PQM technical support for prequalification of medicines

The Programme for Promoting the Quality of Medicines (PQM) is funded by the US Agency for International Development (USAID) and implemented by the US Pharmacopeial Convention (USP). Its aim is to increase the availability of affordable, high-quality medicines to treat patients worldwide suffering from multidrug-resistant tuberculosis by providing technical assistance at no cost to manufacturers. The initiative has yielded its first antituberculosis medicine, cycloserine, 250 mg capsule, which has now achieved prequalification status from the World Health Organization (WHO).

The WHO Prequalification of Medicines Programme (PQP) evaluates and assures the quality of medicines bought by international aid programmes. This improves treatment results in developing countries and beyond. Given the policy of many organizations and agencies that only medicines prequalified by WHO or approved by a stringent regulatory authority are suitable for procurement, the increase in demand for prequalified products has stretched WHO’s resources.

To address this resource gap, the PQM programme — which also works to combat substandard and counterfeit medicines in developing countries and increase the supply of quality-assured medicines — offers technical assistance by providing support to interested manufacturers to achieve prequalification.

PQM may provide assistance during preparation of product dossiers for submission to PQP by guiding manufacturers toward compliance with WHO good manufacturing practices or by addressing WHO comments on manufacturer submissions. Assistance is particularly focused on «second-line» antituberculosis medicines used for multidrug-resistant tuberculosis. This form of tuberculosis is more difficult and lengthy to manage — often requiring up to two years of treatment. Poor-quality medicines can lead to drug resistance and undermine desired treatment outcomes.

By expediting the process of prequalification with WHO, PQM is able to expand the pool of viable manufacturers and, in turn, increase the supply of quality-assured medicines. Ultimately, these medicines can help prevent unnecessary patient deaths, particularly among vulnerable populations including many women and children.

In its efforts to improve access to quality-assured medicines, the PQM technical assistance programme also supports the Global Drug Facility (GDF) — a pooled procurement system for antituberculosis medicines operated by WHO. PQM, in collaboration with GDF, USAID and WHO, identify promising manufacturers who may then receive PQM technical assistance.

PQM offers technical assistance for twelve types of medications to treat multidrug-resistant tuberculosis. PQM is currently working with approximately twenty manufacturers of finished products or active pharmaceutical ingredients from around the world to prepare products for prequalification. Some of these manufacturers produce multiple second-line tuberculosis medicines.

Through a series of workshops held in conjunction with WHO and GDF, PQM has been reaching out to manufacturers in regions of the world with a high burden of tuberculosis or where manufacturers are working to improve their manufacturing practices.