Three MMV-supported antimalarials listed as essential medicines

New revisions of WHO's Essential Medicines Lists include vital, child-friendly antimalarials brought forward by MMV and partners

16 June 2017, Geneva. On the International Day of African Child, Medicines for Malaria Venture (MMV) welcomes the inclusion of three medicines from the MMV-supported product portfolio on the World Health Organization's Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc). These are two artemisinin-based combination therapies (ACTs) for adults, children and infants; and a rectal artesunate formulation specifically for young children:

- **A fixed-dose combination of pyronaridine tetraphosphate and artesunate** in tablets for the first-line treatment of both uncomplicated *Plasmodium falciparum* and *Plasmodium vivax* malaria in adults and children ≥ 20kg, and child-friendly granules for children and infants weighing 5 kg to under 20 kg.
- **A fixed-dose combination of dihydroartemisinin (DHA) + piperaquine phosphate (PQP)** for the first-line treatment of uncomplicated *P. falciparum* malaria in adults, children and infants.
- **Artesunate rectal dose form (100mg presentation)** for the pre-referral management of severe malaria in young children.

WHO's Model EML[1] identifies medicines that *"satisfy the priority health care needs of the population."* In practical terms, the WHO Model EML can help countries consider revisions to their national EMLs, which in turn, inform the procurement decisions of central medical stores and the prioritization of medicines for use in-country.

With concerted global effort, malaria incidence and deaths fell dramatically between 2001 and 2015: it is estimated that of the 6.2 million lives saved from malaria over that period, 5.9 million (95%) were those of children under the age of 5 years. Despite this significant gain, in 2016 malaria took an estimated 429,000 lives, 306,000 of whom were young children. Inclusion of these new antimalarials into the EML will help make more child-friendly antimalarial treatments accessible to those who need them most and increase the number of high-quality ACT options for inclusion in national EMLs.

"MMV is delighted with the addition of these three important antimalarials to the Essential Medicines List," *said Dr David Reddy, CEO of Medicines for Malaria Venture*. "Young children bear the brunt of this terrible disease – a child dies of malaria every two minutes. With strongly committed partners like Novartis, Shin Poong, Sigma-Tau, Cipla and Strides Shasun, we have been able to prioritise the development and introduction of new, tailored medicines, including for this vulnerable population. We are working with a worldwide network of partners to accelerate the progress of new therapies and interventions in the global drive towards malaria elimination. Listing on the EML marks a major step forward in making these vital and often life-saving treatments and interventions accessible to those hardest hit by malaria."

[1] WHO's Model Essential Medicines List (EML) is a globally accepted set of selected therapies to help countries identify priority medicines to meet their health needs
http://www.who.int/features/2013/essential_medicines_list/en/

For enquiries please contact:

Jaya Banerji
Senior Director, Communications
Tel: +41 22 555 0327
Mob: +41 79 707 7181
email: banerjij@mmv.org

Information for editors on the Essential Medicines List (EML)

WHO reviews EML dossier applications and evaluates medicines based on their relevance for public health needs, while also considering evidence on efficacy, safety and cost-effectiveness. Revised every 2 years, the EML (now in its 20th edition) and the Essential Medicines List for Children (EMLc – in its 6th edition) is intended to help countries decide which medicines should be *"available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford."*[2]

Information for editors on medicines included on the EML

Pyronaridine-artesunate (brand name: Pyramax®), developed by Shin Poong Pharmaceutical and MMV, became the first ACT to receive a positive scientific opinion under the European Medicines Agency's article 58 procedure in 2012. It is already referenced on the WHO's list of prequalified medicines and thus can be purchased with donor funds. Both the tablets and paediatric granules are undergoing national approvals in malaria-endemic countries. *Pyramax* has already received regulatory approval in 17 African countries and 5 Asian malaria-endemic countries, and Pyramax granules in 5 African countries

Rectal artesunate suppositories (RAS) for the pre-referral management of severe malaria are intended for infants and children who are critically ill and unable to take oral medicines. Untreated severe malaria can be fatal, especially in the first 24 hours; but this risk can fall to 10-20% with prompt treatment and care. In many malaria-endemic countries, treatment delays due to distance from health facilities can result in fatal outcomes. The WHO recommends pre-referral administration of RAS, in young children[3] to reduce the risk of death or permanent disability[4].

WHO's EML has listed 50 mg and 200 mg strength RAS since 2007. MMV and its partner Cipla have developed the only RAS presentation (100 mg suppository) that has been approved for purchase with donor funds (via Global Fund's ERP product list, while WHO prequalification review is ongoing). In addition, MMV partner Strides Shasun's RAS product is currently undergoing review by the WHO prequalification programme.

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[2] http://www.who.int/topics/essential_medicines/en/:
[3] Guidelines for the treatment of malaria - 3rd edition. Geneva: World Health Organization; 2015. Available from: http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf?ua=1&ua=1.
[4] Rectal Artesunate Stakeholders' Meeting Report Nairobi, 19 February 2016
https://www.mmv.org/sites/default/files/uploads/.../MMV_RASreport_20160513.pdf

Eurartesim ® (Dihydroartemisinin-piperaquine [DHA-PQP]), developed by Sigma-Tau (Alfasigma Group) and MMV, was approved by the European Medicines Agency (EMA) in 2011 and received WHO prequalification in 2015. The medicine is available in 14 malaria-endemic countries. DHA-PQP is currently being evaluated in multiple research centres as a possible replacement for sulfadoxine-pyrimethamine for intermittent preventive treatment of malaria during pregnancy in areas where SP is no longer recommended due to resistance. A dispersible paediatric formulation has been submitted for regulatory approval to the EMA.

About Medicines for Malaria Venture

MMV is a leading product development partnership (PDP) in the field of antimalarial drug research and development. Its mission is to reduce the burden of malaria in disease-endemic countries by discovering, developing and delivering new, effective and affordable antimalarial drugs.

Since its foundation in 1999, MMV and partners have developed and brought forward six new medicines that are now treating patients: Coartem® *Dispersible* (artemether-lumefantrine), a child-friendly formulation developed with Novartis; Guilin's injectable artesunate, Artesun® for the treatment of severe malaria; Eurartesim® (DHA-PQP) with Sigma-Tau (Alfasigma Group); Pyramax® (pyronaridine-artesunate) and Pyramax® Granules for children co-developed with Shin Poong; and Guilin's sulphadoxine-pyrimethamine + artesunate amodiaquine (SP+AQ) for seasonal malaria chemoprevention, which received WHO prequalification with MMV's support. Furthermore, with MMV support, Cipla's rectal artesunate (RAS) product was issued a 12-month authorization for procurement by the Global Fund Expert Review Panel (ERP), while regulatory/WHO prequalification review is ongoing for the same product as well as that of Strides Shasun. In addition, MMV has taken over the stewardship of two approved artemisinin combination therapies (ACTs) developed by Drugs for Neglected Diseases *initiative* (DND*i*) and partners – artesunate-amodiaquine (ASAQ) and artesunate-mefloquine (ASMQ).

It is estimated that since 2009, MMV-supported medicines have saved over a million lives. Over 300 million courses of *Coartem® Dispersible* treatment have been supplied to 50 malaria-endemic countries; and since prequalification in 2010, an estimated 75 million vials of Artesun® have been delivered, saving 450,000–500,000 additional lives.

MMV and partners manage a portfolio of 65 projects, the largest portfolio of antimalarial R&D and access projects ever assembled. The portfolio includes nine new drugs in clinical development addressing unmet medical needs in malaria, including medicines for children, pregnant women and relapsing malaria, and drugs that could support the elimination/eradication agenda. MMV's success in research and access & product management comes from its extensive partnership network of over 400 pharmaceutical, academic and endemic-country partners in more than 55 countries.

MMV's vision is a world in which innovative medicines will cure and protect the vulnerable and under-served populations at risk of malaria, and ultimately help to eradicate this terrible disease.

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