appg ON ANTIBIOTICS

HOW TO INCENTIVISE THE DEVELOPMENT OF ANTIBIOTICS:

LESSONS FROM MALARIA DRUG RESEARCH PARTNERSHIPS

This is the report of a meeting held jointly with the All-Party Parliamentary Group on Malaria and Neglected Tropical Diseases on 27th February, 2018

BSAC BRITISH SOCIETY FOR ANTIMICROBIAL CHEMOTHERAPY

ANTIBIOTIC ACTION

INTRODUCTION

Thank you for picking up this report. It covers a recent meeting of our All-Party Parliamentary Group on Antibiotics, which addresses, in its own way, one of the most pressing threats to the way we live now.

The idea for this meeting occurred during a Westminster Hall debate that I'd sponsored to mark World Antibiotic Awareness Week in November 2017. Then, my fellow MP, and the Chair of the APPG on Malaria and Neglected Tropical Diseases, Jeremy Lefroy, pointed to the pathfinding work of the Medicines for Malaria Venture - before asking if the model for developing new anti-malarial drugs might not be used to inform the model for developing new anti-bacterial treatments.

We thought it was a question best answered together. This report represents that attempt. It comprises each of the presentations given at a meeting we held jointly in February 2018.

Despite the extreme winter weather, and the last-minute change of venue, it was standing room only – which is testament to the fact that this subject matters so much to so many: academics, clinicians, politicians, civil servants, journalists, and, indeed concerned members of the public.

We hope you find this short dossier interesting and informative – but, above all, useful.

If you have any questions about the nature of our work, I would urge you to contact the British Society for Antimicrobial Chemotherapy, which provides the secretariat for our APPG. You will find contact details on the last page of this document.

With kind regards

Julian Sturdy

Member of Parliament for York Outer

Chair of the APPG on Antibiotics

April 2018

AGENDA

'How to incentivise the development of antibiotics: lessons from malaria drug research partnerships'

A joint meeting of the APPG on Antibiotics and the APPG on Malaria and Neglected Tropical Diseases

Date: Tuesday 27th February 2018

Time: 16:00 to 18:00

Location: Room C, 1 Parliament Street

1600 Welcome and introduction

Chairs, Julian Sturdy MP, and Jeremy Lefroy MP

1615 Setting the scene: the global and historical context for antimicrobial drug discovery

Dr Nicholas Brown, Consultant Medical Microbiologist, Director of Antibiotic Action, and past member of the DRIVE-AB initiative

1625 Incentivising drug discovery: what have we learned since the inception of the Medicines for Malaria Venture?

Dr David Reddy, Chief Executive Officer of Medicines for Malaria Venture

1650 Effective treatment for malaria in Africa: are current drugs under threat, and if so can we replace them?

Colin Sutherland, Professor of Parasitology at the London School of Hygiene and Tropical Medicine

1715 Response from Dr Nicholas Brown, Consultant Medical Microbiologist, Director of Antibiotic Action, and past member of the DRIVE-AB initiative

1730 Panel discussion – What are the lessons? What are the next steps?

Chairs and all speakers

1745 Closing remarks

Chairs, Julian Sturdy MP, and Jeremy Lefroy MP

EXECUTIVE SUMMARY

The work of the Medicines for Malaria Venture, to date, has shown that the 'pipeline coordinator' model can help to facilitate drug development. Its success, in terms of the number of drugs in the current portfolio, has relevance to antibiotic development too, and so this model deserves further investigation.

The Chair of the APPG for Antibiotics, Julian Sturdy MP, and Dr Nicholas Brown, the Director of Antibiotic Action, believe that this investigation should be furthered through another meeting of the APPG – which would this time explore, more specifically, the work of partnership bodies like CARB-X and the Global Antibiotic Research & Development Partnership (GARDP) in relation to antibiotic development, pipeline coordination, and the legacy of the DRIVE-AB initiative.

SETTING THE SCENE: THE GLOBAL AND HISTORICAL CONTEXT FOR ANTIMICROBIAL DRUG DISCOVERY

Dr Nicholas Brown, Consultant Medical Microbiologist, Director of Antibiotic Action, and past member of the DRIVE-AB initiative

Antimicrobial resistance is not a new issue. We were warned of its existence by Alexander Fleming in the early 20th century. The concerns we face today are mainly due to the rate at which resistance is increasing.

Historical clinical practice had been to simply change to an alternative antibiotic when resistance became significant. Increasingly, there are now no alternative options left.

Data from the PEW Charitable Trust describe the 'discovery void' in the last three decades with no new class of antibiotic (subsequently licenced/approved) described since 1984.

Both the Chief Medical Officer for England's Annual Report published in February 2013 and the AMR Review undertaken by Lord O'Neill discuss the urgent need to revitalise the antibiotic discovery and development pipeline.

The UK Government AMR Strategy 2013-2018 is now due for renewal and therefore this is a very opportune time to discuss what progress has been made.

The PEW Charitable Trust has reported that 49 antibiotics are currently in various stages of development, but that only a handful (perhaps 4 to 6) are expected to reach the market by 2024.

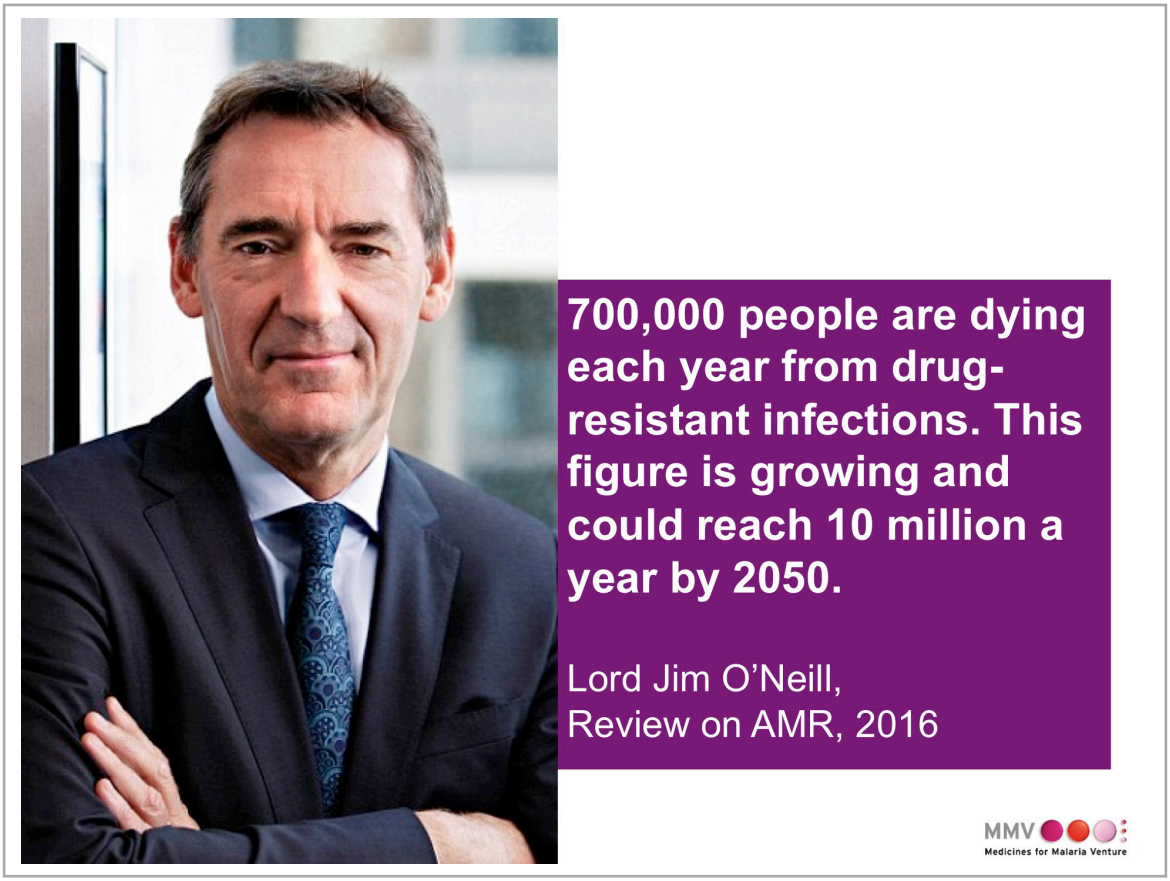
This compares with 170 drugs in development for diabetes and 700 for cancer.

The purpose of this APPG discussion is to review the Medicines for Malaria Venture (MMV) process for engagement in new drug development. They have existed since 1999 and therefore have significant experience in this area.

We want to capitalise on the work that has been done, avoid duplication of effort and see what lessons have been learned.

INCENTIVISING DRUG DISCOVERY: WHAT HAVE WE LEARNED SINCE THE INCEPTION OF THE MEDICINES FOR MALARIA VENTURE?

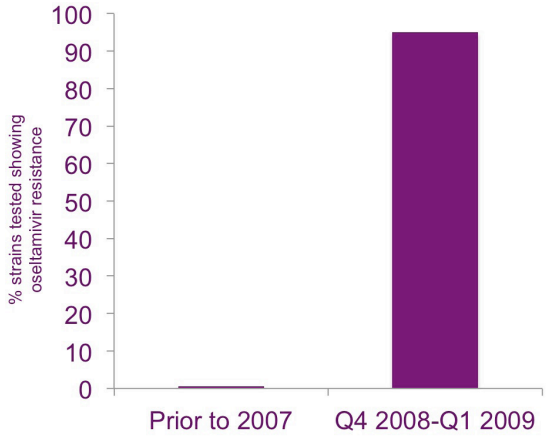
Dr David Reddy, Chief Executive Officer of Medicines for Malaria Venture



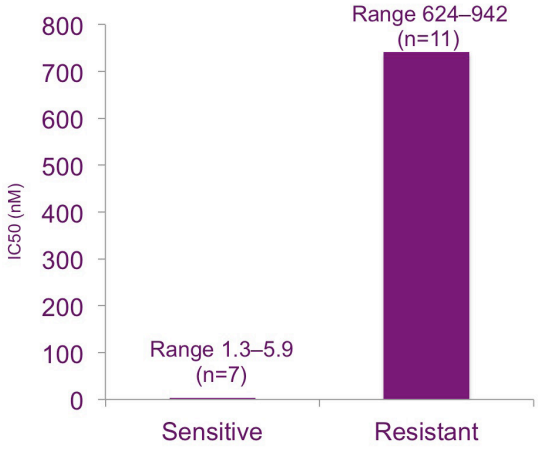
Sensitivity of H1N1 seasonal influenza to oseltamivir

Why continued R&D is essential

Prevalence of oseltamivir-resistant Influenza[1-5]



Sensitivity of 2007/2008 H1N1 to oseltamivir (IC_{50};nM)[6]

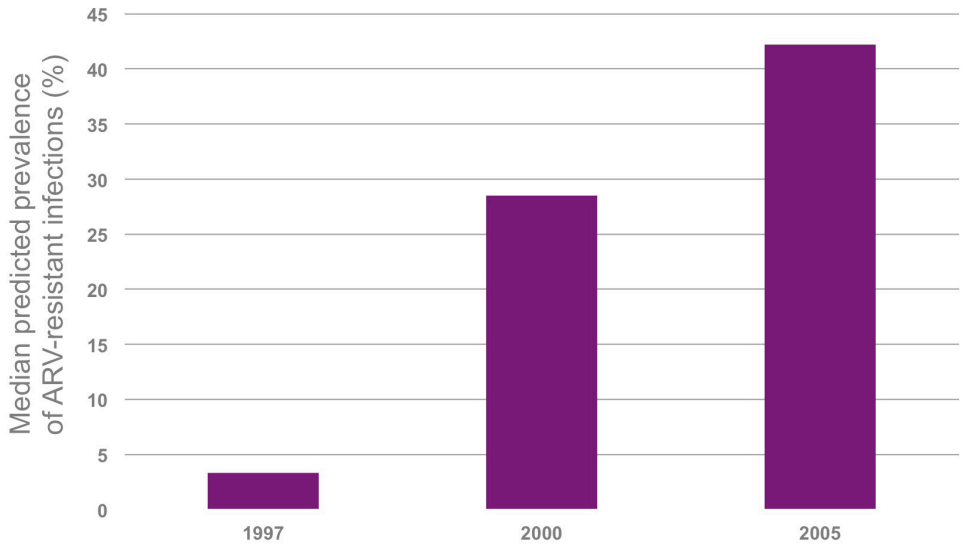


1. Hurt AC et al. (2004) Identification of a human influenza type B strain with reduced sensitivity to neuraminidase inhibitor drugs. Virus Res 103: 205–211.
2. McKimm-Breschkin J et al. (2003) Neuraminidase sequence analysis and susceptibilities of influenza virus clinical isolates to zanamivir and oseltamivir. Antimicrob Agents Chemother 47: 2264–2272.
3. Monto AS et al. (2006) Detection of influenza viruses resistant to neuraminidase inhibitors in global surveillance during the first 3 years of their use. Antimicrob Agents Chemother 50: 2395–2402.
4. Mungall BA, Xu X, Klimov A (2004) Surveillance of influenza isolates for susceptibility to neuraminidase inhibitors during the 2000–2002 influenza seasons. Virus Res 103: 195–197.
5. World Health Organization. Influenza A(H1N1) virus resistance to oseltamivir - 2008/2009 influenza season, northern hemisphere 18 March 2009.
6. Rameix-Welti MA et al. Enzymatic Properties of the Neuraminidase of Seasonal H1N1 Influenza Viruses Provide Insights for the Emergence of Natural Resistance to Oseltamivir. July 25, 2008DOI: 10.1371/journal.ppat.1000103

MMV Medicines for Malaria Venture

Changing face of HIV in developed world

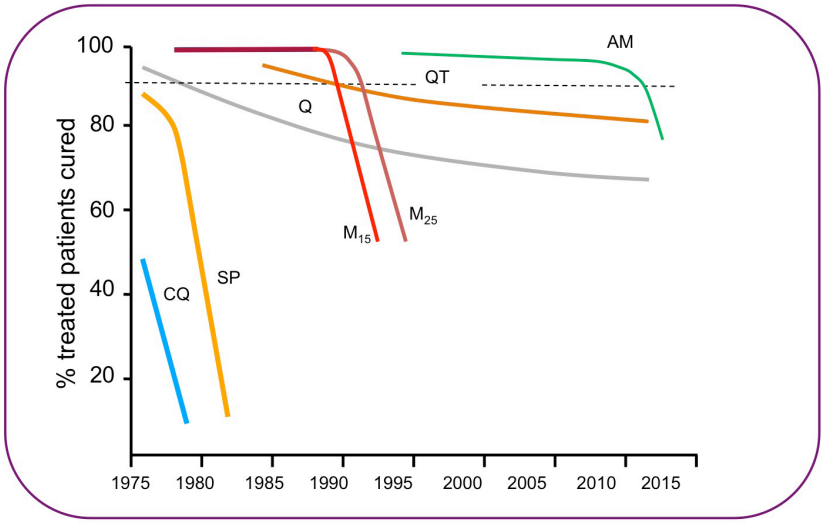
Growing epidemic of drug resistant HIV



Blower *et al.* Resistance defined as lost suppression of viral replication to a three-drug regimen: Nature Medicine. 2001; 7: 1016-1020

The cliff - malaria drug resistance

Declining cure rates in SE Asia (%)



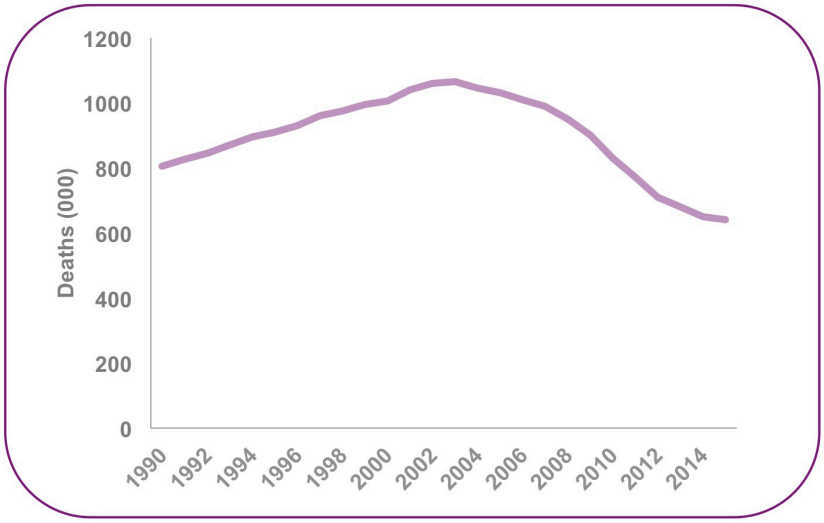
In Cambodia a 5-10 fold increase in treatment failure rates

CQ = chloroquine; SP = sulphadoxine-pyrimethamine; M_{15} = mefloquine 15 mg/kg body weight; M_{25} = mefloquine 25 mg/kg body weight; Q = quinine; QT = tetracycline; AM = amodiaquine

Slide courtesy of Professor Nick White

MMV Medicines for Malaria Venture

Malaria mortality in Africa 1990-2015



Adapted from Gething, PW *et al.* Mapping Plasmodium falciparum Mortality in Africa between 1990 and 2015. NEJM. 2016. 375;25: 2435-2445.

MMV's mission

Strong R&D portfolio of innovative antimalarial drugs that address current unmet medical needs and emerging drug resistance, and increase the operational feasibility of malaria elimination programs

DISCOVER	DEVELOP	DELIVER
New tools for containing resistance & eliminating malaria	Better antimalarial medicines for clinical case management & vulnerable populations	Equitable access to quality antimalarial medicines
Brings together network of partners & technical platforms	Rigorous portfolio management & strategic, data driven oversight	Equitable access and maximum health impact

Contributing to the achievement of WHO Global Technical Strategy elimination targets

LIVES SAVED | CASES AVERTED | COUNTRIES APPROACHING & ACHIEVING ELIMINATION

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MMV Medicines for Malaria Venture

MMV Medicines for Malaria Venture

Operating model

Syndicated investment
Governments, philanthropic

Partnership
Funders, industry, academia, NMCPs, UN agencies, CROs

Drug pipeline
R&D and portfolio management

Independent expert scientific review
Supports clinical candidate selection and stage-gating

Strong contractual framework
Increases access and good governance

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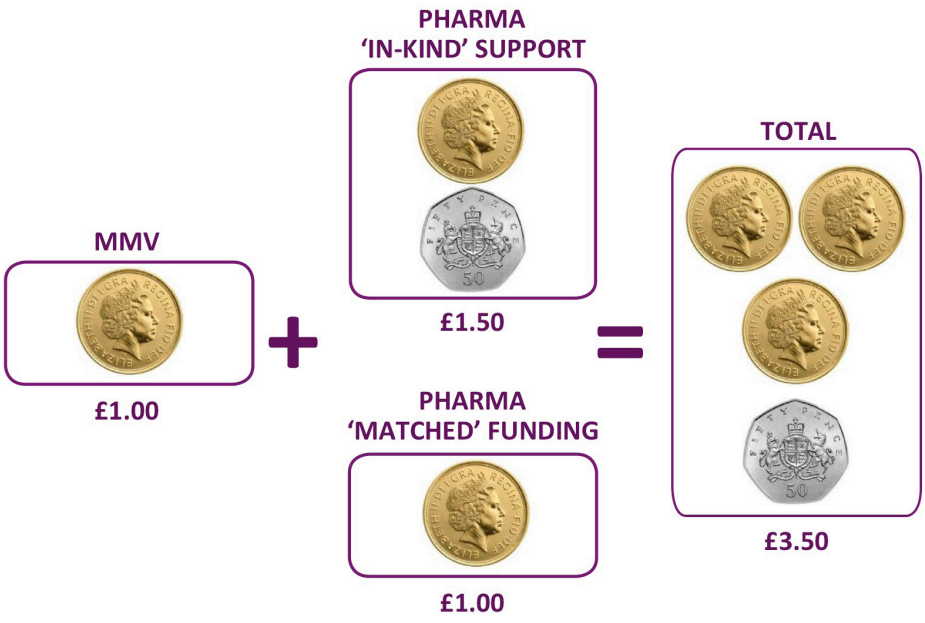
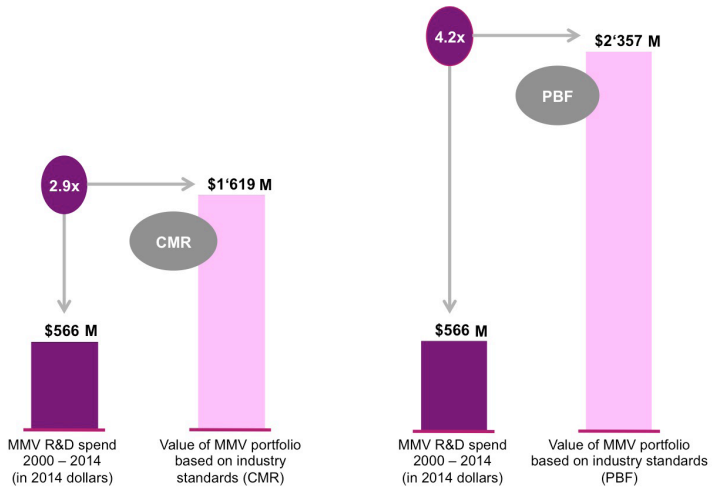
MMV's industry partners: 2000-2018

Leveraging donor funds



Donor investment to create MMV portfolio versus standard industry costs



Note: Figures inflated to 2014 dollars using the CPI inflator for both MMV and industry benchmarks
*Source: CMR (Thomson Reuters pharmaceutical benchmark, 2013 data based on sample of development projects from 2006-2010);
PBF (Pharmaceutical Benchmarking Forum, using data from 13 large pharmaceutical firms, 2010 data)

MMV Medicines for Malaria Venture

1999

Research
Lead generation: Lactate dehydrogenase inhibition
Lead optimization: Cysteine proteinase inhibition; Synthetic peroxide

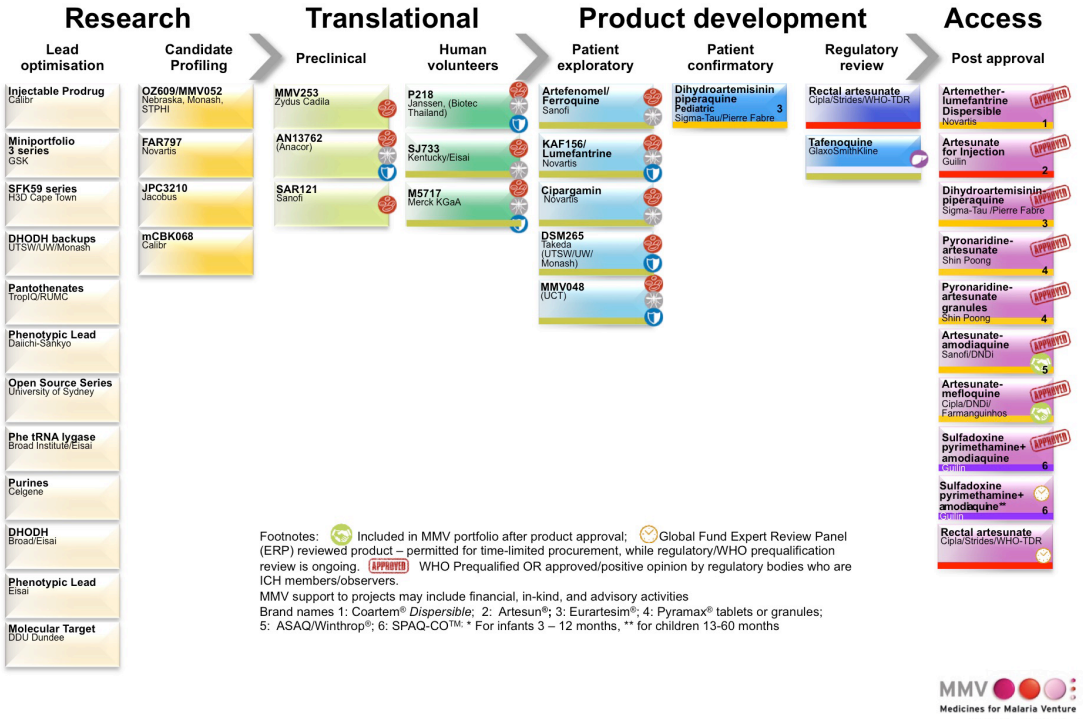
Translational
Preclinical
Human volunteers

Product development
Patient exploratory
Patient confirmatory
Regulatory review

Access
Post approval

Exploratory projects:
1. DHFR
2. DHODH
3. Heme

MMV-supported projects 2018



Footnotes: Included in MMV portfolio after product approval; Global Fund Expert Review Panel (ERP) reviewed product – permitted for time-limited procurement, while regulatory/WHO prequalification review is ongoing. WHO Prequalified OR approved/positive opinion by regulatory bodies who are ICH members/observers.
MMV support to projects may include financial, in-kind, and advisory activities
Brand names 1: Coartem® *Dispersible*; 2: Artesun®; 3: Eurartesim®; 4: Pyramax® tablets or granules; 5: ASAQ/Winthrop®; 6: SPAQ-CO™: * For infants 3 – 12 months, ** for children 13-60 months

MMV Medicines for Malaria Venture

MMV-supported products have had saved an estimated >1.5 million lives since 2009

COARTEM DISPERSIBLE

350 million treatment courses[1] delivered by Novartis to over 50 countries

Saving an estimated >875,000 children lives

ARTESUN INJECTED

>100 million vials of Artesun delivered since 2011[2]

Saving an estimated 650,000 additional lives[3]

SP-AQ

Reducing uncomplicated and severe malaria episodes by 75%[4]

Protecting 19 million children – reducing uncomplicated and severe malaria by 75%[5]

ARTESUNATE SUPPOSITORIES

Available starting 2017, with 460,000 treatments delivered in 2017

Halving disability and death[6]

1 Source – Novartis press release 2017
2 Source – Fosun 2017
3 Additional childrens lives saved by providing injected artesunate versus injected quinine to children with severe malaria – AQUAMAT and SEAQUAMAT studies
4 WHO
5 Gulin distribution data (2017)
6 WHO TDR Study 13

Key lessons learned

- Evolutionary biology dictates that drug resistance is inevitable and that we must plan for the failure of current and future antimicrobials
- To date, the most successful approach for developing new treatments for NTDs is through public-private partnerships
- Requires funding for public sector academic research and incentives for the private sector
- Private sector partners possess capabilities needed to successfully address the AMR challenge, but have different barriers to entry - these require different incentives and support
  - Financial risk-sharing (syndicated investment, PRV)
  - Use of intellectual property to frame rewards and responsibilities
  - Strategic alignment and external validation
  - Technical guidance (disease-specific, drug development and registration, market knowledge)
  - Advocacy and reputational enhancement / protection

"If international cooperation on malaria – and indeed other diseases… has achieved such results in less than 20 years, can we not apply a similar model to other global challenges?"

Jeremy Lefroy, MP, UK Parliament

MMV Medicines for Malaria Venture

485
Products in the Neglected Disease R&D Pipeline

MALARIA	TB	HIV	KINETOPLASTIDS
124	117	82	44

DIARRHOEAL DISEASES	HELMINTH INFECTIONS	HEPATITIS C	SALMONELLA INFECTIONS
31	24	17	13

BACTERIAL PNEUMONIA & MENINGITIS	DENGUE	TRACHOMA	BURULI ULCER
12	5	4	4

LEPROSY	LEPTOSPIROSIS	RHEUMATIC FEVER	CRYPTOCOCCAL MENINGITIS
3	2	2	1

203	142	124	16
VACCINES	DRUGS	DIAGNOSTICS	VECTOR CONTROL PRODUCTS

The Unrecognised Revolution in Global Health. An update on the state of the neglected disease R&D product pipeline Policy Cures 2015. http://pipeline.policycures.org

MMV are Grateful to our Committed Funders

Australian Government
Department of Foreign Affairs and Trade

Bill & Melinda Gates foundation

ExxonMobil

GHIT Fund
Global Health Innovative Technology Fund

Irish Aid
Department of Foreign Affairs
An Roinn Gnóthaí Eachtracha

Ministry of Foreign Affairs of the Netherlands

National Institutes of Health (NIH/NIAID)

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Confédération suisse
Confederazione Svizzera
Confederaziun svizra
Swiss Agency for Development and Cooperation SDC

UKaid
from the British people

UNITAID

USAID
FROM THE AMERICAN PEOPLE

wellcome trust

World Health Organization

Gouvernement Princier
PRINCIPAUTÉ DE MONACO

SPONSORED BY THE
Federal Ministry of Education and Research

18

EFFECTIVE TREATMENT FOR MALARIA IN AFRICA: ARE CURRENT DRUGS UNDER THREAT, AND IF SO CAN WE REPLACE THEM?

Colin Sutherland, Professor of Parasitology at the London School of Hygiene and Tropical Medicine

Effective treatment for malaria in Africa: are current drugs under threat, and if so can we replace them?

All Party Parliamentary Group on AMR

All Party Parliamentary Group on Malaria & NTDs

February 2018

Colin Sutherland

Professor of Parasitology

London School of Hygiene & Tropical Medicine

Clinical Scientist

PHE Malaria Reference Laboratory

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Current antimalarial chemotherapy for Plasmodium falciparum *is based on fixed combination formulations comprising:*

- *an artemisinin compound from* Artemisia annua
- *a partner drug from a different pharmaceutical class*

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Muwanguzi *et al. Malar J (2016) 15:36*
DOI 10.1186/s12936-016-1095-y

Malaria Journal

RESEARCH Open Access

CrossMark

Lack of K13 mutations in *Plasmodium falciparum* persisting after artemisinin combination therapy treatment of Kenyan children

Julian Muwanguzi[1], Gisela Henriques[1], Patrick Sawa[2], Teun Bousema[1,3], Colin J. Sutherland[1] and Khalid B. Beshir[1*]

Resistant parasites described in SE Asia are not the explanation …

The Journal of Infectious Diseases

IDSA Infectious Diseases Society of America

hivma hiv medicine association

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Volume 211, Issue 5
1 March 2015

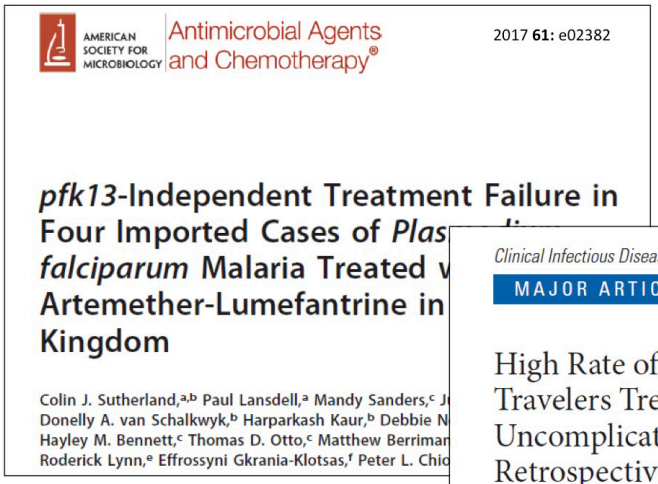
Absence of Putative Artemisinin Resistance Mutations Among *Plasmodium falciparum* in Sub-Saharan Africa: A Molecular Epidemiologic Study

FREE

Steve M. Taylor, Christian M. Parobek, Derrick K. DeConti, Kassoum Kayentao, Sheick Oumar Coulibaly, Brian M. Greenwood, Harry Tagbor, John Williams, Kalifa Bojang, Fanta Njie … Show more

The Journal of Infectious Diseases, Volume 211, Issue 5, 1 March 2015, Pages 680–688, https://doi.org/10.1093/infdis/jiu467

Cambodian style K13-dependent phenotypes are not present …



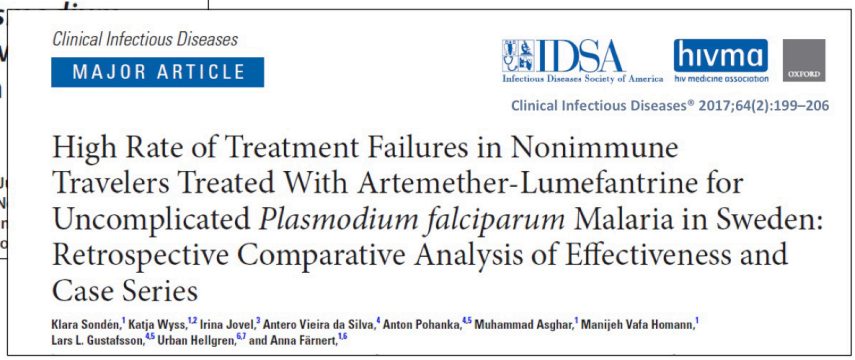
AMERICAN SOCIETY FOR MICROBIOLOGY | Antimicrobial Agents and Chemotherapy®

2017 **61:** e02382

***pfk13*-Independent Treatment Failure in Four Imported Cases of *Plas* *falciparum* Malaria Treated v Artemether-Lumefantrine in Kingdom**

Colin J. Sutherland,[a,b] Paul Lansdell,[a] Mandy Sanders,[c] J
Donelly A. van Schalkwyk,[b] Harparkash Kaur,[b] Debbie N
Hayley M. Bennett,[c] Thomas D. Otto,[c] Matthew Berriman
Roderick Lynn,[e] Effrossyni Gkrania-Klotsas,[f] Peter L. Chio

And in imported European malaria cases from Africa:



Clinical Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America | hivma hiv medicine association | OXFORD

Clinical Infectious Diseases® 2017;64(2):199–206

High Rate of Treatment Failures in Nonimmune Travelers Treated With Artemether-Lumefantrine for Uncomplicated *Plasmodium falciparum* Malaria in Sweden: Retrospective Comparative Analysis of Effectiveness and Case Series

Klara Sondén,[1] Katja Wyss,[1,2] Irina Jovel,[3] Antero Vieira da Silva,[4] Anton Pohanka,[4,5] Muhammad Asghar,[1] Manijeh Vafa Homann,[1] Lars L. Gustafsson,[4,5] Urban Hellgren,[6,7] and Anna Färnert,[1,6]

K13-dependent phenotypes are not the explanation for observed treatment failure.

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Does Africa have a problem with artemisinin resistance?

If the answer is yes *(or maybe…)*, **what needs to be happening now?**

- *Routine* in vivo *surveillance of ACT efficacy more widely*
- *Validation of suitable markers*
- *Active testing of alternative treatment strategies using current drugs*

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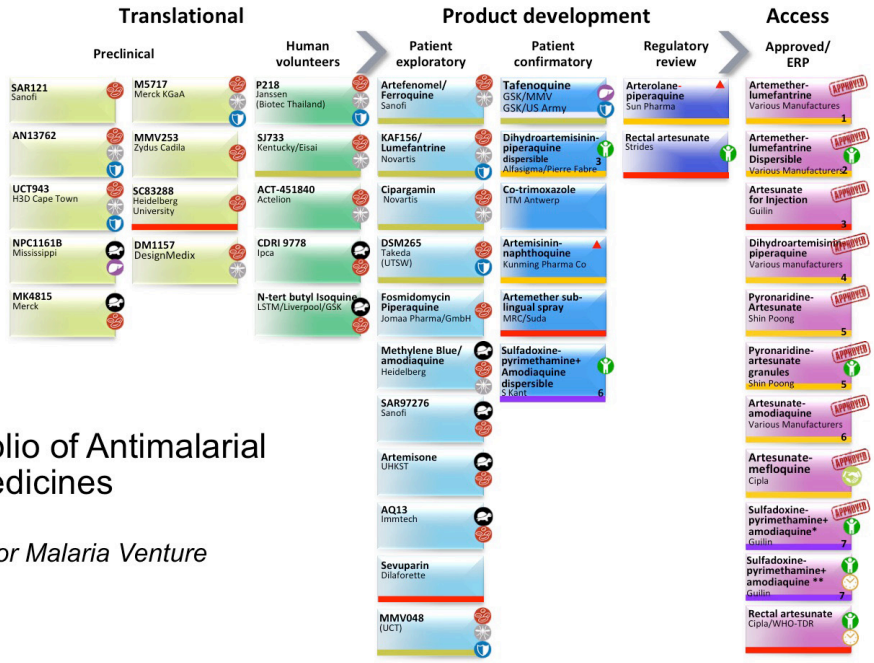

Global Portfolio of Antimalarial Medicines

Medicines for Malaria Venture

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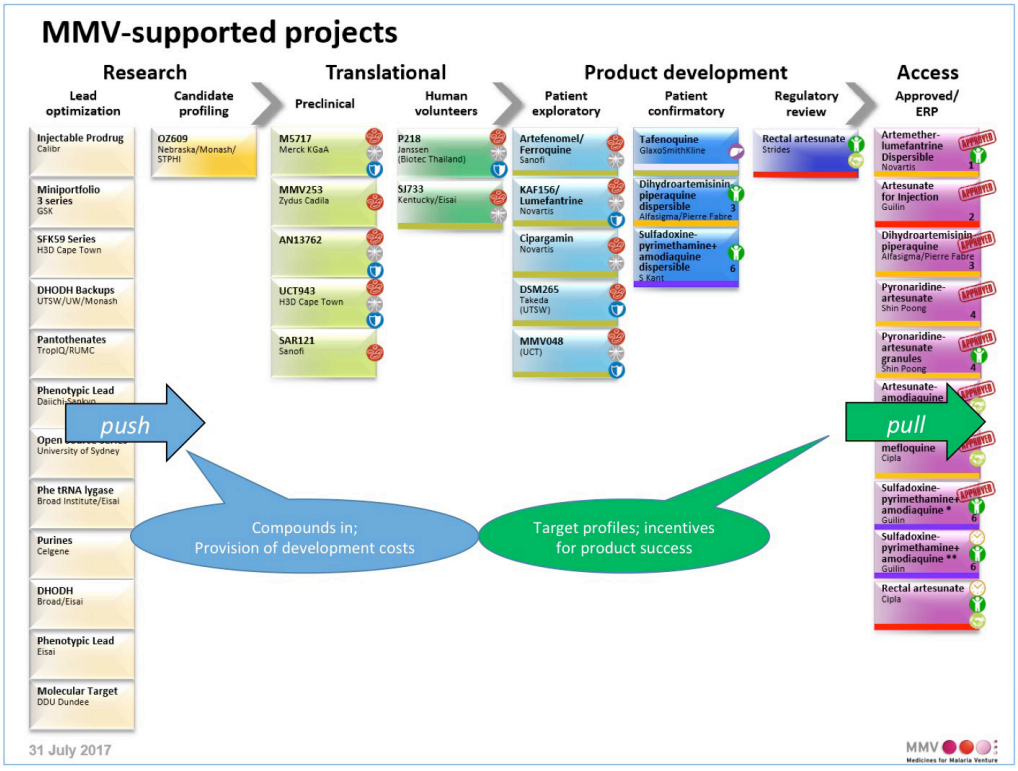

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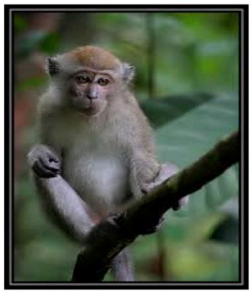
Case Study 1:
Parasite susceptibility studies, LSHTM



J Antimicrob Chemother 2017; **72**: 3051–3058
doi:10.1093/jac/dkx279 Advance Access publication 30 August 2017

Journal of Antimicrobial Chemotherapy

Comparison of the susceptibility of *Plasmodium knowlesi* and *Plasmodium falciparum* to antimalarial agents

Donelly A. van Schalkwyk[1], Robert W. Moon[1], Benjamin Blasco[2] and Colin J. Sutherland[1,3]*

Table 2. Susceptibility of *P. knowlesi* and *P. falciparum* to three DHODH inhibitors assessed using the SYBR Green I assay

	EC_{50} values (nM)			
Compound	*P. knowlesi* (A1-H.1), 27 h exposure	*P. falciparum* (3D7), 48 h exposure	Fold difference (*P. falciparum*/*P. knowlesi*)	P^a
DHFR inhibitors				
pyrimethamine	5.1±0.8	54.0±5.0	10.6	<0.0001
cycloguanil	1.3±0.3	11.8±0.6	9.08	<0.0001
trimethoprim	265±47	3098±229	11.7	<0.0001
P218[b]	4.1±0.7	3.5±0.2	0.85	0.4884
Transfection reagents				
WR99210[c]	0.16±0.04	0.43±0.03	2.69	0.0003
blasticidin[c]	31684±3485	1413±190	0.04	<0.0001
DSM1[c]	509±11	149±5	0.29	<0.0001

EC_{50} (nM), single life cycle | EC_{50} (nM), two life cycles

falciparum, 96 h | fold difference

91±10 | 4.6
21±1 | 8.9
42±4 | 2.9

of 1%. The EC_{50} values are reported
EC_{50} value. For each DSM compound,
over either a single parasite life cycle

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Case Study 2: WANECAM Consortium

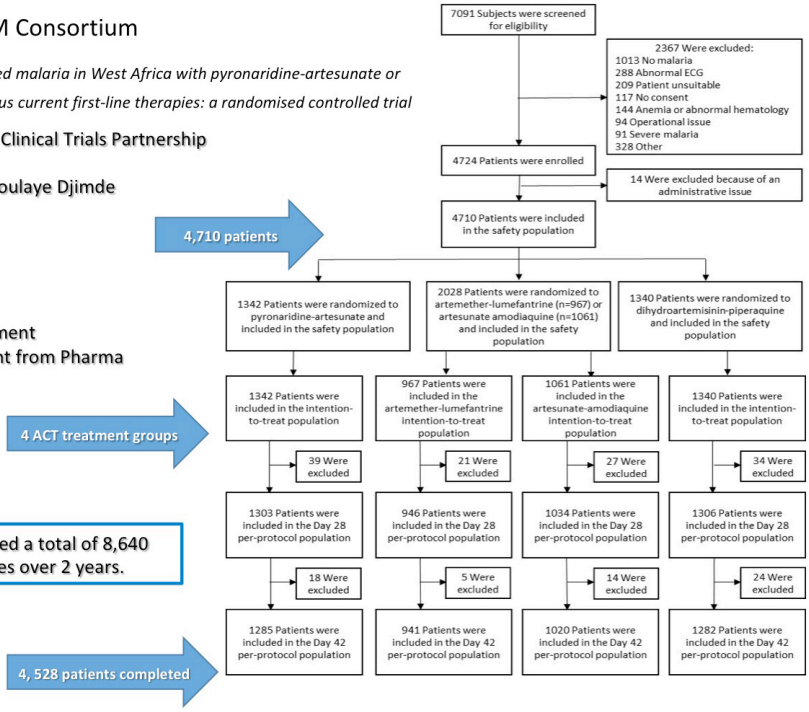
Repeated treatment of uncomplicated malaria in West Africa with pyronaridine-artesunate or dihydroartemisinin-piperaquine versus current first-line therapies: a randomised controlled trial

European & Developing Countries Clinical Trials Partnership

Co-ordinator: Prof Abdoulaye Djimde

Burkina Faso, Mali, Guinée
UK, Sweden, Germany, France

MMV provided:
- Guidance in protocol development
- Brokerage of drug procurement from Pharma
- Some gap finance



These patients experienced a total of 8,640 repeat malaria episodes over 2 years.

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Recommendations 1: *Lessons from the MMV model for developmental of antibacterial and antiviral drugs*

- pharma investment in R&D cannot (and will not) adequately drive the whole pipeline
- "pull" incentives from well-funded public-private funding partnerships, through publication of Target Profiles and reward for success, are part of the answer
- "push" incentives, funding the early pipeline development activities, are needed to ensure potential drugs enter the pipeline and can be recognised for advancement
- Academia, WHO, NGOs and learned societies (e.g. BSAC) should be given seats at the table in agreeing Target Profiles, and designing push incentive funding programmes

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Recommendations 2: *How can parliamentarians and policy makers support the science behind AMR advances?*

- Support grass roots science, ensuring a secure employment path for early career academics
- Revive low-cost, hi-risk, winnable project funding for scientists "mucking about in the lab" (Remember Florey and Fleming!)
- Do not penalise students for taking degrees in science, technology, engineering and mathematics
- Ensure that post-Brexit UK policy maintains membership of European science funding initiatives such as EDCTP, Horizon 2020 (or its successor) and the Erasmus exchange programmes
- Remember that infectious diseases are a global issue requiring international co-operation, and are not well-managed by nations acting alone

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Thank you!

Lab group, LSHTM

Gisela Henriques
Ryan Henrici
Julian Muwanguzi
Ify Aniebo
Don van Schalkwyk
Khalid Beshir
Mary Oguike
Colin Sutherland

PHE Malaria Reference Lab

Debbie Nolder
Paul Lansdell
Valerie Smith
Marie Blaze
Chris Whitty
Claire Rogers
Peter Chiodini

MMV

RESPONSE FROM DR NICHOLAS BROWN, CONSULTANT MEDICAL MICROBIOLOGIST, DIRECTOR OF ANTIBIOTIC ACTION, AND PAST MEMBER OF THE DRIVE-AB INITIATIVE

The DRIVE-AB research project (driving reinvestment in research and development for antibiotics and advocating their responsible use) was a collaborative venture which formed part of the Innovative Medicines Initiative (IMI) co-funded by the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The output of the project has just been published and it was interesting to see the similarities between its conclusions and the Medicines for Malaria Venture.

In particular, the concept of a pipeline coordinator role was akin to the establishment of bodies such as the Global Antibiotic Research and Development Partnership (GARDP), which is a joint venture of the WHO and Drugs for Neglected Diseases initiative, and CARB-X (Combating antibiotic resistant bacteria), which receives funding from various sources, including national governments.

One area that has not been emphasised during discussions is the importance of equitable availability of any new antibiotic. Access to antibiotics, particularly in low and middle income countries is an important barrier to responsible and sustainable use of new agents.

Another important area for discussion is the concept of de-linkage. This was taken to mean the separation of drug company revenue from sales for the DRIVE-AB project. Revenues would be based on the value to society, not on the number of units sold. This aims to make drug discovery more attractive to the developer, while encouraging good stewardship.

However, an alternative WHO definition of de-linkage refers more to the separation of the unit sale cost from the research and development costs. This has an important consequence of lowering the starting cost of the new agent. This is clearly an advantage in low and middle income countries, but does not encourage good stewardship necessary to prevent the overuse of the new agent and prevent the rapid emergence of resistance.

appg ON ANTIBIOTICS

The All-Party Parliamentary Group on Antibiotics exists to raise the profile of: antibiotic resistance, the need to preserve antibiotics through education on their appropriate use (including non-human use), the lack of new treatments for bacterial infections, and efforts to discover, research, and develop new treatments.

The British Society for Antimicrobial Chemotherapy (BSAC) provides the Secretariat for the APPG, which is chaired by Julian Sturdy MP.

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