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Developing medicines, saving lives

Dr David Reddy describes the work of a global partnership developing medicines to help the world defeat malaria

'If you want to go fast, go alone. If you want to go far, go together.'
African proverb

In the 13 years since its inception, the global research and development partnership, Medicines for Malaria Venture (MMV), has gone both fast and far in its endeavours to discover, develop, and deliver the medicines needed to defeat malaria.

In 2012, MMV was proud to bring forward its fourth drug: Pyramax® (pyronaridine-artesunate) was developed in partnership with Shin Poong and received positive scientific opinion from the European Medicines Agency in February 2012. Its registration follows that of two other high-quality artemisinin-based combination therapies (ACTs), Eurartesim® (dihydroartemisinin-piperaquine) developed with Sigma-Tau; and Coartem® Dispersible (artemether-lumefantrine), a child-friendly formulation developed with Novartis. In addition, MMV worked with Guilin Pharmaceutical to obtain WHO prequalification for the treatment of severe malaria, Artesun® (injectable artesunate).

Thanks to the scale-up of preventive measures and improved access to effective medicines, the malaria landscape is changing. Mortality and morbidity are decreasing.[1] Yet signs of resistance to artemisinin[2] – the cornerstone of current antimalarial therapy – are increasing, albeit still limited to one region of southeast Asia. These signs are a stark reminder that our gains are fragile and the need for next-generation medicines is growing more urgent.

Developing new medicines faster

New tools, such as mathematical modelling and MMV's human clinical pharmacology platform, allow us to better understand whether a compound will work in humans, what dose is optimal, and to make more informed choices. These tools have already helped us bring down the cost of proof-of-concept studies for next-generation medicines, and will shave an estimated 2 years off the development process.

An endoperoxide, OZ439, has just completed Phase IIa trials and interaction studies with partner drugs have been initiated. Meanwhile, KAE609, discovered by a research consortium,[3] with funding from the Wellcome Trust and MMV, is being progressed by Novartis. These two molecules could become part of the next-generation medicines to cure malaria in a single dose and revolutionise the treatment landscape.

With Pfizer, we are developing a new combination of two well-tolerated medicines to prevent malaria in pregnant women (azithromycin-chloroquine) that will also help to cure sexually transmitted infections. This combination is due to be submitted for registration in 2014 and could be set to replace the current regimen of sulfadoxine-pyrimethamine (SP), to which the parasite is becoming resistant.[5]

To protect young children in areas of seasonal malaria transmission in Sahelian Africa, the World Health Organization recommends using a complete treatment of sulfadoxine-pyrimethamine (SP) and amodiaquine (AQ) once a month for 4 months during the season. To support the implementation of this recommendation, MMV is working with Guilin Pharmaceutical to obtain WHO prequalification for SP+AQ. In addition, the partnership is working to develop a lower-dose formulation for younger children, blister packaging and, eventually, a dispersible formulation – all with the goal of making dispensing and administration easier for doctors and children alike.

Dr David Reddy, CEO, Medicines for Malaria Venture

Discovering new compounds together

MMV and partners conducted an extensive screening campaign of 6 million compounds between 2008 and 2012, leading to a huge pool of high-quality chemical starting points for new antimalarial projects. This pool of projects has put us in a strong position to prioritise the most promising molecules, best matched to our target product profiles for malaria eradication.

Pooling the best scientific minds to progress promising compounds, we recently launched an exciting new initiative, the Open Source Drug Discovery (OSDD) programme. The concept is simple: researchers post their study results and challenges online, and experts from across the world openly share solutions and drive progress. The OSDD programme combined with the sharing to date of 103 copies of MMV's Malaria Box – a treasure trove of 400 diverse compounds with antimalarial activity – has shown that we can start to change the prevailing research paradigm and conduct drug research for diseases associated with poverty in a more open format.

We are also committed to working with scientists in Africa, Asia, and South America to establish cutting-edge research platforms and models to identify and develop new malaria transmission-blocking and relapse-preventing treatments. For example, in Tanzania, MMV is working with Dr Salim Abdulla to establish an insectary and clinical research centre in Bagamoyo to determine the transmission-blocking activity of in-development medicines.

Getting new medicines farther

In 2011 and 2012, Eurartesim and Pyramax were added to the global malaria medicine box. Providing a greater choice of treatments could help slow down the development of resistance to artemisinin derivatives and partner drugs.[5] Eurartesim has now been registered in Ghana, Tanzania, and Burkina Faso, as well as Cambodia and

across Europe. These first African registrations mean it can now be used in the INDEPTH Effectiveness and Safety Studies of antimalarials (INESS) programme, led by Prof. Fred Binka of the University of Ghana, to monitor its real-life safety and effectiveness.

In addition, with the financial support of the European & Developing Countries Clinical Trials Partnership (EDCTP) led by Prof. Charles Mgone, MMV is working with the West African Network for Clinical Trials of Antimalarial Drugs (WANECAM) led by Prof. Abdoulaye Djimde of the University of Bamako to conduct a longitudinal study with Eurartesim and Pyramax. The results of the WANECAM and the INESS studies will help National Malaria Control Programmes to choose the right ACTs for their people.

MMV and Novartis continue to fulfil the promise to make better medicines available for children. By June 2013, more than 200 million treatments of Coartem Dispersible had been delivered to 35 countries. In an effort to address further unmet needs, the partnership is now working to determine whether Coartem Dispersible can be used safely in the smallest of babies, 5 kg and under.

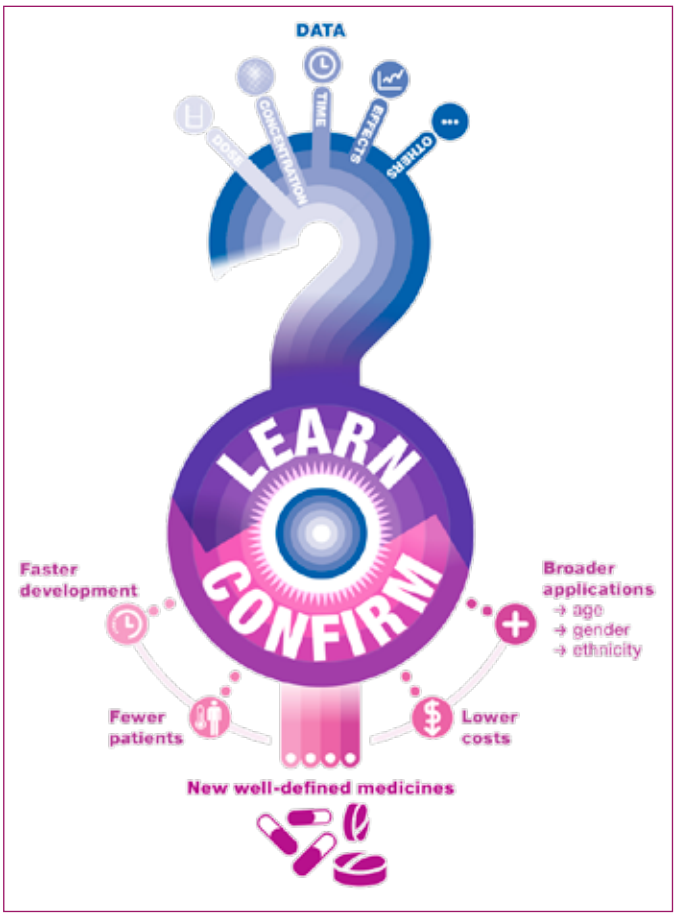
Focusing on severe malaria, MMV is working with partners to help countries make the switch from quinine to injectable artesunate since the update in the WHO guidelines recommending the use of injectable artesunate. In the space of just 2 years, an estimated 40 000–50 000 additional lives were saved thanks to the delivery of 6 million vials of Guilin's MMV-supported Artesun.[6]

Access is not just about delivering new, effective treatments to disease-endemic countries; it is also about helping to ensure appropriate structures are in place so medicines reach patients who need them most. Our CAPSS (Consortium for ACT Private Sector Subsidy) Plus programme in Uganda demonstrated the value of engaging private-sector drug shopkeepers to help improve their ability to diagnose and treat malaria and other childhood illnesses[7] appropriately.

In Tanzania, the SMS for Life programme, which uses mobile phone technology to monitor antimalarial stock levels at healthcare facilities to help prevent stock-outs, continued to provide weekly data feeds in over 5000 public health facilities. The implementation of the programme was an international collaborative effort comprising the Tanzanian Government, Novartis, MMV, SDC, Roll Back Malaria Partnership (RBM), Vodacom Tanzania and service providers including PSI and Vodafone Global Enterprises. After nearly 2 years of support for the scale-up and evaluation of the programme, MMV and partners were proud to hand over the management to the Tanzanian Government in early 2013.

The quest for elimination and eradication

With a focused strategy in place, and new tools and platforms to enable us to be even more rigorous in our portfolio management, together with our partners we are going faster and farther in our research and development (R&D) and access efforts than ever before. As a result and thanks to the continued support of our donors, MMV and partners are making significant headway in the quest for malaria elimination and eradication. MMV's network includes over 300 public and private research partners in 50 countries. The more partners we work with, the more we achieve.



PK/PD modelling. The pharmacokinetics (PK) and pharmacodynamics (PD) of a drug characterise how it works in the body and determine what dose is needed over what course of time. PK/PD measures can vary depending on the patients' age, gender, ethnicity, diet, and the severity of the disease.

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7. Childhood illnesses such as pneumonia and diarrhoea.
8. Millennium Development Goal 4 is to reduce by two-thirds, between 1990 and 2015, the under-5 mortality rate. The mortality figure in 1990 was 12 million annual deaths; we now need to save another 4.4 million lives to reach the goal. Current mortality figures for malaria are between 610 000–971 000, 86% of which are children under 5, according to WHO.