Access to and price of medicines globally

Essential medicines are those that satisfy the priority health care needs of the population. Access to essential medicines is a human right. Why do these medicines have a price that makes them unattainable for a large share of the world's population?

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Not all medicines are equally important. The World Health Organisation (WHO) defines essential medicines as those «that satisfy the priority health care needs of the population» (1). It is thought that around 400 different substances will be sufficient for preventing and treating most common ailments and diseases. The WHO's list of essential medicines includes both older substances that are no longer protected by a patent and newer patent-protected medicines.

Access to essential medicines is influenced by four main factors: rational selection, affordable prices, sustainable financing and a reliable health system. Today, the availability in low-income and middle-income countries is hampered by poor medicine supply and distribution systems, an inadequate number of health facilities and lack of health personnel, low level of investment in health care, high medicine prices and a lack of health insurance (1). In this article I will discuss one of the four factors – price.

The pharmaceutical market

The pharmaceutical market is an imperfect market. Such markets are distinguished by the existence of monopolies or oligopolies, where a small number of manufacturers exercise control over supply and prices (2). Factors that contribute to such a market include market exclusivity due to patent or data exclusivity, a limited supply of active ingredients, registration barriers and sellers with strategies for underbidding on price. The information is asymmetric, because the supplier has full access to market information on prices, while the buyer does not. The supplier has thus an obvious advantage during contract negotiations. This is also reflected in some of the new initiatives that have been launched to make essential medicines more accessible (3).

One would think that the price of a medicine would be set based on a desire to ensure that it would be available to anyone in need of the medicine, in other words that there would be some relation between price and the ability to pay. However, that is not the case – quite the opposite in fact. Measures such as equity pricing and differential or tiered pricing have by and large not left the drawing board. Equity pricing entails measures that ensure that the price is considered fair in the eyes of society and the consumers, even for the poor and/or the health system they use. Concepts such as differential pricing and segmentation of the market are often used to describe a practice whereby a different price is charged in different markets. This does, however, not necessarily result in a more affordable price or equal access to a product. They can be viewed instead as commercial terms for a price practice that aims to maximise the seller's profit. This *may* also result in equal access, but it does not necessarily mean that even the lowest price is low enough (4).

In poor countries, medicines are therefore expensive for the majority of the population, both in terms of the absolute price and buying power. And the patients must often pay out of pocket, because there are no insurance schemes. For example, 80 % of the health care expenses in India must be borne by the patients themselves, and medicines account for 60–90 % of these expenses (5). This is despite the fact that medicine prices in India are low compared with many other countries.

Differences between countries

A total of 4.8 billion people live in low-income and middle-income countries, and 2.7 billion of them live on less than USD 2 per day (USD 730 per year). This can be countries in which a majority of the population is poor (39 countries), or middle-income countries where as much as three-fourths of the population may be poor, (6). In comparison, the average consumption of medicines alone in the EU was USD 540 per person annually in 2008 (7). The US ranked the highest of the OECD countries, with USD 897 per person annually. Norway's estimated consumption was USD 381, while Mexico's consumption was the lowest at USD 241 per personal annually.

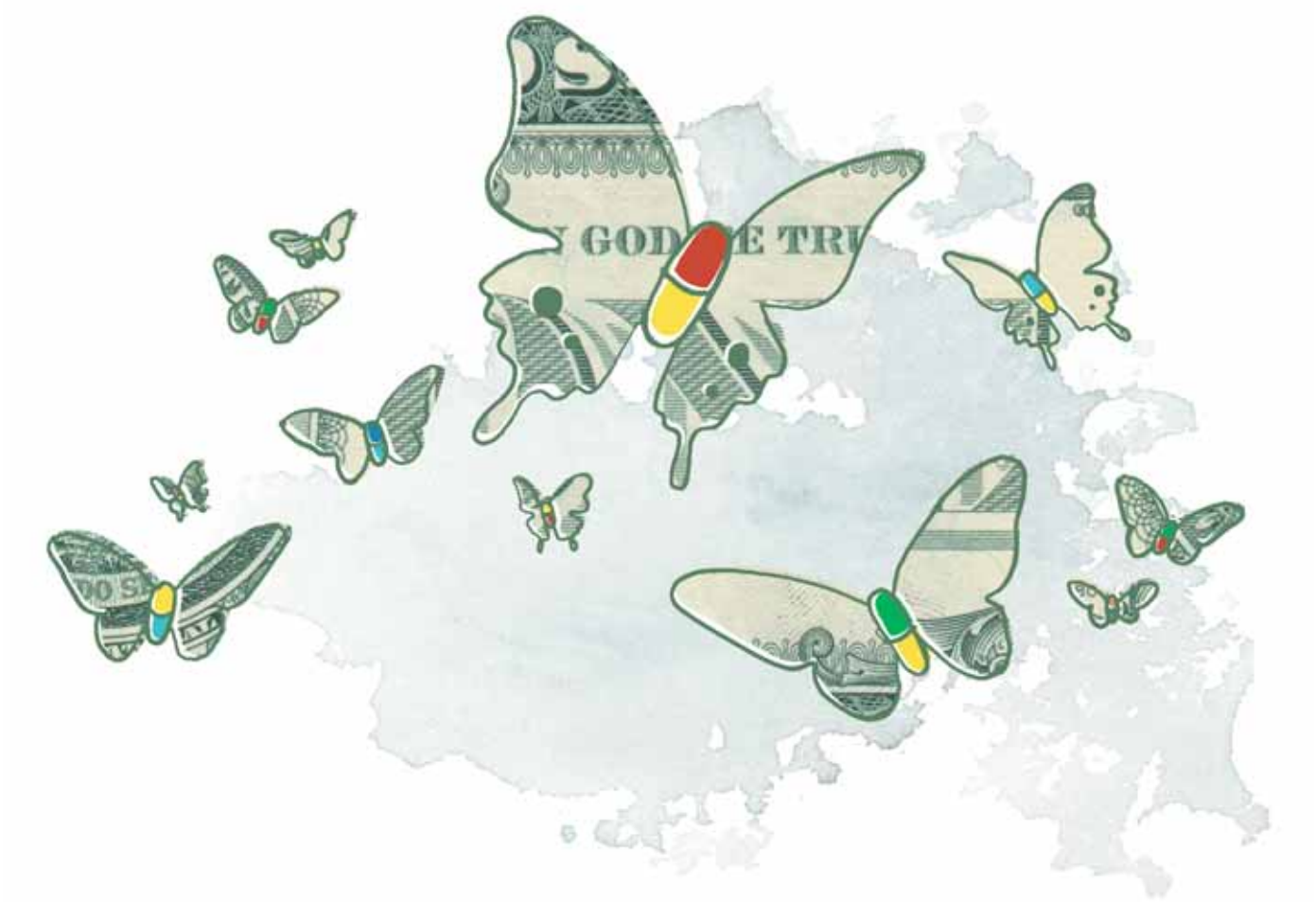
In Norway the National Insurance Scheme covers most of our medicine expenses. In Malawi the lowest paid government worker must work 20 days to pay for one month's treatment with four common medicines for the treatment of cardiovascular disease (8). It is obvious then that such treatment is unattainable. In addition, the lowest paid government worker is better off than most of the population in poor countries, who are farmers or unemployed. In many countries, a seven-day treatment with generic ciprofloxacin can cost at least one day's wages for the lowest paid government worker, and the patented Ciproxin can cost at least ten days' wages (9). In Mali a farmer has to sell two kilos of cotton to pay for a strip of ten paracetamol, which costs 84 cents (10). He has to have paracetamol because the pesticides give him a headache.

Patented products and generics

There are not only large price differences for medicines between different countries, but also between the original manufacturer's product and copies of the same product (generics) (8, 9). Medicines that are referred to as branded generics may also carry a high price because they are more popular. In the private sector the original manufacturers' products may be more readily available than copies, and it is often perceived that they are of higher quality. If price-regulating measures are not implemented, then the individual regulatory authority must ensure that the quality of both the originals and copies is satisfactory, so that people will have confidence in the market.

How to obtain information on medicine prices

It is not easy to compare medicine prices in different countries. Researchers and authorities have tried for years to compare the prices in, for example, the US, Canada, Japan, Australia and Europe – without much success (11). In 2011 the WHO published the 3rd edition of the book *World medicines situation* (12). Abundant information is available here on selection, procurement, distribution and rational use, in



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addition to information on access, human rights, good governance, human resources and national medicine policies.

A new chapter on prices, access and affordability has been introduced, which includes the results from more than 60 studies conducted by means of a methododology developed by WHO and Health Action International (HAI) (9). A standardised method is used to study medicine prices in low-income and middle-income countries, make price information openly available and help countries with measures to improve the situation (13).

Prices, patents and free trade agreements

The situation worsened after the introduction of the international patent regulation agreement TRIPS (Trade-Related Aspects of Intellectual Property Rights) in 1995 (14, 15). TRIPS is a framework agreement for intellectual property rights negotiated through the World Trade Organisation (WTO) between the member countries. All the member countries must have patent legislation in accordance with TRIPS.

Because medicines are only a small part of the TRIPS Agreement, this agreement was not viewed in a public health perspective – and this had serious consequences. After the patent period has expired, copies can be manufactured that are much less expensive. However, competition is necessary to bring prices down, and more than one copy is needed, because the original manufacturer does not normally lower prices in the face of competition (15).

Parallel importation

South Africa's battle at the end of the 1990s to gain access to parallel imported medicines for HIV/AIDS intensified the battle against the high prices of patented medicines. Parallel importation means importing the same product from a country with lower prices. This was not popular with the powerful pharmaceutical industry, and 39 firms filed suit against the authorities in South Africa. Right before the trial was to start, however, they came to their senses and dropped the lawsuit. It is a paradox that we have legal parallel imports here in Europe.

In 2001 two clauses were added to the TRIPS Agreement that were designed to allow countries to obtain essential medicines at more reasonable prices. This was to take place by parallel importation or compulsory licensing (14, 15). Compulsory licensing entails that a country can manufacture a patented medicine itself or purchase it from a country that is allowed to export in return for paying a fee to the patent holder. This is so difficult that it is impossible to carry out in practice (15).

Data exclusivity and free trade agreements

The TRIPS Agreement gives the patent holder a monopoly for at least 20 years. Pressure is being exerted now through bilateral free trade agreements, for example, to extend this patent period, introduce data exclusivity and deny parallel importation and compulsory licensing (15). This is often referred to as TRIPS+. Data exclusivity entails protection of the original manufacturer's efficacy and safety data for five to eleven years.

Free trade agreements override TRIPS. Free trade agreements are designed to facilitate increased trading between the contracting parties, and ideally the agreement should be balanced and give both parties rights. However, this is far from true in all cases. For the pharmaceutical sector, which is not viewed as a public health matter and exempted here either, the same principles that the strong party wants for other trade areas apply. In a country such as Jordan, where several agencies have monitored the pharmaceutical market before and after the US and Jordan signed a free trade agreement, medicine prices have increased 20 %.

Data exclusivity has delayed generic competition for 79 % of the medicines for which the pharmaceutical companies applied for a market authorisation during the period from 2002 to June 2006 (16). In addition, there has in practice been no technology transfer from the large pharmaceutical companies to local manufacturers, as is the intention in these free trade agreements.

The EU has been negotiating a free trade agreement with India since 2007, and is still negotiating (17). The content of this agreement will be of great importance, since India plays a major role in supplying poor countries with reasonably priced medicines. Indian medicines for the treatment of HIV/AIDS account for 80 % of this market (15). It will have major consequences if the EU manages to impose restrictions beyond those on which the TRIPS Agreement is based.

Other factors affecting price

The research-based pharmaceutical industry claims that the prices have to be high in order to cover the research and development costs. The amount that they state
(in 2006: USD 1.3 billion to get a new medicine to market) is high and applies only to a few new medicines. The estimate has been strongly criticised (18, 19). In addition, sales in affluent countries represent the majority of a company's revenue. For HIV/AIDS medicines, where more than 90 % of the disease burden is in countries outside the US and Europe, these two markets account for 94 % of the sales of first-line treatment and 97 % of the market for second-line and third-line treatment. (Ellen 't Hoen. HIV/AIDS Market – the situation. Lecture at NORAD, 26 May 2011).

Taxes and fees

The manufacturer's price is just one part of the retail price, and thus just part of the problem with high prices and access to essential medicines. The rest of the price (the add-ons) consists of various national taxes and fees (import tax, value-added tax) and a profit to the various links in the distribution chain. Because there is free pricing, a progressive profit margin and weak control in most poor countries, the add-ons can be high and increase the price considerably, 100–500 % is not unusual (9). It goes without saying that a profit margin that is progressive on expensive medicines will have a big impact, while the mark-up for the lower priced generics will be relatively modest. A pharmacist can, however, be tempted to increase the mark-up on cheap medicines, because the lower priced medicines drastically reduce the profit.

Why can't the authorities manage to ensure that the poor receive the medicines they need at a price they can afford? All the low-income and middle-income countries have a public sector where the medicines are procured by tender, and are supposed to be available to the patients free of charge or highly subsidised. The price studies conducted by WHO/HAI and others document, however, that the poor are taxed in many countries through high mark-ups in the public sector. In addition, there is unfortunately often very little or no stock due to inefficient purchasing, corruption and a poor distribution system (8, 9). The poor are therefore forced to use the private sector, where the prices are so high that most people cannot afford it (9).

Improvement in sight?

Some measures have been implemented through partnerships between the public and private sectors in order to improve access to essential medicines. These measures apply only to HIV/AIDS, tuberculosis, malaria and vaccines. Two of the measures aim to stimulate market access for new products. The advanced market commitment model (AMC) is being tested with funding from GAVI (Global Alliance for Vaccines Initiative). Support for development and a guaranteed price and sales volume are to make investments in the production of vaccines attractive. The first project involves a pneumococcal vaccine. With funding from UNITAID, Gates Foundation and the British Department for International Development (DFID) a model is being tested where quality-assured antimalarial agents are being subsidised by a co-payment to the manufacturer (Affordable Medicines Facility malaria, AMFm). It is hoped that the market will be able to regulate itself, and that the patients will ask for these products.

Conclusion

High price is one of at least four factors preventing poor people from obtaining treatment with essential medicines. Other factors include, for example, weak national pharmaceutical control, irrational selection, financing that is not sustainable and an unreliable health care system. Patients are forced to acquire medicines from private pharmacies, where the prices are so high that a large portion of the family's income will go towards medicines.

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