



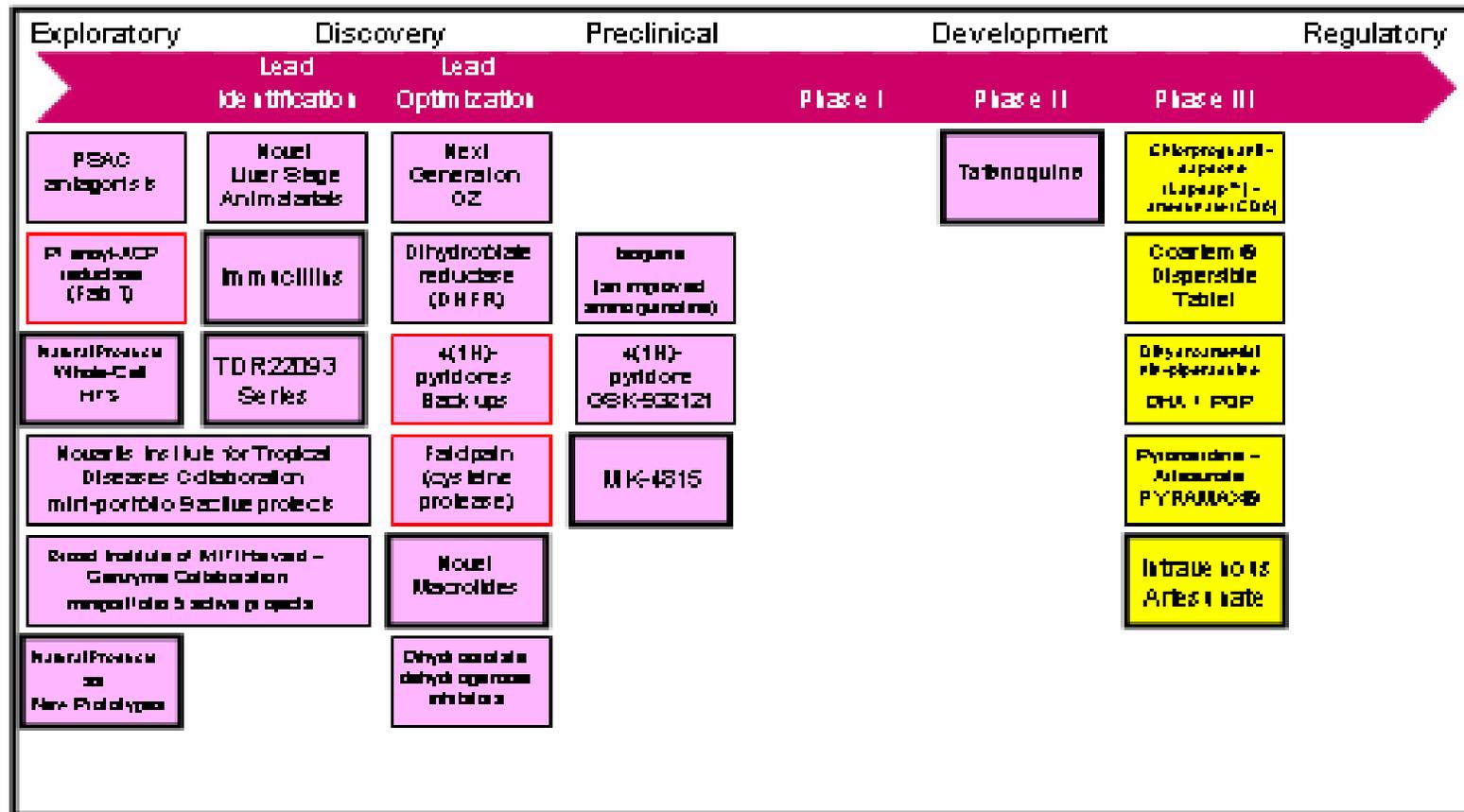
Joint MMV WHO Artemisinin production and market needs: Meeting Global Demand

Ian Bathurst

25 June 2007



MMV's Portfolio 2007



The Artemisinin Consortium



- The Consortium was set up by the Bill and Melinda Gates Foundation (BMGF) to explore ways of increasing the supply of and thus decreasing the cost of artemisinin derivatives and their synthetic equivalents from the then price of about USD 1,000 per kg to about USD 100 per kg. University of York is seeking to breed high-yielding varieties of *Artemisia*. IOWH has engineered the biosynthetic pathway for artemisinic acid into *E.coli* which it then converts synthetically to artemisinin. MMV is engaged in the discovery and development of completely synthetic peroxides.



The Artemisinin Consortium



- On June 19, an Artemisinin Consortium Meeting with Key ACT Manufacturers was held in the MMV Offices in Geneva, Switzerland. Representatives from the BMGF, IOWH, MMV and University of York UK, who make up the Consortium, met with representatives from GSK, Holly, Mepha, Novartis, Pfizer, Sanofi Aventis and Sigma tau, companies who are already or likely soon will be involved in the manufacture of Artemisinin-based Combination Therapies (ACTs) and staff from the World Health Organization's RBM partnership / Global Malaria Programme.



The Artemisinin Consortium



Questions on current supply:

- What is your long term forecast for artemisinin supply needs?
- Does your company buy artemisinin derivatives as API or do you buy artemisinin starting material and convert this to API yourself?
- What criteria do you use in choosing a source of artemisinin supply?
- Do you use a single supplier or multiple sources?
- Do you buy their entire production?
- Is the seasonal nature of artemisinin supply an issue?
- Under what conditions do you store and ship your plant material or API?



The Artemisinin Consortium



Questions on current supply:

- What is your long term forecast for artemisinin supply needs?
- Does your company buy artemisinin derivatives as API or do you buy artemisinin starting material and convert this to API yourself?
- What criteria do you use in choosing a source of artemisinin supply?
- Do you use a single supplier or multiple sources?
- Do you buy their entire production?
- Is the seasonal nature of artemisinin supply an issue?
- Under what conditions do you store and ship your plant material or API?



The Artemisinin Consortium



Answers to the Questions on current supply:

- The expectation is that the global requirement for artemisinin itself will rapidly build to around 200-300 metric tonnes pa and that this could double to 400-600 metric tonnes pa in succeeding years if control programmes do not succeed.
- Some companies purchase artemisinin; others one of the derivatives (principally dihydroartemisinin, artesunate or artemether).
- At the present time, when artemisinin is freely available at a modest price, quality of material and sustainability of supply are more important than price.
- All companies used more than one source of material and none appeared to buy the whole production of an individual supplier.
- The seasonal nature of the supply is an issue, but its impact can be minimized by holding a reserve stock of one season's supply. This is stored at <25C and protected from light and water.



The Artemisinin Consortium



Questions on current quality/regulatory issues:

- What quality criteria do you have for incoming artemisinin over and above those stated in the WHO monograph?
- What sort of problems do the differences in the quality of artemisinin present to your company?
- Would introduction of a more rigorous standard than the existing monographs be an advantage?
- Are there any particularly problematic plant-derived contaminants in artemisinin?



The Artemisinin Consortium



Answers to Questions on current quality/regulatory issues:

All companies based their requirements on the existing Monograph, but supplemented this with company-specific and country of manufacture-specific requirements (eg additional data on solvent residues, heavy metal levels, microtoxins and etc).

There are no real issues to be solved in this area.

Current plant derived-artemisinin has no problematic contaminants, new methods of production must make sure this situation does not change as artemisinin content increases.





Joint MMV WHO Artemisinin production and market needs: Meeting Global Demand

Thankyou

