



PQP
QUALITY MEDICINES FOR EVERYONE

PREQUALIFICATION OF
MEDICINES PROGRAMME
A UNITED NATIONS PROGRAMME
MANAGED BY WHO



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Acceptance of non-plant-derived-artemisinin offers potential to increase access to malaria treatment

The WHO Prequalification of Medicines Programme (PQP) is pleased to announce the acceptability of the first source of non-plant-derived-artemisinin, manufactured by Sanofi, for use in the manufacture of active pharmaceutical ingredients or finished pharmaceutical products submitted to WHO for prequalification, or that have already been WHO prequalified.

Artemisinin is the key chemical compound used to prepare several active pharmaceutical ingredients (APIs), including artemether, artesunate and dihydroartemisinin, that exhibit antimalarial properties and that are used to manufacture artemisinin-based combination therapies (ACTs), which are the WHO-recommended treatment for uncomplicated malaria caused by the parasite *Plasmodium falciparum*.

Until recently artemisinin has been obtainable only by extraction from the plant *Artemisia annua*, also known as sweet wormwood plant, or “qinghao”. Recent biosynthetic developments now enable artemisinin to be obtained by synthetic or semi-synthetic means. The availability of non-plant-derived-artemisinin offers the potential for important advances in the treatment of malaria since it means that seasonal production of artemisinin no longer limits the production of ACTs. But as with all pharmaceutical products, quality must be assured. The challenge presented by non-plant-derived-artemisinin is to ensure that such material is comparable to plant-derived-artemisinin, rather than to assess the acceptability of non-plant-derived-artemisinin as an API per se. Recognizing the importance of this substance to achieving public health treatment goals, PQP therefore developed a procedure for assessing it, and for its introduction by manufacturers participating in WHO medicines prequalification.¹

PQP assessment of non-plant-derived-artemisinin

In line with the aforementioned procedure, Sanofi submitted a master file to PQP, outlining the preparation, control and stability of its non-plant-derived artemisinin product, together with information demonstrating adherence to good manufacturing practice at its manufacturing facility. This information was assessed and found to be acceptable.

Procedure for FPP or API manufacturers wishing to use non-plant-derived artemisinin

FPP manufacturers whose antimalarial product was prequalified using API information submitted through the “full dossier route”, and who now wish to use this new API source, should submit a variation to their prequalified FPP to PQP.

http://www.who.int/prequal/info_applicants/info_for_applicants_variation-clarification.htm

¹ http://www.who.int/prequal/info_general/documents/guidelines/procedure_non-plant-artemisinin.pdf



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API manufacturers who are already participating in the APIMF procedure, or who maintain a prequalified artesunate, artemether or dihydroartemisinin API, and who now wish to use this new source of artemisinin, should submit an amendment to PQP.

http://www.who.int/prequal/info_applicants/API_amendment.htm

Potential treatment advances

An estimated 219 million cases of malaria occur around the world each and cause 660,000 deaths, mostly in children under five years of age. But the availability of semi-synthetic artemisinin could help make quality-assured malaria treatment more affordable, enabling more patients to be treated.

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