Proguanil 100mg</td>
<td>12’s</td>
<td>Tablets</td>
</tr>
<tr>
<td>11</td>
<td>Proguanil 100mg</td>
<td>12’s</td>
<td>Tablets</td>
</tr>
<tr>
<td>12</td>
<td>Primaquine Phosphate 15 mg</td>
<td>10’s</td>
<td>Tablets</td>
</tr>
<tr>
<td>13</td>
<td>Primaquine Phosphate 5 mg</td>
<td>10’s</td>
<td>Tablets</td>
</tr>
<tr>
<td>14</td>
<td>Primaquine Phosphate 7.5mg</td>
<td>10’s</td>
<td>Tablets</td>
</tr>
</tbody>
</table>
Challenges faced and way forward

- PRICING-The current pricing is not sustainable due to the current situation of artemesinin on pricing and availability.

- The earlier MSA (Master supply agreements were agreed and signed when Artemesinin was available at USD300), however current pricing of artemesinin has gone up by more then 50%.

- The MSA are applicable for the formulation manufacturers but not Artemesinin extractors bringing the whole supply situation in a potential problem.

- The current MSA should be linked to the Artemesinin pricing so that pricing can be revised in case of Artemesinin variation. We expect that new negotiating agent appointed by AMFM would link formulation pricing to artemesinin pricing.
Challenges faced and way forward

- Capacities - We have huge capacities but not enough orders, we have scaled up the production but not getting enough orders. Companies incur huge cost on inventories and interest cost are high too.

- Wherever the orders are not awarded, the reasons should be informed to the manufacturers so that we can try to improve in future quotations e.g. lead times, pricing, registrations.

- The countries ordering should be informed of the challenges pertaining to supply situations and lead times in ordering, most of the countries request for 3-4 weeks lead time which is not realistic at times.
Challenges faced and way forward

- The forecast provided are not realistic and at times there are no forecast at all which leaves formulation manufacturers in a spot as to how much to keep in stocks and how much API to procure. Even in absence of forecast manufacturers are expected to hold stocks provide lead times of 3-4 weeks.

- Scale up-Due to the current AMFM programmes there is definitely a need for huge scale up on formulation capacities, however the current pricing makes it less interesting for the companies to expand mfg capacities. Most of the companies are operating on Not for profit basis due to the current pricing structure.

- PMI-Need a clarity if PMI can procure WHO approved products as we haven't received any orders from PMI programme for more then a year for Arte/Lume and more than 3 years for As/Aq.
Challenges faced and way forward

- **Shelf life-** Due to the current non predictable ordering manufacturers do keep stocks however most of the procurement bodies ask for 80%-90% remaining shelf life. This should be brought down to number of remaining months or 65% shelf life as these medicines are consumed much faster and are required urgently.

- **GF/A2S2 –** Formulation manufacturers need some help on current artemesinining pricing it is unaffordable and scarce, more extractors and farmers should be motivated to grow artemesinin.

- **Evaluation of quotations-VPP-** This takes more time, the evaluation takes more then a month making it difficult for manufacturers to stick to lead times and stocks quoted, we will appreciate if we can be given forecast for complete year under VPP.
AMFm program

- We appreciate this initiative and believe that this will definitely improve access to better quality medicines.
- Cipla has received orders of more than 5 million doses of A/L 20/120 tablets under the AMFm program from the First Line Buyers.
- The forecast quantities cannot be estimated at this stage as the feedback of AMFm products are to be evaluated with the current products to be entered into the market.
- The prices fixed under AMFm program is for 2 years when the current prices of Artemisinin are increasing and suppliers face the crunch of it.
- As there are very minimal margins earned by the suppliers with the fixed prices under AMFm, it will become very difficult to continue in a long run.
- A large scale promotion and awareness campaigns is essential under AMFm program.
Thank you