

Fair Pricing Forum 2019, Johannesburg

Plenary: Is fair pricing achievable? A trip back in history of the pricing of HIV medicines

Are we there yet? Lesson's for today's pricing problems

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No. That's the short answer to this question.

No. We are nowhere close to achieving fair pricing.

No. Not even for the pricing of HIV medicines.

To start, I think we can't be here in South Africa without remembering:

Through the late 1990s and 2000s, the amazing battle that South Africa's Treatment Action Campaign (TAC) fought for their lives electrified all of us as treatment activists around the world.

The world was rightly focused on sub-saharan Africa as it bore the brunt of an avoidable tragedy when millions died without treatment that already existed. Over the next decade, the global HIV/AIDS community made significant progress in ART scale-up. **But the lazier sharp focus only on low-income countries (LICs)** contributed to a growing disparity in drug pricing and treatment coverage between LICs and MICs, particularly those outside of sub-Saharan Africa (SSA).

MICs not only receive substantially less donor funding, but are generally excluded from generic voluntary licenses and originator "access pricing" programs. As a result, pricing for second- and third-line ARVs in particular (which have higher rates of patent protection) remain exorbitantly high in many MICs – in some cases up to 50x higher than generic prices in LICs.

Tactics employed by many pharmaceutical companies maintain illegitimate monopolies and keep drugs expensive. The cost of HIV treatment in Argentina, Brazil, Thailand and Ukraine is at least US\$3,000 per patient per year. Companies can charge high prices because patents in each country prevent competition from manufacturers of generic drugs.

This disparity in drug pricing contributed to a treatment rate in non-SSA MICs that lagged behind the global average:

- Middle-income countries are home to almost half of the world's population, and have a large and growing share of HIV infections (62%).
- One third of people living in MICs survives on less than US\$2 per day.
- Almost 6 million people in middle-income countries (excluding sub-Saharan Africa) need antiretroviral treatment. **However**, less than a third are currently able to access it.

Extortionate price-tags for treatment, whether purchased directly by an individual or by a health ministry, **results in choices**. The '**choice**' to sell your house or buy meds, or a government's '**choice**' of *which* citizens to treat if you can't treat them all.

With forecasts indicating that MICs will comprise a majority of global HIV infection by 2020, it has become increasingly clear that the UNAIDS 90-90-90 targets **will not be achieved** without addressing the unique challenges faced by MICs – **namely the higher rates of patent protection and prohibitively high pricing for key ARVs.**

I will highlight three examples:

The first. The Dolutegravir Pricing Arrangement.

In September of 2017, an announcement from CHAI, the Gates Foundation and partners, revealed that a dolutegravir (DTG)-based HIV treatment regimen, would become available to low and middle-income countries (LMICS) at a more affordable price. DTG is an optimal HIV drug with a high resistance barrier and few side effects. The price-lowering licensing agreement for DTG-based treatment supposedly included **ALL** low- and middle-income countries, **but many countries were omitted.**

The announcement described it as “breakthrough pricing agreement”, one which “will accelerate the availability of the first affordable, generic, single-pill HIV treatment regimen containing dolutegravir (DTG) to public sector purchasers in LMICS at around US\$75 per person, per year”. **Unfortunately, despite the involvement of UN agencies,** the pricing arrangement based on the ViiV/MPP licenses **omitted/excluded 39** countries. It took us months and months... repeated requests to the agencies involved to issue a clarification that these countries are permitted to procure generic DTG-based combinations at a lower price. Only CHAI did so far...

This shows that even when licenses exist, a fairer price is not systematic and we have to fight for it.

The second. The cost of key second line medicines in the Ukraine.

Today thanks to generic competition, several LMICS countries are able to source an HIV second-line regimen for less than US\$ 500 per patient-year, **except some MICs including Ukraine.** [LPV/r] sourced from the originator was recognized as is a major cost driver; secondary patents on LPV and ritonavir were granted or applications are pending that may prevent them from purchasing generic versions

Until the patents for lopinavir/ritonavir are invalidated, other affordable generic versions of the drug cannot enter the Ukrainian market and the potential additional 138,000 patients that could benefit will have to continue to wait. The Network of People Living with HIV has calculated that the Ukrainian government overpays more than one million hryvnias (UAH) a day by purchasing AbbVie’s monopolised product.

In 2018 the government spent UAH 536 million (more than 19 million USD) *solely* on the purchase of Aluvia/Kaletra, providing just 27,000 patients with HIV treatment. If the patents are invalidated, allowing generics to enter the market, the Network has calculated that it would be possible to buy this drug at a price about three times lower, spending UAH 163

million (5-6 million USD) a year. This would potentially fund treatment for another 138,000 patients with HIV. An estimated 240,000 people are living with HIV in Ukraine. In May 2016, the All Ukrainian Network of People Living with HIV the Network filed a lawsuit claiming that AbbVie's patents are invalid and in October 2017, Kiev's Economic Court of Appeal agreed to examine the patents.

Finally. The cost of Prep in High Income Countries.

In 2012, the US FDA approved as daily PrEP, the use of a combination of emtricitabine and tenofovir. PrEP reduces risk of contracting HIV. Gilead has a monopoly on this new use of this old combination and charges approx. \$1,600; **while it costs** less than \$6 to make the medicines.

The interesting thing with this drug as PrEP is that the research was almost entirely funded through public money through the US CDC. Gilead's contribution: providing TDF/FTC doses free of charge to test in the monkeys at CDC labs in Atlanta.

As a result of the high costs in 2016, less than 10 percent of the 1.1 million people who should be on PrEP treatment were receiving the drug in the US. Gilead has earned \$36.2 billion on TDF/FTC since 2004, according to its annual reports.

In the meanwhile, several gay and bisexual men, transgender people, migrants, sex workers, people who inject drugs and other key populations for whom PrEP is a life saving development are not accessing it in High and MICs and only few privileged ones do!

In each of the examples I have highlighted, high prices and decreased availability and access is directly linked to the abuse of the patent system by the companies involved.

President Nelson Mandela's face off with big pharma in the late 90s and the global outrage **it resulted in** led us to the Doha Declaration on TRIPS and Public Health. The Doha Declaration reaffirmed the right of all WTO members to use TRIPS flexibilities to ensure **access to medicines for all**. And post Doha, there is a remarkable history of the prices of HIV medicines brought down by actions taken by PLHIV and CS groups to challenge patents on medicines in middle income countries. These have included:

1. Patent Oppositions: In 2005, when India changed its patent law to comply with TRIPS and start granting patent applications on medicines, the Indian Parliament included some key TRIPS flexibilities. This included Section 3(d), which restricts evergreening patents. Making use of this provision and of patent oppositions, networks of people living with HIV have successfully challenged multiple patents in India. As a result, in India first and second line ARVs remain off patent. Today civil society organizations around the world have opposed patents on key medicines in China, Argentina, Brazil, Russia, Ukraine, Thailand and even in the European Union and the United States.

2. Compulsory Licenses: Over the years several MICs have issued compulsory licenses to access affordable generic ARVs. Between 2005 and 2006, the Thai government exercised its right to issue multiple compulsory licenses. Two of the licenses covered two ARVs (efavirenz and lopinavir/ritonavir, marketed as Kaletra by Abbott). These licenses resulted in substantial reductions in the prices and significant improvements in accessibility of these two drugs. Other countries used the CL mechanism like Ecuador, Indonesia and more recently Malaysia.
3. Patent Law Reform: Many MICs have recognized the importance of TRIPS flexibilities and that in fact their laws do not reflect the full extent of these flexibilities. This is of course the situation in South Africa where the Fix the Patent Laws campaign has over the past 10 years campaigned with the government to include all TRIPS flexibilities – **Can this make a difference?** In 2012, Argentina’s Health Ministry and Patent Office jointly issued patent examination guidelines for pharmaceuticals to prevent evergreening; Argentina does not grant patents for new forms and new uses of old medicines.
4. Campaigning for the rejection of TRIPS-plus provisions: TRIPS already requires developing countries to grant 20-year monopolies on medicines. TRIPS-plus provisions can make that period longer and add on more forms of monopoly on medicines like data exclusivity. Take the example of the free trade agreement between my country Morocco and the United States. This agreement has strict provisions as far as IPR is concerned and has been in existence for 13 years. Morocco accepted at least 5 important TRIPS plus measures. The prices of medicines are very high here in Morocco and some medicines in Morocco have higher prices than in Europe. A study from the Moroccan Parliament mentions this and yes, all this has happened in the last 13 years. Now Morocco is negotiating a free trade agreement with the EU. **But this time**, negotiations are blocked due to many reasons **because many people are opposing it**, including on the issue of access to affordable medicines.

So affordable prices in the history of HIV have been achieved when TRIPS flexibilities have been used to remove patent barriers. These actions have ripple effects. The government use license issued by Thailand resulted in the patent holder cutting prices across several other countries. Malaysia’s compulsory license on sofosbuvir resulted in four additional MICs being included in Gilead’s license.

Before carrying on, I do want to make one thing clear: WE ARE PRO INNOVATION

For years Big Pharma has conflated patents with innovation, repeating that high prices are necessary due to the costs of research and development (R&D). **This is not true.**

There is clear evidence showing the huge difference between the COST and PRICE of medicines, while still allowing for a profit margin. We also know that the practice of extending patents actually *stifles* innovation, leading to less medical breakthroughs. After-all, when a company can get away with extending or ‘evergreening’ a patent beyond the original 20 years there is less incentive to invest in new drugs.

It is here that I would also make a few comments about WHO's definition of fair pricing: *A fair price is one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines. In this context, fairness implies positive incentives/benefits for all stakeholders, including purchasers and those involved in the research and development and manufacture of medicines.*

In many ways the WHO's definition reinforces this **flawed assumption** of linking innovation with prices. As South African activists pointed out yesterday, the beginning point for this discussion **is in transparency of costs, R&D expenses and pricing** but its not clear that this is even part of the discussion on fair pricing.

When we see what big pharma spends on R&D and how that is dwarfed by what they spend on marketing, we see that the assumption that a certain price would incentivise innovation may not be a correct one.

The definition also over-simplifies the roles of different actors:

- it characterises governments and patients as **buyers**
- and pharma as **innovators and suppliers**

When we know **that this is not the case.**

The case of the new MDR TB drug bedaquiline shows that nothing could be further from this scenario.

There is an extraordinary amount of public funding from governments around the world being poured into clinical trials on this medicine. And a large number of people with MDR TB taking this medicine and the data from their experiences with this medicine are all going towards clarifying how and when this drug should be used – there is in effect a global peoples phase III trial on bedaquiline.

So the governments and the people are not simply buyers here. A USD400 price was practically forcibly announced by South Africa to be available to other developing countries; but we know that even with a profit bedaquiline could be priced at around USD 50 to for a six month course.

The choice facing countries is to continue with the older MDR Tb drugs that can feel like fire when being injected, could make you deaf or in some cases psychotic. **Janssen meanwhile** is of course focussed only on extending its monopoly on this drug through evergreening.

It is notable that the WHO itself has declared TB an emergency as far back as 1993. And an emergency is the one area that even big pharma agrees that the governments should act.

You want a fair price on bedaquiline? We need multiple countries **to immediately** issue compulsory licenses on bedaquiline where patents on the molecule have been granted. And to revoke or reject patents on the evergreening of bedaquiline.

The WHO definition of fair pricing also **seems completely oblivious** to the political context of patents and pricing. Of the pressure, lobbying and strong arm tactics big pharma and several developed countries employ **to force countries not to use TRIPS flexibilities or price controls.**

Of the pressure that developed countries like the US are now putting on UN and international agencies that support the work on TRIPS flexibilities. **You think that the Pretoria Trial is history? You are wrong...** It is the same drug companies who are lobbying the US government to take sanctions against UN agencies because they support the use of TRIPS flexibilities... You have probably seen their report submitted to USTR few weeks ago.

The Fair Pricing forum cannot and should no de-politicise the context in which developing countries are able to make medicines, procure medicines, regulate their prices, regulate their patents, prevent further monopolies, prevent evergreening and other abuses of the patent system.

With a pure focus on “positive incentives” I fear that this will inevitably be the result of any discussions in this forum.

So I get back to the question: Are we there yet?

No. Not even close. People with cancer, TAC, SECTION27, the Cancer Alliance and so many other groups rallied outside the venue of this meeting to demonstrate exactly that. And to show us that the situation is even more grim for diseases outside of HIV.

High prices or unfair prices are a **SYMPTOM** of a system gone **horribly wrong** and flawed to begin with. If we do not fix the system, the abuses will continue. And as any one in the health sector knows and surely the world's health agency knows this better than any of us; **treating the symptoms might provide some short term relief, but in the end you have to treat the disease itself.**

So from the history of HIV medicine pricing what lessons can we draw:

Lesson 1: A sustainable response to HIV, TB, hep C, cancer and indeed any other disease cannot be achieved without tackling the overpricing of medicines. And the overpricing of medicines cannot be tackled without challenging the abuses of the patent system.

And make no mistake this is a problem now in all countries regardless of the income classification that the World Bank gives to us.

A classification that has been used to deny patients in many countries access to affordable medicines. It is a classification I have been forced to use in this presentation because this myopic, cold view of the world has allowed companies to play havoc with universal access to medicines.

But getting back to my point, a study by our friends at I-MAK on 12 of the US's highest-grossing drugs found astonishing results that we must take note of as it is this very system that is now being implemented in all our countries:

- There are 125 patent applications filed and 71 granted patents per drug.

- There are 38 years of attempted patent protection blocking generic competition sought by drugmakers for each of these top grossing drugs – or nearly double the twenty year monopoly intended under U.S. patent law.
- Over half of the top twelve drugs in America have more than 100 attempted patents per drug.
- AbbVie, which markets the world's number one selling drug, Humira (\$18bn in global sales in 2017), is also the worst patent offender with 247 patent applications.
- Herceptin, a cancer drug sold by Roche / Genentech, had patents first filed in 1985 and has current patent applications pending that could extend patent exclusivity until 2033, a 48-year potential monopoly span.
- **And what did they find on the prices: Prices have increased by 68% since 2012, and only one of the top twelve drugs has actually decreased in price. These top grossing drugs have already been on the U.S. market for 15 years.**

Lesson 2: Unjustified patents enable drug companies to charge exorbitant prices for key antiretroviral drugs – particularly second and third-line drugs. As our colleagues in the cancer movement in South Africa have shown, this is true in every disease area. And in every scenario we can see that a fair price is possible only when there is unrestricted generic competition.

I want to specifically distinguish this from the era of managed competition through voluntary licenses that we find ourselves in today. These licenses exclude many developing countries. While these licenses may be useful for covered countries, if we are not careful and rely only on these we may undermine the use of key TRIPS flexibilities and entrench big pharma's control on key medicines in countries left out of the license – by entering deals with key suppliers they effectively cut off supply options for excluded countries leaving governments and patients at the mercy of big pharma and their patents.

Lesson 3: TRIPS flexibilities work! They really do!

Since 2014, ITPC has worked with key civil society organisations in Argentina, Brazil, Thailand and Ukraine to challenge unmerited patents. By July 2018 we had significantly exceeded our target savings of \$140M USD. Our actions catalyzed an average price reduction of 67% across 15 target ARVs in the four countries and contributed to total annualized savings of \$472M. These savings were achieved by an ecosystem of actors, within which the ITPC consortium played a catalytic or enabling role in challenging patents, strengthening patent laws and policies and providing leverage for price negotiations. From this year onwards, we plan to expand this work from 4 to 17 countries!

Lesson 4: Treatment activism, treatment activists, are the heart and soul of the use of TRIPS flexibilities and challenging the power of big pharma

Civil society, and in particular people living with HIV or hepatitis C or cancer, have a unique perspective on the issues of access to medicines. These organisations and networks have painstakingly and often with little or no funding learnt to use TRIPS flexibilities like filing patent oppositions. They use mobilisations, demonstrations, dialogue and difficult legal work. They stand up with their governments and create counter pressure to that of the EU

and the US. Earlier generic companies would file patent oppositions and even CL applications – in today's world where they are tying up with big pharma, it is now left only to CSOs to file these challenges.

And it is a great pity that many developing country governments see the work of civil society in a negative manner. With the wave of right wing conservatism taking root in many countries not only is the work of many of our groups and partners under threat, their freedom often is as well. Crackdown on NGOs, limits on their funding are all negatively impacting the work of organisations working on access to medicines. Global agencies turning away from developing countries are only making the situation worse.

And finally Lesson 5: We know from hard experience that any initiative based on the goodwill or generosity or on negotiations with big pharma – whether they are price discounts, donations, negotiations voluntary licenses – will inevitably work against patients and governments. If you focus your energies on the language of the market, then you will be left with market segmentation, with false and artificial economic classifications by income, and you are left with market logic. As Lorena di Giano of FGEP in Argentina, a lawyer and woman living with HIV who has filed successful patent oppositions in Argentina says: we are people, not markets.

Finally, I would like to remember Jonas Salk, the inventor of the polio vaccine, who when asked *“Who owns the patent?”*, famously said: *“The people, I would say. There is no patent. Could you patent the sun?”*

Medicines are public goods. And until we start treating them as such, we will not be able to truly deal with the multitude of problems of drug pricing.