The Medicines Quality Database (MQDB): Successfully Sharing Information about Poor Quality Medicines for Infectious Diseases in Asian Countries

Abstract #456

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INTRODUCTION

One important means of safeguarding the public from counterfeit and substandard medicines lies in the vigilant oversight of products circulating in the marketplace. Considering that pharmaceutical markets operate globally, it is equally important that information on the quality of medicines be readily available and disseminated widely. Medicines Regulatory Authorities (MRAs), as well as international agencies and programs involved in procuring and managing the medicines supply chain, have limited access to updated and reliable data on medicines quality.

OBJECTIVES

Through systematic screening of the quality of medicines collected from various regions, laboratory testing, and subsequent data analysis, a country can better ensure the quality of its medicines, especially those essential to national health programs treating endemic diseases such as malaria, HIV/AIDS, and tuberculosis.

METHODS

To meet this need, the Promoting the Quality of Medicines program (PQM)—funded by the United States Agency for International Development (USAID) and implemented by the U.S. Pharmacopeial Convention (USP)—created the MQDB, a free, publicly available, online database that contains medicines quality testing results from 17 countries in Africa, Asia, and South America. Unique features of this database include standardization of sampling and analytical procedures, and thorough assessment of the data. More countries will be added to the MQDB in 2014 and 2015.

RESULTS

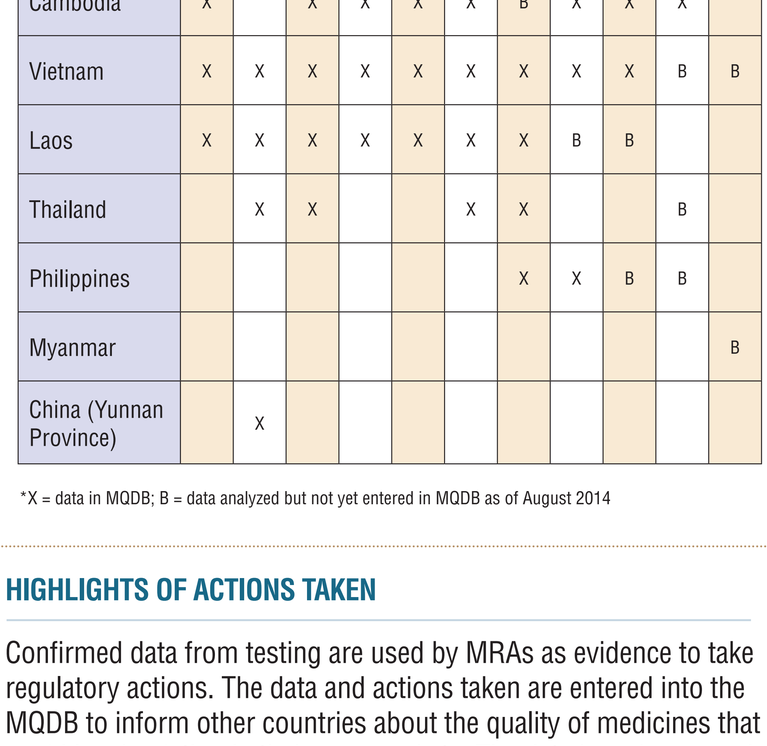
Data in the MQDB include results of samples collected and tested in Asia (2003–2013) from Cambodia, China (Yunnan Province), Laos, Myanmar, Philippines, Thailand, and Vietnam. The information can be used by MRAs to take regulatory actions against violators and by other countries as a reference tool. The information is intended to be shared among MRAs, manufacturers, international health and development agencies, nongovernmental organizations, academics, researchers, and programs involved in the procurement and management of medicines.

CONCLUSIONS

Due to the nature of sample collection in participating countries, where only select anti-infective and analgesic/anti-inflammatory medicines were collected (convenience sampling), a precise estimate of the true prevalence of poor quality and counterfeit medicines circulating in these countries is not possible to obtain. The primary purpose of the MQDB is to offer MRAs and other organizations access to reliable data to help them understand the quality of medicines in their markets and to appropriately respond when poor quality medicines are identified.

PQM continues to work with international and regional agencies to establish mechanisms to alert relevant country partners in a timely manner when poor quality medicines are identified and to include this information in the MQDB.

Total Number of Samples Collected in Asia (2003–2013) by Therapeutic Indication (N = 9,868)

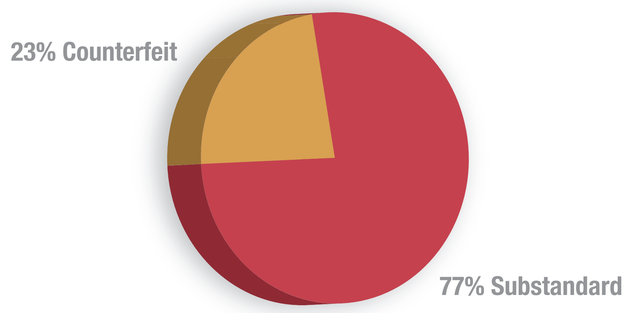


Data Submission per Country by Year*

Country	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Cambodia	X		X	X	X	X	B	X	X	X	
Vietnam	X	X	X	X	X	X	X	X	X	B	B
Laos	X	X	X	X	X	X	X	B	B		
Thailand		X	X			X	X			B	
Philippines							X	X	B	B	
Myanmar											B
China (Yunnan Province)		X									

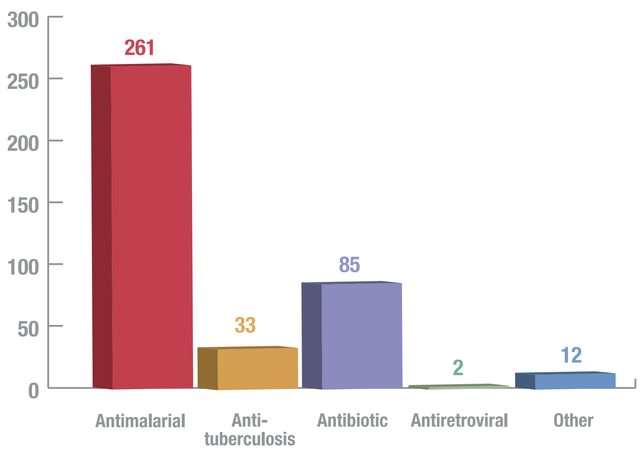
*X = data in MQDB; B = data analyzed but not yet entered in MQDB as of August 2014

Substandard and Counterfeit Medicines[1] Found During Testing 2003–2010* (N = 393)



*As of 2013, no counterfeits have been found in the Greater Mekong Subregion since 2010.
[1]The MQDB classifies medicines as "counterfeit" according to the specific country's legal definition of a counterfeit drug; definitions may differ between counterfeit and substandard medicines in country-specific laws and regulations. See the MQDB website (http://www.usp.org/app/worldwide/medQualityDatabase/) for more information.

Total Number of Samples That Failed Medicines Quality Testing (N = 393)



Out of 261 antimalarials that failed quality testing, 24.5% (64) were counterfeit; out of 85 antibiotics that failed quality testing, 30.6% (36) were counterfeit.

Counterfeit Medicines Found by Year, Country, and Therapeutic Indication

Year	Country	Therapeutic Indication	Total Number
2003	Cambodia	Antimalarial	33
	Laos	Antimalarial	10
2004	Laos	Antimalarial	2
	China	Antimalarial	2
2005	Cambodia	Antimalarial, Antibiotic	3
	Laos	Antimalarial	3
2006	Cambodia	Antimalarial	2
2007	Cambodia	Antibiotic	1
	Laos	Antimalarial	3
2008	Cambodia	Antimalarial	1
	Laos	Antibiotic, Antimalarial	2
	Thailand	Antibiotic	4
2009	Cambodia	Antibiotic, Antimalarial	21*
	Laos	Antimalarial	1
	Thailand	Antimalarial	1
2010	Vietnam	Antimalarial	1
Total 2003–2010			**90**

Of the 90 counterfeits found, 31 were artesunate monotherapy. Despite being banned for the treatment of malaria since 2008, counterfeit monotherapies are still found in many Asian countries.

* Cambodia Ministry of Health carried out a special investigation in 2009 targeting antibiotics suspected to be of poor quality. These data are not yet included in the MQDB.

HIGHLIGHTS OF ACTIONS TAKEN

Confirmed data from testing are used by MRAs as evidence to take regulatory actions. The data and actions taken are entered into the MQDB to inform other countries about the quality of medicines that could be circulating in their own markets. The data have been used in several INTERPOL-WHO-led investigations.

In 2010, the Department of Drugs and Food publicly banned products made by five companies from China and Thailand. Thousands of leaflets and hundreds of posters were distributed throughout the country to raise awareness of poor-quality antimalarial medicines. An Inter-Ministerial task force reduced the number of illegal medicines outlets from 1,420 in 2009 to almost zero by the end of 2011.

The Ministries of Health and Public Security arrested 14 people at one pharmaceutical company who were engaged in repackaging and falsely labeling products to mimic legitimate medicines. The company owner was sentenced to 16 years in prison.

The Food and Drug Department (FDD) issued regulatory notices about counterfeit antimalarial and antibiotic products being sold. Pharmacy owners were educated, warned, and fined according to offenses; remaining stocks were seized and destroyed; and information on products involved were published in newspapers and on the FDD website.

With NGO partners, the governments of Cambodia, Laos, Thailand, and Vietnam developed the "Pharmacide" series of TV and radio ads, a documentary film, and art exhibits warning of the dangers of using counterfeit medicines.