The Medicines Quality Database: a free public resource

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The availability of poor quality medicines – i.e. medicinal products that are substandard, spurious, falsely labelled, falsified or counterfeit, as defined by the World Health Organization (WHO) – has become an issue of public health concern. Such medicines can jeopardize patient safety, lead to treatment failure and to the development of drug resistance[1,2] and represent a waste of financial resources.[3]

The problem of poor quality medicines is particularly widespread and potentially more devastating in low-income countries.[4–7] It is therefore extremely important to strengthen such countries' capacity for quality assurance (QA) and quality control (QC) of medicines. However, many low-income countries lack the resources to develop appropriate regulatory frameworks and the necessary QA and QC systems.[7]

In addition to good QC, public, transparent access to reliable state, regional and global data on the quality of medicines is also a necessity.[8] To fulfil this need, in 2011 the Promoting the Quality of Medicines (PQM) programme – funded by the United States Agency for International Development (USAID) and implemented by the United States Pharmacopeial Convention (USP) – introduced the Medicines Quality Database (MQDB). The public and freely accessible online tool that tracks medicines tested for quality in selected countries in Africa, Latin America and south-eastern Asia is available at: http://www.usp.org/around-world/pqm-usp-usaid/medicines-quality-database-mqdb

A unique feature of the MQDB is that the protocols used to gather data for the sampling and analysis of the medicines follow standard guidelines.[9–11] This makes the data comparable across countries and enhances their technical quality, validity and reliability. In addition, all records are thoroughly evaluated by PQM staff for completeness and accuracy before being included in the MQDB. Only one individual is authorized to input data. MQDB data, which are updated approximately twice a year, are meant to be shared among national regulatory authorities, manufacturers, international health and development agencies, nongovernmental organizations, academics, researchers and programmes involved in the procurement and management of medicines. Most of the medicines in the MQDB are listed in the WHO Model List of Essential Medicines, are relevant to national health programmes in countries receiving USAID assistance and are used to treat endemic diseases, such as malaria and tuberculosis.

The medicines are collected from outlets in the public, private and informal sectors (i.e. unlicensed facilities). They are monitored following standardized procedures or undergo testing either in the country's official medicine control laboratory (OMCL) or in other accredited laboratories.[12]

Currently, the MQDB contains over 13 000 records of medicines collected and tested from 12 countries: Cambodia, Colombia, Ecuador, Ghana, Guyana, Kenya, the Lao People's Democratic Republic, Mozambique, Peru, the Philippines, Thailand and Viet Nam. The relevant authorities of the participating countries reviewed the accuracy of the data and approved its inclusion in the MQDB, which can be searched by geographical location (region, country, province); year of sampling; facility from which samples were collected, organized by facility sector (public, private, informal) and type (pharmacy, hospital, clinic); medicine information (product name; manufacturer's name; therapeutic indication; active pharmaceutical ingredient; dosage form; lot number); quality test results (pass, fail); and counterfeit status (yes or no), which depends on the legal definition of each country. Not all medicines collected and screened in the initial field testing, particularly those that passed the quality test, were sent for confirmatory analysis at a country's OMCL. The search tool allows the user to generate various reports on the medicines collected and their quality.

Some aspects of the MQDB, especially its user functionality and appearance, need to be improved. These issues are being addressed but funding is scarce. There are also plans to add a mapping feature that pinpoints the exact location from which a medicine was collected.

Since its public launch in 2011, the MQDB has been extensively consulted. The stringent data collection process, the standardization of procedures and protocols, and the thorough screening of results generate confidence in the quality of the data and make the tool unique among others of its kind.

By providing free and public access to medicine quality data, the MQDB helps country authorities to act swiftly in conducting investigations and in withdrawing poor quality medicines from the market. ■

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