

WHO's QUALITY CONTROL LABORATORY SCHEME

Quality of medicines is a major public health challenge,

particularly in light of the cross-border health-related issues and the international dimensions of trade. Quality assurance is a wide-ranging concept that helps to ensure that quality medicines reach the patient; it covers all matters that individually or collectively influence the quality of a product. Quality control (QC) has traditionally been one of the key elements in quality assurance and therefore pharmaceutical QC laboratories play a major role in protecting patients.

QC testing is complex, and errors are costly and may jeopardize patient safety. Patients may receive ineffective or even harmful medicines; if genuine quality deficiencies are not identified, conversely, if non-conforming results are falsely interpreted as quality failures, expensive medicines may be returned or destroyed, potentially leaving patients without life-saving treatment until the products are replaced at sometimes enormous additional cost. Given these high stakes, trust in a QC laboratory's capabilities is essential for all stakeholders who request its services.

WHO is pleased to announce Phase 11 of its External Quality Assurance Assessment Scheme (EQAAS) at preferential fees far below cost for participants from lower- and middle-income countries.



In order to enhance the efficiency and save costs, for each shipment two or three different studies will be carried out. Fees are based on the [World Bank classification of income](#).



The cost per shipment for these three studies is as follows:

Laboratories from low-income countries	US\$ 1000
Laboratories from lower and upper middle-income countries	US\$ 2000
Laboratories from high-income countries	US\$ 4000

The fee covers shipment of the test samples together with the study protocols and the subsequent statistical evaluation of the submitted results. WHO informs the laboratories about their performance and provides additional guidance for improving their capabilities. The scheme is set out in close cooperation with related WHO programmes, including the programme dealing with the prequalification of QC laboratories.

International donors may be approached for funding of participation in the EQAAS. The Global Fund to Fight AIDS, Tuberculosis and Malaria encourages grant applicants to include this item in their applications for funding. The Global Fund requires grant recipients to arrange for systematic random QC testing of products throughout the in-country supply chain for medicines. Every year, approximately half of the Global Fund's investments – about US\$2 billion – is used to procure key medicines and health products. It also funds large quantities of laboratory equipment and reagents. Other donors have similar policies.

WHO invites laboratories to participate in EQAAS Phase 11 studies. To ensure continued assistance to laboratories in Member States, WHO will offer advice on possible funding sources through WHO country projects for laboratories in developing countries that have no means to recuperate the fee, and for whom the fee presents an obstacle for participation.

WHO at present offers the only global, independent scheme to measure laboratories' QC testing capabilities. The EQAAS was established by WHO in 2000 at the request of the Global Fund as a mechanism to maximize health benefits achieved on grant investments in pharmaceuticals and laboratory supplies. The EQAAS has proven to be a major asset to WHO Member States. Laboratories across WHO's six regions have participated in the past comparative external assessment studies and more than 1100 studies involving 36 different tests were carried out. Participation in such studies is mandatory according to [WHO's good practices for pharmaceutical quality control laboratories](#) and for ISO 17025 accreditation.



For more information and expression of interest to participate in this new phase in WHO's QC laboratory scheme, please contact WHO at the following email: EQAAS@who.int

