



PQP  
QUALITY MEDICINES FOR EVERYONE

PREQUALIFICATION OF  
MEDICINES PROGRAMME  
A UNITED NATIONS PROGRAMME  
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## WHO INITIATES PILOT PREQUALIFICATION OF ACTIVE PHARMACEUTICAL INGREDIENTS

The WHO Prequalification of Medicines Programme (PQP) will pilot prequalification of selected active pharmaceutical ingredients (APIs) for products for treating HIV and related diseases, for antimalarial medicinal products and for anti-tuberculosis products, as of 21 October 2010. Its 1st Invitation to Manufacturers of Active Pharmaceutical Ingredients to Submit an Expression of Interest (EOI) for Evaluation is available at <http://www.who.int/prequal/>

Globalization of pharmaceutical production has led to diversification of API sources and made verification of API quality more difficult. WHO's decision to start prequalification of APIs responds to concern increasingly expressed by medicines regulators regarding API quality, especially with respect to non-compliance with Good Manufacturing Practices (GMP).

WHO PQP already assesses API master files (APIMFs) as part of its evaluation of finished pharmaceutical products (FPPs). This can include inspection of the manufacturing site(s) to assess compliance with WHO GMP, if risk assessment indicates that on-site inspection is necessary. An API submitted for evaluation will generally undergo both dossier assessment and inspection of the manufacturing site.

Each prequalified API — including details of the supplier and manufacturing site(s) — will be added to the WHO List of Prequalified Active Pharmaceutical Ingredients. The List will be of great interest to FPP manufacturers seeking to ensure the good quality of APIs used in their FPP production, and to national medicines regulatory authorities who wish to verify the standard of APIs that have been used to manufacture nationally registered medicines or medicines for which an application for registration has been received.

It is expected that time taken to reach prequalification will be shorter for FPPs that are manufactured using WHO-prequalified APIs, than for FPPs that are manufactured using APIs that have not previously been evaluated by WHO PQP.



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An APIMF that has already been accepted by WHO in relation to the prequalification of an FPP may be included in the WHO List of Prequalified APIs without reassessment or re-inspection. This is contingent upon the APIMF meeting certain administrative criteria and the relevant manufacturing site(s) having passed inspection by WHO or a stringent regulatory authority.

Selection of APIs for inclusion in the 1st Invitation was based on APIs for which APIMFs have already been submitted in connection with evaluation of an FPP. WHO PQP anticipates that future Invitations will be expanded to incorporate additional APIs. New Invitations will be posted on the PQP web site and manufacturers are therefore encouraged to consult it regularly.

*Further information: Anthony Gould, Programme Manager, WHO Prequalification of Medicines Programme. Tel: +41 22 791 29 53. Email: [goulda@who.int](mailto:goulda@who.int)*