3rd Invitation to Quality Control Laboratories (QCLs) to Submit an Expression of Interest for Prequalification to the WHO Prequalification Team: medicines

(September 2007 – amended June 2011)

In the context of increasing access to quality control laboratories that meet recommended international standards for testing of medicines, WHO, together with UNICEF, UNAIDS, UNFPA, UNITAID and with the support of the World Bank, invite **quality control laboratories which are committed to providing a service of testing of products used in the treatment of hepatitis B and C, HIV/AIDS, malaria, neglected tropical diseases and tuberculosis, and in reproductive health, to UN agencies** to submit an Expression of Interest (EOI) for WHO prequalification.

The first and second invitations for EOIs for quality control laboratories were published in 2004 and were limited to quality control laboratories in Africa.

Basis for this invitation

This invitation is published in accordance with the *Procedure for Assessing the Acceptability, in Principle, of Quality Control Laboratories for Use by United Nations Agencies*, adopted in 2003 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, first published in 2004 (WHO Technical Report Series, No. 917, Annex 4), and amended subsequently in 2007 and 2010. The current version is published as Annex 1 to the 45th report of the Committee (No. 961 of the WHO Technical Report Series, 2011).

Quality control laboratories included in the 3rd invitation for EOI

The aim of this 3rd invitation for EOI is to promote testing of pharmaceutical products internationally by quality control laboratories which meet WHO recommended standards and to increase the range of quality control laboratories for which the acceptability for use by United Nations agencies has been proven.

Participation in the prequalification procedure is voluntary. This invitation is not limited to quality control laboratories from a specific region, however, WHO reserves the right to prioritize the assessment of:

- National quality control laboratories or those laboratories which provide testing services to the government in the respective country, and
- Quality control laboratories in areas where UN agencies identify the need for quality testing.

Scope of the procedure

The Prequalification of Quality Control Laboratories procedure relates to chemical and microbiological testing (including bacterial endotoxins test) of medicines. It does not relate to medical devices, cosmetics or food, as well as immunological, pharmacological and toxicological tests.

How to submit an EOI

Quality control laboratories interested in being assessed under the prequalification procedure should provide WHO with:

1. **A letter** expressing interest in participating in WHO prequalification and confirming that the submitted information is complete and correct.
2. **Information on the laboratory and the services offered**, compiled according to the Guidelines for preparing the laboratory information file. If the laboratory has documented its quality system as a quality manual this can be submitted, provided that it is supplemented with the information required for the Laboratory Information File that is not provided in the Quality Manual.

All of the above-mentioned information should be submitted in English. Submissions that are not made in English must be accompanied by a certified English translation.

The letter and the required information should be sent to the following address:

Mr Rutendo Kuwana
World Health Organization
HIS/EMP/RHT/PQT
WHO Prequalification Team: medicines (PQT)
20 Avenue Appia
1211 Geneva 27
Switzerland
E-mail: prequallaboratories@who.int

Assessment procedure following submission of an EOI by a quality control laboratory

The procedure established by WHO for assessment of quality control laboratories which expressed their interest includes:

- Evaluation of the information submitted by a laboratory and assessment of its readiness for the inspection, and
- On-site inspection of a laboratory to assess the compliance with the guidelines Good Practices for Pharmaceutical Quality Control Laboratories and Good Manufacturing Practices as recommended by WHO for such laboratories.

If assessment demonstrates that a laboratory meets WHO recommended standards, it will be included in the WHO List of Prequalified Quality Control Laboratories that are considered to be acceptable for use by United Nations agencies as well as the others.

Re-evaluation and monitoring of complaints

Once a laboratory is included in the WHO List of Prequalified Quality Control Laboratories, ongoing monitoring of its activities will be performed including re-inspections at regular intervals (at least once every three years), evaluation of results from participation in an appropriate proficiency testing scheme, and monitoring and investigation of complaints concerning the results of analysis or service provided by the listed laboratories. Each prequalified laboratory is requested to submit a brief annual report on its activities related to quality control of medicines within a calendar year. WHO may suspend or withdraw a prequalified quality control laboratory from the List of prequalified quality control laboratories when there is evidence of non-compliance with the WHO recommended quality standards for such laboratories and/or this procedure.

For further information on WHO medicines prequalification, please visit: http://www.who.int/prequal. If you have any questions relating to the procedure or responding to this invitation, please write to prequallaboratories@who.int