



The Future of Global Health Procurement: Building an Enabling Environment for Quality Generic Competition

CGD Fact Sheet | June 2019

To help build a robust enabling environment for healthy generic competition, international technical bodies and national governments should ease barriers to quality generic entry.

The Status Quo: A Broken Generics Market

Functioning generic markets provide wide access to quality essential medicines at the lowest possible prices. But in many low- and middle-income countries, generic competition breaks down—either because quality generic competitors are unable or unwilling to enter the market, or because consumers cannot trust or accurately evaluate the quality of the products they need.

- **Barriers to entry:** Even for off-patent drugs—the vast majority of the market in low- and middle-income country markets—onerous and costly local registration processes can prevent additional generic companies from entering the market. As a result, these markets are often dominated by a single or a small number of suppliers, which directly affects the prices paid by public procurers and consumers. In some low- and middle-income countries, the largest seller of certain therapy and product classes accounts for upwards of 85 percent of all sales, such as with contraceptives in Senegal, cancer medicines in Kerala, diabetes medicines in Zambia, and antiparasitics in South Africa.
- **Asymmetric information:** In countries with robust regulatory regimes, patients can trust that all drugs on the pharmacy shelf are safe, authentic, and high-quality. This allows many OECD markets to build robust and vibrant generic markets; in countries like the United States and United Kingdom, for example, generics comprise about 85 percent or more of all medicines (by volume). But in the absence of a reliable regulatory regime to ensure

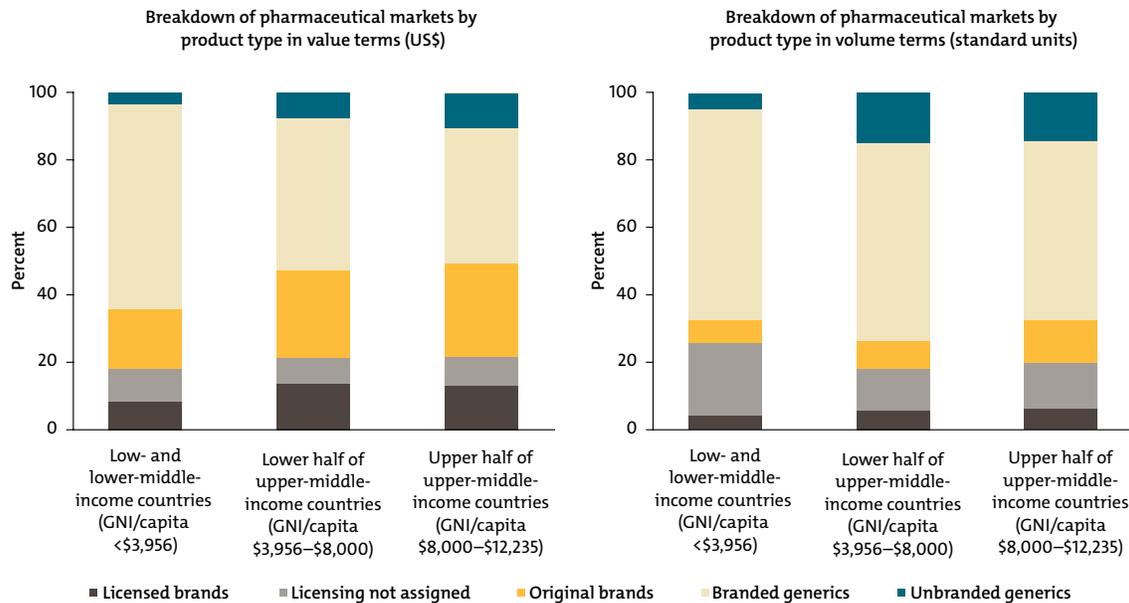
medicine quality—a frequent problem in low- and middle-income countries—patients and health workers cannot trust or independently evaluate medicine quality. This prevents them from making fully informed purchasing decisions between different suppliers and creates a market failure.

When Quality Competition Breaks Down, Purchasers and Patients Pay the Price

Ultimately, public purchasers and patients pay the price for broken generics markets—both with their wallets, and, too often, with their lives.

- **The poorest countries pay high—and highly variable—prices for basic medicines:** In some low- and middle-income countries, purchasers pay as much as *20 to 30 times* a minimum international reference price for basic generic medicines, such as the heartburn treatment drug omeprazole or the common pain reliever paracetamol.
- **Patients pay more for a familiar brand:** When institutional quality control systems break down, patients (and health workers) must rely on alternative “signals” of quality—most often through a familiar and trusted brand name, typically priced at a higher level than its unbranded competitors. In some of the poorest countries, these higher-priced branded generics make up two-thirds of the pharmaceutical market, while unbranded generics represent a tiny sliver—only 5 percent of medicine consumption (by volume; Figure 1).

Figure 1. Health Product Markets in Low- and Middle-Income Countries by Brand and Licensing Status



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- Low-quality, substandard, and fraudulent drugs infiltrate the supply chain:** In countries that have weak regulation and enforcement of quality standards, substandard and falsified medicines, devices, and other health products may enter the market. Estimates suggest the prevalence of substandard and falsified medicines in low- and middle-income countries ranges from 10 to 13.6 percent. Substandard and falsified malaria medications, to take one example, are estimated to cause 116,000 deaths in sub-Saharan Africa each year.

The Way Forward: Easing the Barriers to Quality Generic Competition

By reducing barriers to quality generic entry, international technical bodies and national governments can help build a robust enabling environment for healthy generic competition:

- Expand nascent WHO efforts to align and expedite drug registration:** Country-by-country review of a product dossier is often unnecessarily duplicative and slow. To address this problem, the WHO has set up the Collaborative Registration Procedure (CRP)—a voluntary process that allows national regulatory bodies to receive WHO product assessment data (in lieu of a country-specific dossier) for expedited review. Building on these existing efforts, the WHO should fully fund, expand, and endorse expedited and common registration for prequalified and/or stringent regulatory agency

(SRA)-approved products as the norm in smaller low- and middle-income countries.

- Adapt national laws and regulations to enable expedited registration of quality-assured products:** Following a WHO endorsement, international funders and technical bodies should actively encourage countries to adopt national laws and regulations that enable expedited registration procedures for quality-assured medicines, including through the CRP. This may include easing or removing country-specific labelling requirements.
- Open national tenders to broader competition:** National procurement offices often provide explicit purchasing preferences for locally manufactured products. Though this may be understandable from an industrial policy perspective, countries should carefully consider the downsides of overly restrictive regulations, which can severely limit competition for public tenders and lead to inflated prices; open international bidding would greatly increase the number of bids and increase the likelihood of procurement savings. Procurement offices should also consider allowing quality-assured but unregistered products to compete for public tenders under an expedited registration process.

This factsheet is based on the final report of CGD's Working Group on the Future of Global Health Procurement. The full report, Tackling the Triple Transition in Global Health Procurement, is available at www.cgdev.org/better-health-procurement.