

17 February 2012
EMA/CHMP/114875/2012
Press Office

Press release

European Medicines Agency recommends new anti-malaria treatment for use outside the European Union

EMA opinion intended to support countries outside the EU to get new treatment option to market to fight WHO target disease

The European Medicines Agency (EMA) has recommended Pyramax, a fixed combination consisting of pyronaridine and artesunate, an artemisinin derivative, from Shin Poong Pharmaceutical Co. Ltd, for the treatment of acute, uncomplicated malaria infection caused by *Plasmodium falciparum* or by *Plasmodium vivax* in adults and children weighing 20 kg or more, in areas of low transmission with evidence of artemisinin resistance.

The scientific opinion for Pyramax was given under Article 58 of Regulation (EC) No 726/2004, which allows the Agency's Committee for Medicinal Products for Human Use (CHMP) to give a scientific opinion, in cooperation with the World Health Organization (WHO), on medicines for human use intended exclusively for markets outside the European Union (EU). Applicants can use the CHMP's scientific opinion as a basis when applying for a marketing authorisation in countries outside of the EU. The scientific opinion also facilitates the WHO prequalification process.

Medicines eligible for this procedure are used to prevent or treat diseases of major public health interest, including vaccines used in the WHO Expanded Programme on Immunisation or for protection against a public health priority disease, as well as medicines for WHO target diseases such as HIV/AIDS, malaria or tuberculosis.

The application for Pyramax was evaluated by the CHMP with participation of WHO experts and experts and observers from medicines agencies from countries outside the EU. The Committee concluded that the efficacy of Pyramax was demonstrated. However, due to concerns about severe liver problems associated with repeated use, Pyramax should only be used as single 3-day treatment course, in areas of low transmission with evidence of decreased efficacy of other oral artemisinin-based combination therapies, consistent with WHO recommendations. Pyramax should only be used at controlled sites where a patient's liver function can be systematically monitored and where exhaustive collection of adverse events as well as reliable information on resistance can be ensured.

The development program for Pyramax was a joint development program between Shin-Poong Pharmaceuticals and Medicines for Malaria Venture, a not-for-profit foundation dedicated to drug development of treatments for malaria. The clinical trials were conducted in Africa and Asia in adults and in children weighing 20 kg or more.

The applicant has agreed to further investigate possible mechanisms of liver toxicity and to perform repeated dosing studies to determine the full scope of liver toxicity of Pyramax and the safety of repeated treatment courses in endemic areas. These data will allow the CHMP to consider whether the current recommendations can be altered.

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected mosquitoes, and affects mainly young children and pregnant women. The WHO estimates that in 2010, there were 216 million cases of malaria with some 655 000 deaths.

Approximately half of the world's population is at risk of malaria. Most malaria cases and deaths occur in sub-Saharan Africa. However, Asia, Latin America and to a lesser extent the Middle East and parts of Europe are also affected. In 2010, malaria was present in 106 countries and territories.

P. falciparum, the parasite causing the most lethal type of human malaria, has become resistant to many conventional treatments in most parts of the world. Artemisinin derivatives, including artesunate, are widely used anti-malarial drugs, clearing parasites rapidly. Resistant strains of *P. falciparum* might develop if artemisinin derivatives are used alone. In order to prevent the occurrence of drug resistance to artemisinins and to address the issue of its relatively short half-life, artemisinins are recommended by the WHO to be given in combination with another anti-malarial agent with a longer half-life. In the case of Pyramax the artemisin derivative has been combined with pyronaridine.

In January 2011, the WHO released the Global Plan for Artemisinin Resistance Containment to deal with the threat of artemisinin resistance, with the objective of protecting artemisinin-based combination therapies as an effective treatment for *P. falciparum* malaria by defining priorities for the containment and prevention of artemisinin resistance.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A summary of the opinion of the CHMP is available on the Agency's website.
3. The scientific assessment of the CHMP will be published within 2 to 3 months after adoption of the scientific opinion as part of the European public assessment report on a scientific opinion in cooperation with WHO and will be available on the Agency's website.
4. Regulatory and procedural guidance on Article 58 applications can be found on the Agency's website:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000157.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240d1
5. Opinions on medicines for use outside the European Union can be found on the Agency's website:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000312.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d12c
6. More information about the WHO's fight against malaria is available here:
<http://www.who.int/topics/malaria/en/>
7. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu