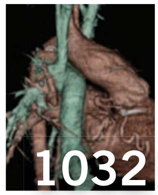
Central processing: Centralized review boards proposed for all multisite US trials

Infectious thinking: European innovation institute expands into biomedicine



Young at heart: First tissue-engineered blood vessels tested in children

Cheap drugs pulled despite wealth gap in middle-income countries

Most pharmaceutical and aid groups base their tiered pricing schemes for drug discounts on average per-capita income levels by country. But the growing wealth of many developing countries is adding a wrinkle to the calculus of which nations get cheap access to essential medicines. Some experts assert that basing prices on average income doesn't work for the growing pool of middle-income countries, where many people are left below the poverty line and are therefore unable to afford medicine despite booms in local industries.

"The poor people in the countries are stuck in the middle," says Prashant Yadav, the director of healthcare delivery research at the University of Michigan's William Davidson Institute in Ann Arbor. "That's where the big problem lies."

According to data from the World Bank, around 70% of the world's poor now live in middle-income countries—defined as those with a gross national income of between $1,006 and $12,275 per capita—up from less than 10% two decades ago. But supporters of cheap drug access are retreating from making their medicines available at subsidized rates in these countries, opting instead to negotiate prices on a country-by-country basis. An 18 July report from Geneva's Médecins Sans Frontières (MSF) notes that in the past year Merck scrapped their discount pricing tier for middle-income economies for HIV drugs, joining Johnson & Johnson and ViiV Healthcare (a partnership between Pfizer and GlaxoSmithKline) in negotiating prices on a per-country basis.

Even well-meaning measures to expand access can miss the mark. The nonprofit GAVI Alliance adjusted its criteria this year for discounted vaccine eligibility, taking countries' economic growth into account. Countries with gross national incomes under $1,500 per capita now qualify for discounted vaccines, up from under $1,000 last year. Despite the effort to be inclusive, however, only the 56 poorest countries in the world were eligible to apply to GAVI for cheap meds this year, compared to 72 in 2004. And, whereas the California drugmaker Gilead Sciences has garnered praise for licensing patents for HIV medications to UNITAID's Medicines Patent Pool for generic distribution on 12 July, the drugmaker's deal excludes a number of middle-income countries from its discounted intellectual property.

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Middle road: Countries such as India have updated patent laws to deal with rising drug prices.

Insurance companies and governments in more developed countries shoulder most of the burden for drug development, leaving some to wonder at what point a country is developed enough to pay its dues. "There's always a fundamental tradeoff between discovering new medicines for future generations and keeping prices low for current drugs," says Darius Lakdawalla, a health economist at the University of Southern California in Los Angeles. "It's a very risky strategy to cut prices paid to pharmaceutical companies, as the impacts on innovation can be significant, with long-lasting consequences."

According to Yadav, countries that reach the middle-income bracket should, at least in theory, have the capital to beef up government-provided health care to help citizens with creeping drug costs. But, in reality, many transitional governments are reluctant to take on that burden, he explains.

Coping mechanisms

Several of the more developed middle-income countries with a few years of price exclusion under their belts have found ways to cope. India and the Philippines have laws that set a high bar for a drug to be considered a 'novel invention', thereby limiting patent approvals. This allows local companies to manufacture generic versions, driving down the drug's price. "Middle-income countries really need to change how they set up their laws in a way which enables local production to come in," says Tahir Amin, co-founder and director of intellectual property at Initiative for Medicines, Access & Knowledge, a New York nonprofit. Additionally, in a national emergency, such as an AIDS epidemic, countries can issue a compulsory license, which forces the suspension of a company's patents—that is, if the drugmaker isn't willing to renegotiate the medicine's price.

But, even though compulsory licenses sound useful in theory, pressure from other governments and companies often thwart their use. "It puts particularly at a disadvantage some of the smaller countries, because they do not have the same negotiating clout," says Michelle Childs, director of policy and advocacy at MSF's Campaign for Access to Essential Medicines.

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