

Call for Action Against Poor-Quality Medicines in Asia

Access to good-quality, essential medicines is a necessity for every country in order to protect the health of its people. In principle, all medicines should be both safe and effective, but recent evidence has shown that this is not always the case. For example, medicines of poor quality appear to be widely available, especially in Asia where between 10-35% of medicines are either improperly made or illegally produced.

Health and economic consequences of poor-quality medicines

Of the poor-quality medicines reported to the World Health Organization between 1982 and 1999, 77% were from developing countries and, in 60% of those cases, an essential medicinal ingredient was missing. Whether altered deliberately or accidentally produced in factories with substandard manufacturing practices, poor-quality medicines are a danger to people's health because they may not cure the disease and they may contain other substances that are toxic. Specific examples of harmful medicines from Asia include:

- In 1992, at least 233 children died in Bangladesh after swallowing a pain reliever which also contained antifreeze.
- Between April and June 1998 in India, 36 children younger than six years of age experienced sudden unexplained kidney failure after taking a locally-manufactured "cough syrup" which was contaminated with diethylene glycol. Thirty-three of these children died.
- In 1999, at least 30 people died in Cambodia after taking sulphadoxine-pyrimethamine (an older, less effective antimalarial drug) which was sold to them as artesunate, a newer and more-effective medicine for treating malaria.

The problems caused by poor-quality medicines extend beyond the borders of Asia since many essential drugs manufactured in Asian countries are exported to Africa and other parts of the world. The financial cost of poor-quality drugs has been estimated to be about US\$ 22 billion per year, or about seven percent of worldwide pharmaceutical sales. The human cost of poor-quality medicines includes loss of work and income due to death, disability, or extended duration of disease.

Diseases most affected

In the U.S. and other countries where the quality of medicines is carefully regulated and regularly monitored, the products most likely to be produced illegally or improperly are painkillers and drugs to treat sexual dysfunction. However, in countries lacking a strong drug regulatory authority, antibiotics and other essential medicines — those most frequently prescribed — are often found to be of poor quality. For example:

- Artesunate is one of the most effective medicines for treating malaria that is resistant to other antimalarial medicines. Due to its effectiveness and relatively high cost, numerous poor-quality products are sold as artesunate. For example, a recent survey reported that 38 percent of products sold as artesunate in five Mekong countries actually contained none of the medicine.
- In a Vietnam hospital, a vial of Fortum (a type of antibiotic) was found with clear signs of previous use. In addition, it contained streptomycin, a low-cost antibiotic which is an ineffective substitute.



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Growing production of poor-quality medicines

The International Pharmaceutical Manufacturers Associations estimate that the illegal exchange of medicines intentionally made to look like good-quality drugs is currently a three to six billion dollar industry that is still growing. The demand for illegally-produced drugs is likely to increase because in many countries the overall demand for medicines is high, national supplies are often insufficient, the cost of making and distributing illegal and poor-quality drugs is low, and the penalties for producing or selling poor-quality drugs are not sufficient to serve as a disincentive. As the cost of newer, good-quality medicines steadily increases, consumers will be more likely to buy less-expensive drugs which may be of poor quality. This is especially true in countries with little or no control of drug production, importing distribution, and sales and where there is little understanding of the health and financial implications of poor-quality medicines.

Detecting poor-quality medicines and improving the use of good-quality medicines

Ensuring access to good quality, essential medicines — especially in the developing world — requires commitment from individual governments, health staff, and consumers. National drug regulatory authorities, responsible for ensuring that medicines meet acceptable standards of quality, safety, and efficacy, can only guarantee the quality of medicines if:

- governments have appropriate laws to ensure the proper production, importation, distribution, and sale of medicines;
- manufacturers use quality starting materials and follow good manufacturing practices;
- importers/distributors procure, store, transport, and distribute medicines according to set standards;
- dispensers follow recognized good dispensing practices; and
- regulatory authorities establish effective drug registration, inspection, and laboratory testing systems and ensure that all regulations are strictly enforced.

The U.S. Agency for International Development supports the U.S. Pharmacopeia Drug Quality and Information (USP DQI) program and other partners in assisting countries with limited resources to address critical drug quality issues. USP DQI experts assess drug quality systems and provide the necessary training, equipment, and technical assistance to help Asian countries meet international standards for drug quality. The urgent need for drug quality assurance — in individual countries and around the world — can only be met by a collaborative effort which includes individual governments, national and regional partnerships, international health organizations, technical partners, and external donors. This collaborative effort can benefit many countries and millions of people, but the magnitude of the impact is ultimately dependent on the quality of the collaboration and the technical and financial resources provided by the partners.

At this point in time, new partners are needed to expand efforts to improve drug quality in Asia. Specific inputs which new partners could provide include:

- technical assistance;
- equipment and related supplies for monitoring drug quality;
- funding.

For more information, visit www.uspdqi.org.