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# Supply and demand: Why drug prices and trade barriers are blocking drug access and what activists can do about it

## Introduction

In recent years, activists have poured significant energy into pushing for resources for institutions like the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). Yet there has not been nearly as much sustained effort to keep drug prices low. In part, this is because many activists have taken their focus off the macro issues related to access to essential medicines and have focused instead on short-term solutions.

Given the emergency situations that many people in low- and middle-income countries have encountered, the temptation to focus on quick wins has been strong. However, it has come at a cost. After first-line generic antiretroviral (ARV) drugs became cheaply available on the market, a sense developed among the wider AIDS movement that the battle had been won.

> Yet among activists who work on access to medicines issues on a daily basis, it is obvious that the battle has not yet been won.

Certainly a lot has been achieved. In the last decade, the price of front-line ARVs has been considerably reduced, and the efforts of the HIV activist community were instrumental in this regard. Between June 2000 and 2011, front-line ARV prices

decreased from $10,439 per patient per year (PPY) to $347/PPY. To solidify these gains, in June 2011, the high-level meeting of the United Nations General Assembly Political Declaration[1] stated that trade barriers and intellectual property should not stand in the way of HIV treatment access. The high-level meeting was unequivocal: where trade barriers exist they should be removed.

The Declaration was the product of intense negotiations, during which civil society groups pushed hard around essential medicines and drug pricing, and won. The Declaration referenced another crucial statement, the Doha Declaration[2], which had been issued in 2001 as the outcome of the World Trade Organization (WTO) ministerial conference on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and public health. The Doha Declaration stated that public health concerns trump trade concerns.[3] It emphasised that there was room for flexibility within the WTO's TRIPS agreement,[4] and that these flexibilities should be used in the case of medicines.

Specifically, the Doha Declaration states, "Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[5]

Three years after the high-level meeting and 13 years after the Doha Declaration, trade barriers to drug access have not decreased. On the contrary, they have been dangerously strengthened, particularly by a combination of bilateral agreements, restrictive patent laws in certain countries, and a lack of competition in some areas of the production of medicines and medical products. Today, the gains that many activists took for granted after 2001 are under serious threat.

In part, this is because drug companies have played a clever game. Using mechanisms like 'voluntary licensing', 'tiered pricing' and 'standard prices', they have signed deals that appear to be generous. Yet for the countries and generic companies that have entered into these deals, the rewards have been fleeting. Big pharmaceutical companies, like Gilead, Bayer and Novartis, have used their deep pockets and legal muscle to try to dissuade civil society groups and generic manufacturers in middle-income countries from opposing the renewal of dubious patents or the granting of new patents on old medicines. They have also worked hard to spin media stories that portray them as responsive to the public health crises that grip low- and middle-income countries.

The sad truth is quite the opposite. As Doctors without Borders research has found, between 2001 and 2011, only 3.8% of drugs approved for global use were designed to treat diseases where "treatment options are inadequate or don't exist".[6]

While drug companies certainly deserve their share of criticism, they have simply behaved according to the logics of profit making: trying to expand their monopolies

1. United Nations, Resolution adopted by the General Assembly, 65/277. *Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS*, June 2011. Available at: www.unaids.org/en/media/unaids/contentassets/documents/document/2011/06/20110610_un_a-res-65-277_en.pdf
2. World Trade Organization (2009). The Doha Declaration. Available at: http://www.who.int/medicines/areas/policy/doha_declaration/en/
3. World Trade Organization (20 November 2001), *Declaration on the TRIPS agreement and public health. Adopted on 14 November 2001*. [Online] Available at: www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
4. World Trade Organization (20 November 2001), *Declaration on the TRIPS agreement and public health. Adopted on 14 November 2001*. [Online] Available at: www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
5. World Trade Organization (2009). The Doha Declaration. Available at: http://www.who.int/medicines/areas/policy/doha_declaration/en/
6. MSF, 2012, Medical Innovation for Neglected Patients. Available at: http://www.doctorswithoutborders.org/support-us/events/lives-balance-delivering-medical-innovations-neglected-patients-and-populations

and fighting against the competition with generics. Activists, on the other hand, have been rather less consistent in championing the access to medicines issue. Through a combination of strategic blunders, complacency and a focus on other issues that also require attention and activism, many AIDS activists have been diverted from focusing on the primary actions necessary to keeping drug prices low.

> However, in the absence of strong and sustained activism, it is unlikely that essential medicines will become available in the quantities and at the prices needed to ensure universal access.

If activists do not quickly confront this crisis, there is no guarantee that the millions of people who have been placed on treatment will be able to stay on treatment and move on to second- or third-line regimens when they need them.

This insight tells the story of how we have arrived at this difficult and dangerous situation.

## Technical words and important definitions

One of the biggest challenges to advocacy on essential medicines is that some activists see it as a complicated sector, replete with medical, economic and legal terminology. Often, those advocating for AIDS funding for large-scale programmes have not been able to see what is really at stake in drug pricing activism because of the jargon. As a result, essential medicines activists have had to work hard to demystify the language. This essay provides a step-by-step analysis of the big issues in essential medicines, while also making a real effort to use accessible language. Why? Because leaving these issues to the so-called experts would be a strategic mistake.

> Knowledge is an important weapon for empowerment and more activists must become involved.

### TRIPS

What prevents anyone from producing and distributing medicine to people who need it? In short, it is TRIPS7, which was signed by WTO member countries in 1994 and has been in force since 1995. According to WTO, “TRIPS attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations.” The TRIPS agreement obliges each WTO country member to grant at least a 20-year patent on all new medicines.

However, TRIPS gives the leverage to countries to define what can be patented or not. For instance, the Indian Patent Law is known to have quite restrictive patentability criteria (something that activists have embraced), while in other countries, the process of reviewing patent applications is very weak, which means that eventually most patent application will be granted. In other words, TRIPS protects the owners of patents, but also provides a list of circumstances under which patent rights can be minimised or circumvented in the public interest. These are known as TRIPS flexibilities.

7. Trade-Related Aspects of Intellectual Property Rights, in force since 1995, is to date the most comprehensive multilateral agreement on intellectual property.

### Compulsory licenses

One such flexibility is compulsory licensing, which occurs when a government allows someone else to produce the patented product or process without the consent of the patent owner. In recent years, a number of drug companies have tried to avoid situations where countries invoke compulsory licensing. When other companies can produce drugs, this dramatically affects the prices they can charge. It can also threaten to break their monopolies.

### Patent opposition and patent law reforms

Another key flexibility of the TRIPS agreement is the possibility of countries opposing patents. In other words, countries may refuse to grant a patent, including for lack of novelty, and they may also revoke a patent. It is important to remember that each country has the right to define in its patent law what is novel and what can be patented. These are referred to as patentability criteria.

### Voluntary licenses

Contrary to a common belief, voluntary licenses are not a flexibility of the TRIPS agreement but a strategy of the pharmaceutical industry, primarily designed to avoid the use of TRIPS flexibilities and to preserve their monopolies. To address this, many large pharmaceuticals that own patents have begun to grant licenses to other manufacturers in exchange for royalty payments. This is called voluntary licensing. When voluntary licenses are offered to many manufacturers across different countries, drug prices can go down, but this is rare. Most of the time, voluntary licenses are offered in highly restrictive ways. Rather than open up access, they block competition and extend the original company's control over a given market. Often, voluntary licenses are offered as a pre-emptive move, where drug companies think they might lose a case in court, or when they anticipate that a patent application will be rejected, a patent revoked, or a compulsory license issued.

In this scenario it is easy to see why companies would prefer this route. Companies that give voluntary licenses often dictate where the active pharmaceutical ingredient must be purchased, as well as the countries to which the drugs can be exported. As Médicins Sans Frontières notes[8], these arrangements "do not lead to the unhindered competition that allows patients to benefit from the lowest prices possible, nor do they increase access in all countries where the medicines are needed." If a company chooses to offer a license in Vietnam, while there is a bigger epidemic in China, it leaves very few options for people living with AIDS in China. It is also important to note that voluntary licenses are generally not accessible in middle-income countries, even though the largest epidemics exist in places like South Africa, China, India and Brazil. This fact makes voluntary licenses strategy even less relevant for diseases such as hepatitis C, concentrated in middle-income countries.

### Tiered or differentiated pricing

Tiered or differentiated pricing is the concept of selling medical products in developing countries at prices that are lower than in rich countries. Tiered pricing involves segmenting markets in these countries. Companies often negotiate two different prices with the health authorities: one for the public sector and another for the private market. The globally accepted way of separating markets has been to

8. MSF (2011), Untangling the web of antiretroviral price reductions. Available at: https://www.msf.org/sites/msf.org/files/utw_14_eng_july2011.pdf

rely on the World Bank's categorisation of low-, middle- and high-income countries, and in the case of AIDS, to match this with an assessment of the HIV prevalence in a given country. Tiered pricing often goes hand in hand with voluntary licensing.

> In essence, drug companies have seen tiered pricing as a way to preserve their profits while responding to the perception that they are callous and indifferent to the plight of people in poorer parts of the world.

Pharmaceutical companies use the price they charge on the United States or French markets, for example, as a reference point to try to show that they are offering a 'discount' to the country, although countries such as France and the United States still do not have any transparent process for the negotiation of drug prices. The price of the drug is, in reality, not linked to the real cost of research and development, and the production cost of the product. Rather, it is largely based on a formula that maximises profits for the originating company.

Adopting different prices in different markets is supposed to make products more affordable in low- and middle-income countries. Tiered pricing does not imply that a price is fair or affordable. As Moon et al,[9] point out, it just "means that different prices are charged to different segments of the market for the same product."

## How does it all add up?

When compared to the cost of generic drugs, those provided through voluntary licensing agreements are significantly more expensive. A review of over 7,000 developing-country purchase transactions between 2002 and 2007[10] found that the tiered prices for 15 out of 18 ARV drugs were 23–498% higher than the generic price. In an important update, the authors note that as of mid-2011, of the three products for which tiered prices were lower than generic prices, two products now have lower-cost generics available. The short story is that differentiated pricing works to bring prices lower than they otherwise might be, but it is still is not nearly so effective as the production of generics.

Given this definitional and practical landscape, it is not difficult to see why the rapid increase in voluntary licenses in recent years is a worrying step backwards. It is driven by short-term needs rather than by the longer-term objective of increasing supply in order to meet growing demand. Most worrying, international non-governmental organisations (NGOs) have been at the forefront of celebrating and benefitting from voluntary licenses. When the option of using the TRIPS flexibilities is available, there are critical questions to be raised about why important players in the global AIDS movement have not stood firmly against the new practices that seek to strengthen patent regimes and inevitably drive up prices.

In addition, it is important to keep in mind that the strategies of tiered pricing and voluntary licensing are based only on the interests of the pharmaceutical industry. Governments at the national levels, and public interest organisations at the global level, including United Nations agencies, must begin to discuss more rules for better regulating patentability, licenses and pricing issues to prevent abuses from the private sector and guarantee public health needs.

9. Moon, S, Jambert E, Childs, M, von Shoen-Angerer T (2011) A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries, Globalization and Health. Available at: http://www.globalizationandhealth.com/content/7/1/39
10. Waning, B; Kaplan, W; King, A; Lawrence, D; Leufkens, H; Fox, M (2009) Global strategies to reduce the price of antiretroviral medicines: evidence from transactional databases. Available at: http://www.scielosp.org/scielo.php?pid=S0042-96862009000700013&script=sci_arttext

## Is the 'pharmacy to the third world' in danger?

India is known as the developing country pharmacy. Certainly, it has played a crucial role in the development of the generic drug industry. It is estimated than more than 90% of the global supply of ARVs comes from India. The country was able to turn a lack of patent restrictions until 2005, plus a significant population and sizeable technological capacity, into an asset. In 2005, to comply with the TRIPS agreement, India had to amend its patent law. In order to prevent the granting of abusive patents, and to ensure that only new inventions were awarded with patents, activists pushed for India to include safeguards in its national law, including a clause called 'section 3(d)'.

Even in the past few years, India's patent office has made a number of important decisions that have upheld the TRIPS flexibilities. For instance, in April 2013, Novartis lost its legal battle to patent the anti-cancer drug Gleevec/Glivec in front of the Indian Supreme court. The court found that the drug was not 'new' in terms of Indian patent law's section 3(d).

Sadly, the rules of the game have changed since 2005, and India must now abide by TRIPS agreements as defined largely by the companies who stand to benefit most rather than by the country's own assessment. It is now compelled to grant 20-year exclusivity to drugs that are considered to be the 'inventions' of big pharmaceutical players. For instance, a drug like raltegravir (a third-line drug used against HIV) can be considered a real novelty. It would be difficult to oppose, as it is the first drug to be marketed in its own therapeutic class (integrase inhibitor). Fortunately, this is not the case for all new HIV drugs. But it does underscore the strategic error made by AIDS activists who thought that the question of drug treatment costs had been resolved.

The work of Initiative for Medicines Access Knowledge (I-Mak)[11] demonstrates how dramatically out of step this is with reality.

In 2013, I-MAK conducted an analysis of 11 drugs considered to be new inventions that were in the pipeline and would soon require patents.[12] Eight of these were simple modifications of existing compounds, so should not have constituted 'real' inventions. This means that the patents related to these eight drugs can be contested, and that access to each of these medications can be granted for use through TRIPS flexibilities.

The issue of competition and supply of generic forms of new ARV drugs has to be taken very seriously. Without strong and healthy competition from generics, TRIPS flexibilities will be more difficult to use because they are dependent on a generic alternative being available to supply to countries. For instance, there is currently no generic drug of raltegravir available. Because Merck has a strong patent that has been granted across a number of countries, and very deep pockets, there are no generic producers prepared to risk producing a generic only to be sued by Merck either in India or elsewhere.

11. I-MAK (2013), *The roadmap: the HIV drug pipeline and its patents*. Available at: www.i-mak.org/storage/HIV%20Roadmap_19Aug2013.pdf
12. The drugs assessed were tenofovir alafenamide fumarate, Darunavir, CMX157, rilpivirine, dolutegravir, elvitegravir, raltegravir, cobicistat, Complera, etravirine and Stribild.

## What's a fair price for a life-saving medicine?

There has been much confusion related to drug prices and the costs of production. The cost of a drug includes raw materials, labour, capital and a company's investment in research and development. The price refers to the amount that buyers have to pay for goods or services. The price is an artificial construction, which may or may not be linked to the production cost. The difference between both is the marginal profit.

Too often, activist organisations have justified the differentiated pricing logic on the basis that there are costs associated with research and development or on the basis of the socio-economic status of the country. Many have supported the World Bank country classification, which differentiates low-, middle- and high-income countries. Yet this is a questionable way of arriving at drug prices.

Having standardised prices in poor and wealthy countries does not take into account the huge and growing income disparities within and between countries.

> Even in countries that are considered to be wealthy, some people living with HIV cannot afford medication because they are personally poor.

Their country may be wealthy, but they may not have access to social security and therefore to health services. Furthermore, where voluntary licenses are offered in some places and not in others, there continue to be outstandingly large differences between drug prices, and therefore in treatment access and sustainability.

For example, for a treatment regime comprised of tenofovir + emtricitabine or lamivudine + efavirenz, the Russian Federation pays on average US$3,959 PPY, while neighbouring Kazakhstan pays half of that – an average of US$1,933 PPY. Thailand, on the other hand, pays around US$523 PPY.[13] The Argentinian department of health pays around US$1,872 PPY for tenofovir. However, in the Argentinian private sector, the cost of the same drug is US$5,425 PPY.[14] Interestingly, pharmacologists estimate that the average cost of producing tenofovir is less than US$400 PPY.

> How can we explain such differences between the cost of production and the prices that are charged per patient?

Third-line treatments are not available in a generic form and their price is far higher. For example, in Morocco, the cost of the third-line raltegravir, darunavir and etravirine represents 13% of the total ARVs budget allocated by the department of health and the Global Fund. However, this treatment regime is used by only 0.2% of people living with HIV on treatment (only 11 people!). In other words, the purchase of second- and third-line medication for the 14% of people on treatment who need them represents more than a third of the total ARVs budget in Morocco. The amount required to give a single person a third-line treatment for a year is equivalent to the amount required to put 85 people on first-line treatment for a year.[15]

13. UNAIDS (13 June 2013), *International consultation focuses on access to HIV medicines for middle-income countries*. [Online] Available at: www.unaids.org/en/resources/presscentre/featurestories/2013/june/20130613brazil/ and WHO (2014), Increasing access to HIV treatment in middle-income countries; key data on prices, regulatory status, tariffs and the intellectual property situation. Available at: http://www.who.int/phi/publications/WHO_Increasing_access_to_HIV_treatment.pdf
14. Sources: Figures: Ministry of Health, Argentina, 2013, and Di Giano L.
15. Figures : Ministry of Health Morocco, May 2013, calculations ITPC-MENA, Mellouk O., Londeix P. www.itpcmena.org

These price discrepancies prove the artificial nature of ARVs pricing and act as barriers to drug access. Is the fact that Morocco and Argentina are considered to be middle-income countries a good reason to justify such prices when we know that the profits of firms are still very high? In Russia and Kazakhstan, pharmaceutical companies can charge such high prices because there is no competition from generic manufacturers.

## Key debates

Many members of the AIDS community endorse the idea that it is acceptable for middle-income countries to pay higher prices for drugs than low-income countries, and that high-income countries should pay even more. Many advocates in our movement have considered this to be a legitimate argument. However, this debate has been oblivious to one fundamental fact: apart from the elite and members of the highest socio-economic classes, few people in middle-income countries can afford the price of these medicines on the private market. In a context of increasing inequality, does it make sense to hew so closely to broad categories of drug pricing? Can we accept that in most middle-income countries, health budgets are spent on medicine purchase only, even if this is detrimental to prevention and other support programmes? In countries that cannot afford the newest HIV treatments, can we accept that old treatments such as stavudine are still prescribed, even if no longer recommended by the World Health Organization? The bottom line is that the World Bank gross doemestic product (GDP) formula for determining drug prices is irrelevant and out of step with principles of health equity.

One consequence of the gradual endorsement of this differentiated pricing strategy aligned to the World Bank categories can be seen in repeated attempts from the Global Fund and the United Nations system to promote voluntary licensing and tiered pricing as a solution to enable access to treatment.

The furore over the latest Global Fund initiative, The Blue Ribbon Task Force,[16] confirms this. Although the content of the project is still opaque, the idea is that middle-income countries receiving support from the Global Fund will pay more for HIV medicines in accordance with their ranking at the World Bank. If adopted, this initiative risks deeply undermining the work undertaken by activists and governments to ensure access to medicines in their countries.

Taking a strong stand against this practice, the HIV activist community sent a letter signed by more than 200 associations[17] to Mark Dybul, Global Fund CEO, in May 2014. This demanded that the institutions renounce the Global Fund's attempt to introduce tiered pricing into its procurement of drugs, based on the fact that differentiated pricing does not enable access to treatment in middle-income countries.

## Is voluntary licensing really improving access?

Unfortunately, the strong reaction of HIV organisations against differentiated pricing strategies has not yet been matched by a similar mobilisation against the voluntary licensing mechanism, which is still largely misunderstood. Voluntary licenses are not TRIPS flexibilities. On the contrary, they are adopted by drug companies precisely to avoid TRIPs flexibilities, and at the same time to strengthen patent protections and maximise profits.

16. See the great analysis provided by Suerie Moon (1 December 2013), *Is the Global Fund heading backwards on access to medicines?* [Online] Available at: http://blogs.plos.org/speakingofmedicine/2013/12/01/is-the-global-fund-heading-backwards-on-access-to-medicines/
17. View the open letter sent to Mark Dybul (May 2014). Available at http://aidslaw.ca/publications/interfaces/downloadFile.php?ref=2229

Instead of opposing them, agencies such as the Joint United Nations Programme on HIV/AIDS (UNAIDS) and large international NGOs have celebrated the signing of voluntary licenses between pharmaceutical companies and generic companies in the past three years. They have gone so far as to consider these agreements as part of a "major turning point" in drug pricing. However, these licenses exclude most middle-income countries at a time when they are also losing the resources allocated by the Global Fund, either because HIV prevalence is not high enough or because they are considered too wealthy.

> In essence, then, middle-income countries with complex epidemics are caught in the middle of changing global AIDS rules and drug company manoeuvres.

## The divide and rule strategy

Little by little, the HIV activist community has become fractured. There are those who consider that voluntary licenses applied to low-income countries provide an important first step in lowering drug prices. Others are of the view that endorsing voluntary licenses is a strategic mistake because it does not change the structural factors at play in determining drug prices.

The reactions to the licensing agreement between Gilead and the Medicines Patent Pool about tenofovir in July 2011 illustrate this divide. In 2006, Gilead granted a voluntary license to Indian generics manufacturers for 96 countries. In 2011, the company extended the agreement so that it would cover an additional 20 countries.[18] The media covered the 2011 agreement as a turning point in the history of treatment access and announced a "new era in the response to HIV".[19]

Gilead was portrayed as a generous and humane pharmaceutical company. However, the real story was that Gilead insisted on voluntary licenses in this large group of countries because the Indian Patent Office was about to reject the tenofovir patent's application due to its lack of novelty. China's and Brazil's patent offices did the same in the years that followed.

As a result, Gilead was pushed to sign the voluntary license agreements with Indian generic manufacturers in 2006, and by using voluntary licensing Gilead was able to receive royalties even though the legitimacy of the patent was contested. By 2011, the company had learned how to use the PR machine, and sadly a number of agencies, as well as the media, played along with the company.

Two years later, Gilead started marketing sofosbuvir (Sovaldi), the most promising hepatitis C treatment and the backbone of the most promising future therapies against the disease. The same groups that had praised Gilead as a "humane" company were now compelled to acknowledge the fact that Gilead may actually be the greediest firm ever.

It is still not known what the real impact of this voluntary license has been. During a meeting on hepatitis C treatment in February 2014,[20] Gilead representatives argued that as far as they knew, the voluntary licensing agreements negotiated within

18. I-MAK (September 2011), *The Patent Pool-Gilead licences*. Available at: www.i-mak.org/storage/Analysis%20of%20the%20Patent%20Pool%20Gilead%20Licenses.pdf
19. UNAIDS (12 July 2011), *UNAIDS welcomes first voluntary license to the Medicines Patent Pool by a pharmaceutical company*. [Online] Available at: www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2011/july/20110712pspatentpool/
20. HepCoalition, *First Hepatitis C World Community Advisory Board Meeting, February 22 – 25 2014 / Bangkok, Thailand*. [Online] Available at: www.hepcoalition.org/%D8%A3%D8%AE%D8%A8%D8%A7%D8%B1/article/first-hepatitis-c-world-community?lang=en

the Medicines Patent Pool framework have not yet had any impact on access to treatment. This is worrying considering how much investment has been made into the Medicines Patent Pool, which was created to increase access to quality, appropriate, affordable medicines for people living with HIV in developing countries. The Medicines Patent Pool describes itself as a "public-health driven business model that facilitates the production of low-cost versions of existing medicines". This is done primarily through voluntary licensing of key HIV medicines. So far, this model has shown its limits and its failure to address the issue of access in middle-income countries. In addition, as this model was described in the media as revolutionary for access to HIV treatments, it has diverted some governments and organisations from looking at other solutions that have proven to be more appropriate to enabling access.

## We know what to do and we've won in the past

Over time, the activist community seems to have forgotten that the strategies of voluntary licenses in lower-income countries, tiered prices in middle-income countries and 'standard' prices in high-income countries are not concessions that have been made by well-intentioned people within the business sector. Voluntary licenses, tiered prices and standard prices are based on pure business logic. Furthermore, they are not the only, nor are they the best, way to reduce the prices of drugs in a sustainable manner.

There are proven solutions to guarantee universal access to drugs– not only to those who live in the poorest countries. These solutions focus on generic competition and TRIPS flexibilities. Within TRIPS, the Compulsory Licences mechanism is effective, as are patent oppositions and patent law reforms. Lastly, not enough countries have pursued patent law reforms to enable the full range of these options. When used, patent oppositions have shown all their power to enable generic competition, drive prices down and enable access.

This is illustrated by the case of tenofovir in India. In 2006, the main Indian generic manufacturer, Cipla, and a group of Indian and Brazilian NGOs, independently filed oppositions to Gilead's patent applications on tenofovir. Worried that it might lose the court challenge, Gilead responded by giving licenses to 13 other generic manufacturers to make the drug for a 5% royalty. The problem was that the 13 manufacturers could only buy the active ingredient from Gilead-approved suppliers. Worse yet, while they were able to export their generic products to low-income countries, they were precluded from selling the drug to middle-income countries such as China and Brazil. Gilead's actions effectively curbed the price reductions the generic makers could offer because of the conditions it imposed on them.

In other cases and for other drugs, for instance efavirenz in Brazil and in Thailand, local activists have learnt to push for compulsory licences. It is an important strategy in addition to opposing patents. Yet too many AIDS activists continue to push for voluntary licensing, even in instances where compulsory licenses can be invoked. It is regrettable that many HIV organisations have simply ignored compulsory licensing and/or patent opposition despite the fact that there are a number of NGOs with strong experience in this kind of strategic litigation and high-level advocacy. This is especially the case in middle-income countries, where the intellectual property barriers are a direct problem to access.

## Soaring drug prices

> A new frontier for activism in the coming few years will be the cost of drugs, including ARVs, in high-income countries.

Income inequalities within wealthy countries are growing, and as they do so, the idea that GDP should be the basis of drug prices is becoming less sustainable or realistic. Today, the austerity policies in place in many European countries are forcing a rethink.

Research conducted by Médecins du Monde[21] shows that the cost of treating all people with hepatitis C in France using the prices prescribed by Gilead for its new drug patented under the name Soldavi, would be almost double the entire budget of the Paris hospital system. As a result, for the first time the French ministry of health is considering a range of options to avoid the current price of hepatitis C drugs. French advocates are even pushing for the government to issue a compulsory licence for government use in the public health system in respect of Gilead's sofosbuvir.[22]

It has taken far too long for this issue to top the agenda for activists, in large part because until recently it didn't affect those in high-income countries. With the effect of the financial crisis on health budgets, they are now feeling the pinch.

Even though TRIPS flexibilities do provide an effective solution, the TRIPs-plus measures also constitute a threat that should not be overlooked. These measures are bilaterally negotiated between high- and middle- or low-income countries, and reinforce a strict intellectual property rights regime. Indeed, as Oxfam notes in an important policy paper published in 2007, "Since the enactment of the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement in 1995, the USA has imposed progressively higher levels of intellectual property protection (TRIPS-plus rules) on developing countries, which undermines access to affordable medicines."[23]

> It is time to take a more focused approach to bringing drug prices down, irrespective of disease.

This is only possible if health activists join forces. Thus far we have focused too much on AIDS drugs to the exclusion of many other important diseases where pricing is also a major obstacle to access. For example, the treatment for hepatitis C is unaffordable for most people with the virus despite hepatitis C being one of the leading causes of mortality among people living with HIV and AIDS. Other examples include the treatments for non-communicable diseases such as cancer, cardio-vascular or respiratory diseases, which are likely to become the leading cause of death throughout the world by 2030.[24] Today, non-communicable diseases represent one of the most lucrative sectors for pharmaceutical companies, and the same issues of patents, intellectual property rights and low-price generic production will soon become critical in addressing each of these diseases.[25]

21. Londeix, P., with Forette, C. (March 2014), *New treatments for hepatitis C virus: strategies for achieving universal access*, Médecins du Monde. Available at: www.hepcoalition.org/IMG/pdf/daas_strategies_for_achieving_universal_access_en.pdf
22. Act Up-Basel (10 July 2014), *Prix des traitements contre l'hépatite C : Le gouvernement français doit émettre une licence d'office sur le Sofosbuvir et avoir recours aux médicaments génériques*. Available at : www.actupbasel.org/actupbasel/?Prix-des-traitements-contre-l [French]
23. Oxfam (21 March 2007), 'All costs, no benefits: how TRIPS-plus intellectual property rules in the US–Jordan FTA affect access to medicines', *Oxfam Briefing Paper* 102. Available at: www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf
24. United Nations, Resolution adopted by the General Assembly, Sixty-sixth session, Agenda item 117, *Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases*, 19 September 2011. Available at: www.who.int/nmh/events/un_ncd_summit2011/political_declaration_en.pdf?ua=1
25. Mills, E.J. and Ford, N. (2012) 'Political lessons from the global HIV/AIDS response to inform a rapid noncommunicable disease response', *AIDS* 26: 1171–3. Available at: www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/HIV_MedJourn_AIDS_PoliticalLessonsNCDs_ENG_2012.pdf

The recent comments of Marijn E Dekkers, CEO of Bayer, are an excellent illustration of the need for joint advocacy. Dekkers declared that Nexavar, a new drug that has been approved for treating kidney and liver cancer, was not developed "for the Indian market, let's be honest. We developed this product for Western patients who can afford this product, quite honestly."[26]

In 2011, the United Nations organised a high-level meeting on non-communicable diseases, and in 2014 WHO published its first hepatitis C treatment guidelines. Both these initiatives could have used the support of HIV organisations and activists. It would have represented a real win–win for all health activists. That this didn't happen is a testament to the failure of activists to be better organised and strategic in their advocacy on access to essential medicines.

The bottom line is that the issue of price and access to medicines will never be solved on a case-by-case basis because it is a systemic problem. It needs systemic remedies, which should be led by governments and international institutions to protect the principle of the right to health.

## Less supply, greater demand

The issue of the sustainability of the generic pharmaceutical industry deserves serious attention from activists. Since 2005, India has been compelled to implement TRIPS. This has put sustained pressure on generic manufacturers, who are threatened with court cases by pharmaceutical companies threatening to protect their patents or, as was the case with Novartis, intimating that they will leave the country if their intellectual property claims are not "respected".[27] Pharmaceutical companies may not always win in the courts, but they have far more resources than generic companies. Increasingly, these court cases are deterring investment in generic companies and are serving as an incentive for the companies themselves to sign voluntary licenses.

The cumulative effect could be severe. There is a dangerous decrease in the number of generic manufacturers able to produce medicines for countries that have been excluded from voluntary licenses. These tend to be middle- and high-income countries. However, because so many generic manufacturers are based in middle-income countries, the effects of big pharma's practices are significant. When generic companies are forced either to close or to operate on the terms of large companies, it has an impact on supply that in turn pushes prices up. Consumers lose, and drug companies invested in the patent regime win.

Thus, one of the key mistakes activists have made in the past few years has been to support voluntary licenses on the basis of extensive geographical coverage.

> In the race to ensure that many countries had access to cheaper drugs, many activists overlooked the quality of that access and, more importantly, its sustainability in the long term.

Essentially, they neglected to understand the effect of voluntary licenses on the structural elements that most affect drug prices: supply and demand.[28]

26. SemDem (31 January 2013, *Bayer CEO actually said this: cancer is for rich westerners, NOT poor Indians*. [Online] Available at: www.dailykos.com/story/2014/01/31/1273942/-Bayer-CEO-Actually-Said-This-Cancer-Drug-Is-For-Rich-Westerners-NOT-Poor-Indians#
27. BBC News (1 April 2013), *Novartis: India rejects patent plea for cancer drug Glivec*. [Online] Available at: www.bbc.com/news/business-21991179
28. I-MAK and ITPC (10 September 2012), *Voluntary licensing: optimizing global efforts and measuring impact*. Available at: www.i-mak.org/storage/Optimizing%20Voluntary%20Licensing%20IMAK-ITPC%2010%20Sep2012.pdf

In taking stock of what could have been done differently, it must be recognised that the activist community has at times been too self-satisfied, content with past wins and unable to think strategically about the tactics the pharmaceutical industry might deploy in response to big civil society and developing country gains. Valuable time has been lost.

## We've reached the bottom, now it's time to stand up

Yet the past few years also represent a turning point. Today, the convergence of the needs of people living with HIV with those of people with hepatitis C, and with the growing number of people with non communicable diseases, will force a crucial conversation to happen. The HIV treatment community must regain its past strength. This means moving beyond advocacy for more money to be spent on AIDS programmes. This is important but wholly insufficient. Those advocating for better and increased funding, and those pushing for lower drug prices, must join forces so that the issues are tackled jointly.

The default position for activists should be to improve access to medicines using the TRIPS flexibilities and generic competition. But an even more ambitious strategy would be to overturn TRIPS entirely – to push even harder than commercial interests are prepared for us to do. This means reaching a consensus that commercial tactics such as voluntary licensing should be left to companies, and should never be endorsed by activists when we are unable to prove that they are improving access. Where we endorse short-term solutions by corporate citizens who are more beholden to their shareholders than they are to the public interest, we will undoubtedly find ourselves regretting our actions.

> We have undeniably lost ground, but we also have an important opportunity to become more strategic, more ambitious, more coherent and more united in our struggles for universal treatment access and the right to health across the world.

The current debates occurring in high-income countries regarding the price of hepatitis C drugs offer us the opportunity to rethink the issue of pricing and our strategies for access, and to pursue our struggle in the hope of, one day, eradicating HIV and AIDS, and creating a fair system to enable access for all.

International HIV/AIDS Alliance
Together to end AIDS

BIOGRAPHY

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