

QUESTIONS AND ANSWERS
WHO GLOBAL MALARIA PROGRAMME
March 9, 2009, launch of WHO guidelines:

I “Guidelines for the Treatment of Malaria” - Second Edition

II “Good procurement practices for artemisinin-based antimalarial medicines”

1. WHO now recommends parasitological diagnosis prior to treatment for everyone

a. *Are there good diagnostic tests that can be used widely in any situation in a country, including in remote areas?*

Yes, there are two primary diagnostic tools for malaria. One is conventional microscopy which can only be used in health institutions. The other newer tests are rapid diagnostic tests which can be used even outside health facilities in the field, by a person who is trained to use them.

b. *Is the performance of the currently available diagnostic tests good enough to make this a safe practice?*

Yes, there is evidence that when quality assured rapid diagnostic tests are used correctly, or when quality assured microscopy services are deployed, the risks of a false negative test are low, and benefits of basing treatment on a confirmatory diagnosis exceed the risks.

c. *How can countries be sure that the rapid diagnostic tests that they are procuring meet the required quality standards?*

WHO together with other partner organizations evaluates the performance of rapid diagnostic tests submitted by manufacturers, and issues a yearly report ranking their performance. WHO also provides a service whereby countries can send a sample of the tests they purchase for "lot quality assurance" to regional centers, so that batches of tests can be tested prior to their use.

d. *What is being done to help countries improve their malaria diagnostic services?*

WHO has provided guidelines on malaria case management, and a framework for establishing a diagnostic service. WHO is now developing and will shortly provide an operational manual on malaria diagnosis which countries could use to set up and run an effective and good quality diagnostic service.

e. *In situations where a parasitological diagnosis is not possible, what should be the procedure for managing the patient?*

The patient should be treated without delay based on clinical grounds if a diagnostic test is not available. However, WHO urges all countries to improve malaria diagnostic services to enable all patients to have a confirmatory diagnosis prior to treatment.

f. *Will RDTs add to the cost of treating malaria patients?*

On average, the cost of ACTs is higher than the cost of the RDTs. The average cost of ACTs across all age-groups is approximately USD 0.75, while the average cost of RDTs is 0.50 USD. Since the majority of febrile cases are negative for malaria, then the overall cost of testing all suspected malaria cases and treating only the positive ones may be lower than the costs of treating all suspected malaria cases in many settings. However the benefit of parasitological confirmation of malaria diagnosis is not only related to economic cost-savings, but also in providing health workers with the tool that allows them to recognize promptly the majority of patients who have non-malaria febrile illnesses.

2. What is the process by which antimalarial medicines are reviewed for recommendation by WHO?

The process of review of new medicines requires several steps: 1) completion of regulatory dossier by the manufacturer, and its review by national regulatory authorities; 2) approval of marketing authorization by national health authorities (most antimalarial medicines reach this status); 3) review by WHO of clinical efficacy and safety to select medicines relevant to public health and their inclusion in the WHO Guidelines for the Treatment of Malaria and the Model List of Essential Medicines;

The subsequent development of national treatment guidelines and list of essential medicines lists by national authorities in order to select medicines for public sector use is generally based on WHO recommendations.

3. A new ACT has been introduced to the recommended list of medicines for the treatment of malaria. Is this medicine available to countries now, and should countries replace the ACTs they are currently using with this one?

The new combination medicine dihydroartemisinin-piperaquine is being manufactured and available, but none of the available products have yet been granted the pre-qualification status, which is a quality approval seal established by WHO. The companies that manufacture this medicine are therefore currently working on their products to meet the required standards of manufacture for prequalification, or any other stringent regulatory authority approval. Countries do not need to change the medicines which are currently being used unless their efficacy has decreased to below 90%. They should routinely monitor the efficacy of the medicines being used, according to standard procedures stipulated by WHO, and change to a more effective medicine only when the efficacy of the current medicines in use have dropped.

4. Why are some ACTs already available in the market but are not included in the WHO Guidelines?

There is an increasing number of malaria medicines produced by manufacturers and available in the market, for which there are insufficient data to evaluate safety or efficacy. For this reason, WHO strongly urges patients and doctors to use one of the five ACTs recommended in the WHO guidelines. The WHO Guidelines for the Treatment of Malaria look at the safety and efficacy of the pharmacologically active chemical ingredients in the medicines. Medicines are only included once they have been clinically tested and are found to be safe and efficacious. Medicines which are not recommended by WHO can contribute to the increase of resistance to artemisinin derivatives and can damage the health of the patient.

5. Are all antimalarial medicines recommended in the new guidelines pre-qualified by WHO?

No, they are not. Once an ACT appears in the WHO Treatment Guidelines then manufacturers of such compounds can apply for WHO prequalification. Once they are prequalified, they will be published on the WHO website. <http://apps.who.int/prequal/>. This means that ACTs available in different markets do not necessarily meet WHO standards for quality, safety and efficacy.