

MALARIA



ASAQ and ASMQ, the two antimalarial treatments developed by DNDi and partners.

› **ASAQ and ASMQ**, fixed-dose combinations of artesunate (AS) with amodiaquine (AQ) or mefloquine (MQ), were the first projects to be undertaken by DNDi; their development was based on WHO recommendations for artemisinin-combination therapies to treat malaria in 2001. Their development was overseen by the Fixed-Dose Combination Therapy (FACT) Consortium, formed in 2002, with the aim of developing field-adapted formulations that would be easy to administer to all age/weight categories of patients, but particularly infants and young children, and which were able to withstand tropical conditions.

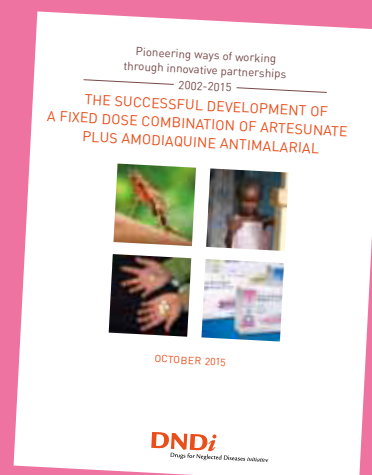
ASAQ-Winthrop®, a generic fixed-dose combination (FDC) of ASAQ, was the first product launched by DNDi in 2007 and was followed by ASMQ FDC the following year. Both feature on the WHO Essential Medicines Lists for adults and children.

The malaria projects were formally handed over to Medicines for Malaria Venture in May 2015, who will continue to implement these treatments in the field. Sanofi produces the generic ASAQ-Winthrop® in Morocco, and a commercial version, Coarsucam™. DNDi is finalizing the technology transfer of ASAQ-Winthrop® to a second manufacturer based in Tanzania, Zenufa, and an application for WHO prequalification will be submitted in 2016. Cipla Ltd., in India, manufactures prequalified

ASMQ FDC, following a successful technology transfer from the Brazilian manufacturer Farmanguinhos/Fiocruz. The shelf-life under tropical conditions for both products was extended from two to three years in March 2016.

By the end of 2015, more than 437 million treatments of ASAQ FDC produced by Sanofi had been distributed, and over 900,000 treatments of ASMQ FDC.

An innovative approach for the successful development of patient-adapted treatments



In 2016 DNDi published an analysis of the lessons learned during the development of ASAQ FDC. The development of ASAQ FDC was characterized by innovation in its development approach (with public and private partners), formulation development, partnership with a major pharmaceutical company, implementation strategy, Risk Management Plan, and choice of a regulatory strategy.

The document reviews the development of ASAQ FDC, and forms part of a broader reflection on DNDi's business model and the lessons learned over a decade since its creation in 2003.

1. www.dndi.org/ASAQreport