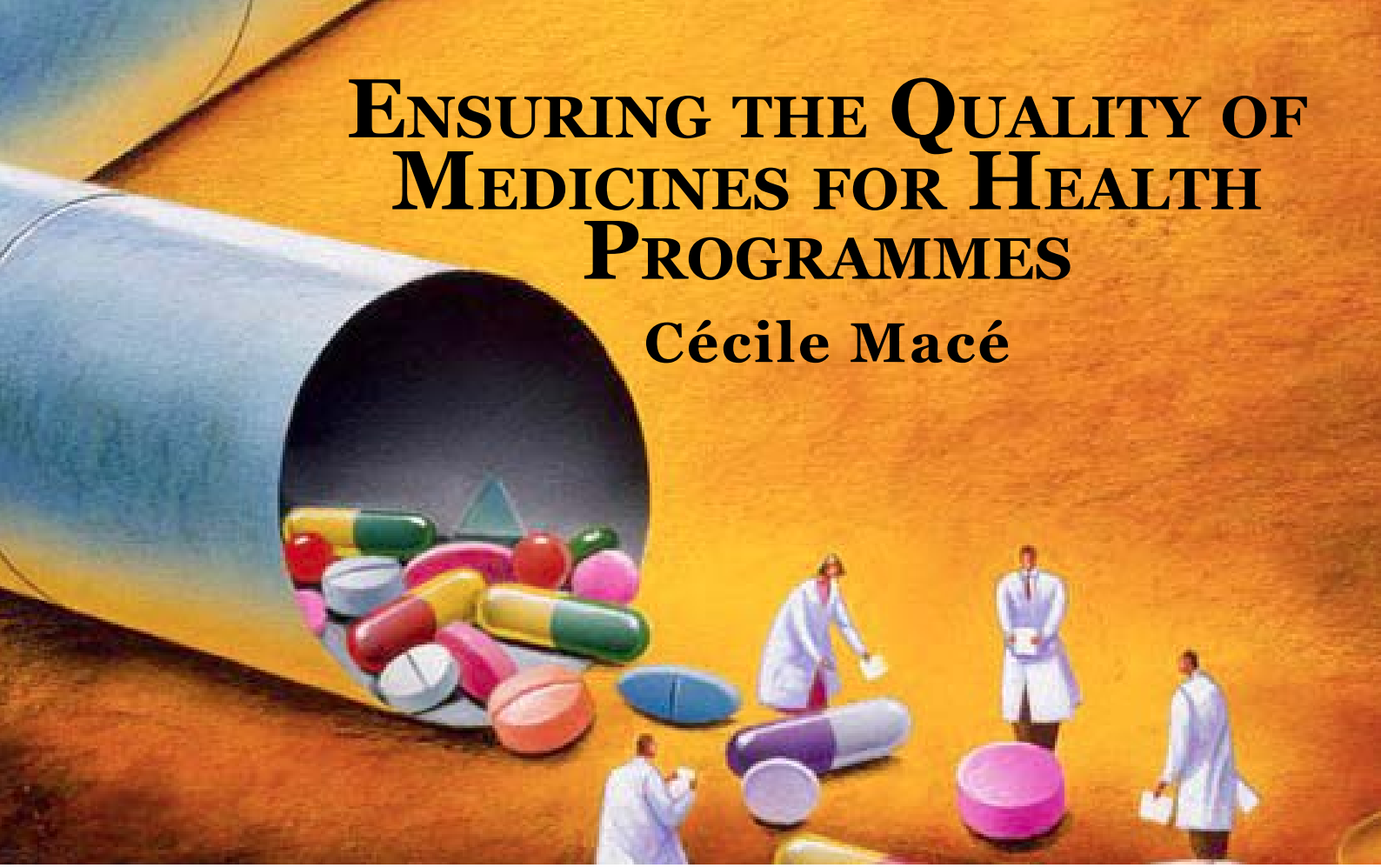
Ensuring the Quality of Medicines for Health Programmes

Cécile Macé



People all around the world deserve to have access to quality-assured medicines. However, the globalisation of the pharmaceutical market and the safeguards designed to protect patients are at times insufficient and increase the risk of having sub-standard medicines available. Typically, the National Pharmaceutical Regulatory Authorities (NRAs) are responsible for guaranteeing the quality, efficacy, and safety of products produced, sold, and/or distributed in a given country, but, according to a World Health Organization (WHO) survey, less than one-third of developing countries have an effective national regulatory system for medicines. Low-income countries often lack the human capacity and resources needed to assess the quality of medicines that are bought and sold in their countries. For this reason_,

professional skills are required on the part of health managers to procure medicines of acceptable quality.

Many health managers believe that the analysis of samples by a quality-control laboratory is enough to guarantee the quality of a medicine. Regrettably, this is not true. Quality must be built into the product – the laboratory testing of a few samples does not guarantee the quality of a product. Fortunately, there are currently tools available to help health managers select quality-assured medicines in the global market.

The Model Quality Assurance System for Procurement Agencies developed by the WHO is a key reference for any organisation dealing with procurement of medicines. This tool can also be used when assessing a procurement agency used as sub-contractor by a health programme.

The WHO Prequalification Programme. This programme assesses the quality of medicines according to WHO norms and standards. It publishes on a regular basis all products that are found compliant with WHO standards based on inspections of the manufacturing sites and an assessment of product dossiers. When procuring medicines, programmes using this list need to make sure that the products supplied are compliant with the prequalified product (based on the specifications available on the WHO website, the reference number, and a written

agreement from the manufacturer).

The Global Fund List of A, B, and ERP-Reviewed Products. In addition to WHO prequalified products, the Global Fund provides a list of medicines that have been approved and classified in three categories, and describes the basis of a medicine's approval. Category A includes medicines approved by the WHO Prequalification Programme. Category B lists medicines that have been approved by stringent NRAs. The ERP Category refers to medicines that were approved by an Expert Review Panel (ERP) for a temporary period when there are not enough products approved under category A or B.

Since the above references don't cover all essential medicines necessary at the country level, The Union strongly recommends that national programmes work closely with pharmacists from National Procurement Centers and NRAs to procure the medicines they need. In cases where information is not readily available, health managers are advised to develop their own quality criteria according to national/WHO standards or to select procurement agents having a quality assurance system compliant with the WHO's standards.

Cécile Macé (cmace@theunion.org) is a pharmacist with The Union providing technical assistance to national tuberculosis programmes.