

Your questions answered



We believe everyone deserves the right to access the medicines they need to keep them alive and healthy. The poorest people around the world are often denied this right – why?

Because branded medicines are too expensive and access to affordable generic medicines is

blocked. Our Trading with Lives campaign calls for developing countries to have access to affordable medicines. A country's ability to pay should never be a barrier to its people's right to health.

What are generic medicines?

Usually 'generic' medicines are copies of branded medicines that are no longer protected by a patent. When a pharmaceutical company obtains a patent on a medicine they have the sole right to brand, produce and sell it at a price they choose, which is often high enough to ensure large profit margins, ignoring developing countries' ability to pay for the medicines. This exclusivity lasts the length of a patent, which currently stands at 20 years. Generic versions of branded, patented medicines cannot be produced for the length of this patent term (with the exception of the use of the TRIPS flexibilities as discussed below). Generics contain the same active ingredient as branded medicines and they have to go through the same quality control requirements demanded of the original product.

Why are generic medicines needed?

Generic medicines are needed because branded medicines under patent are very expensive, costing many times more than their generic counterparts. For example, first generation HIV drugs cost around US\$10,000 per patient per year under patent. Generic HIV drugs cost as little as US\$87 per patient per year today. This makes a huge difference, as a

third of the world's population currently lack access to the medicines they need, rising to 50% in parts of Asia and Africa. In developing countries, medicines account for 60-90% of household expenditure on health. It is therefore vital that developing countries have access to medicines they can afford so their people do not die needlessly. Once purchased, medicines should be distributed to the poorest members of society for free. Access to significantly cheaper generic medicines and their free distribution to the poorest will save many lives around the world.

Why are generic medicines hard to access?

Access to affordable generic medicines is vital for the survival of the poorest people around the world, yet these life-saving medicines are not always available. Why?

Trade agreements

TRIPS

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, agreed at the World Trade Organisation in 1994, introduced 20-year patents for medicines. As discussed, patents can block the production and distribution of generic medicines. The TRIPS Agreement includes 'flexibilities' to protect public health, which in theory allow developing countries to import or produce cheaper generic medicines even if they are still patent protected. Such flexibilities are vital because many countries cannot afford to buy expensive branded medicines.

TRIPS flexibilities look good on paper, but in reality developing countries have to overcome significant obstacles in order to access affordable generic medicines for their people. Some pharmaceutical companies have actively sought to disrupt the right of countries to use the flexibilities because increased competition from generics will lead to a loss in their profits - in this way profits are prioritised over saving the lives of the poorest.

The lack of financial and technical expertise to produce generic medicines within developing countries could also block access to affordable medicines. Political will and stability is also needed. Developing countries need to demonstrate a willingness to put in place the required legislation to use the flexibilities and then to use this legislation to access affordable medicines for their people.

Free Trade Agreements

Free Trade Agreements (FTAs), particularly between the US or Europe and developing countries, often contain 'TRIPS-plus standards' that make it even more difficult for a country to implement TRIPS flexibilities and can extend patent terms beyond 20 years. Data exclusivity is an example of a TRIPS-plus standard. This measure demands that only the pharmaceutical company that originally carried out the medical trials for a drug can use their results. So in order for a developing country to produce and register generic versions of branded medicines they have to carry out their own medical trials. This is an unrealistic option for many developing countries as they lack the financial or technical means to do so. Demanding data exclusivity measures within FTAs will block access to life-saving affordable medicines.

The trade in counterfeit medicines

The trade in counterfeit (fake) medicines has flourished because of the cost of branded medicines and the lack of access to affordable generic medicines. A huge demand for cheaper medicines therefore exists. As the TRIPS Agreement and FTAs block affordable generic medicines, cheap fake medicines disguised as the genuine article have filled this gap in the market. Many poor people in desperate need of help will buy them, often from unlicensed, unregulated pharmacies - unwittingly putting their health and lives at risk.

Efforts to combat the trade in counterfeit medicines have led to the seizure of generic medicines, suspected of being counterfeit. Why? Because life-saving real generic medicines could be classified as fake under current, internationally accepted, definitions of 'counterfeit'. We believe 'counterfeit' should mean fake. It is vital that definitions are made more specific so that there is no possibility of real generic medicines being seized along with fakes.

What we are calling for:

- Rich countries and pharmaceutical companies must not pursue a profit-driven agenda within trade agreements by actively seeking to block access to affordable generic medicines to protect their own interests. Profits must not be prioritised over the lives of the poorest people around the world.
- Developing countries need to demonstrate the political will to acquire affordable medicines using the TRIPS flexibilities and if acquired, distribute affordable generic medicines to the poorest for free.
- At the international level, every effort should be made to find consensus on a narrower definition of 'counterfeit', as the continuing use of overly broad definitions will only serve to endanger the lives of the poorest by blocking access to affordable medicines.

Do you want to take action? Then visit:

www.healthpovertyaction.org/campaigns/trading-with-lives

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