

# Medicines Law & Policy

## WHO 4th Fair Pricing Forum, 6-8 February 2024

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I would like to thank the World Health Organization for the invitation to speak at the 4th WHO Fair Pricing Forum.

I started working on medicines pricing in the late nineties, with Médecins sans Frontières. At the time, medicines to treat HIV/AIDS had begun to turn the deadly disease into a chronic one. But only for people living with HIV in the North; elsewhere in the world, people with HIV died.

Antiretroviral medicines needed to treat the disease had a price tag of 10,000 to 15,000 USD per person per year and were out of reach of most people. But their actual cost of production was modest: once generic manufacturers brought ARVs to the market in the early 2000s, prices fell more than 90%.

The following elements made this happen:

- HIV medicines were added to the WHO Essential Medicines List.
- WHO prequalification of medicines assured quality and confidence.
- As of 2003, funding mechanisms such as the Global Fund and the US President's Emergency Fund for Aids Relief became available.
- Flexible approaches to intellectual property were introduced, including extensive [use of TRIPS flexibilities](#) by countries following the adoption of the Doha WTO Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health in 2001.
- Since 2009, the work of the Medicines Patent Pool (MPP) assured patents on new ARVs did not pose a barrier to the production of low-cost generic HIV medicines.
- And finally, there was transparency: the prices paid for ARVs were collected and were made publicly available almost in real time.

Today, [the Global Fund procures](#) the three-in-one HIV medicine (tenofovir disoproxil fumarate, lamivudine and dolutegravir) for under USD 45 per patient per year, supplied by the sublicensees of the Medicines Patent Pool. Through the work of the MPP, price reductions have been achieved for some other treatments, mostly for infectious diseases such as hepatitis C medicines and more recently for Covid-19 therapeutics (but not vaccines).

And none of the above would have happened without relentless efforts by treatment action groups and their supporters, intense debates at the multilateral institutions, and legal action.

Despite the significant progress made in HIV treatment – and some other infectious diseases – we have to recognise that almost a quarter century later, the lessons have not been learnt for other diseases. New medicines for the treatment of non-communicable diseases, such as cancer, and for rare diseases are priced very highly. Even wealthy nations are struggling to pay for them, leading to a lack or delay in access and rationing of care.

Let's look at a few examples:

### Cancer

The [2021 WHO Expert Committee on Essential Medicines](#) did not recommend the inclusion of a number of effective but highly-priced cancer drugs in the EML because of concern about the displacement of other healthcare at the country level and fear of negative effects on the affordability of healthcare services overall. The committee requested the Medicines Patent Pool to explore licensing possibilities for these oncology medicines, to see if their prices could be brought down to a workable figure.

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Since 2018, the MPP has had a mandate to work on all essential medicines. But so far, the MPP only has one [licence agreement for a cancer drug, with Novartis for the leukaemia medicine nilotinib](#), which was signed in October 2022. The base compound patent expired in July 2023, 9 months after the agreement was signed. The agreement now only has relevance for secondary patents granted or pending in 7 middle-income countries. Therefore, the agreement was mostly symbolic and the hope was that other cancer drug licences would follow. Unfortunately, it remains the only patent licence agreement with the MPP for a cancer drug.

## Orphan drugs

Cystic fibrosis (CF) is a rare genetic disease affecting over 160,000 people globally. Most children born with the disease will, without treatment, die before their first birthday. A new treatment, Trikafta or Kaftrio (containing elexacaftor/ivacaftor/tezacaftor) [offers a normal life](#) expectancy. But access is confined almost exclusively to high-income countries. And even some of those have difficulty affording the high price of the product. In the EU, CF patients in Lithuania cannot access the products. Trikafta's list price is USD 325,300 per patient per year. A generic version is available at USD 48,700. [The estimated cost of production is USD 5,700](#), showing a generous profit margin. The company that holds the market monopoly, Vertex, has spent USD 12 billion on R&D in the last 22 years and made USD 32 billion in the last 5 years with CF products. Still, the company refuses to allow generic producers to enter the market.

## Advanced therapeutics

New cell and gene therapies carry extremely high prices. For example, [the gene therapy Libmeldy](#) to treat children with metachromatic leukodystrophy (MLD). MLD is a very rare genetic disease. In the Netherlands, 1-3 children a year would be eligible. Its wholesale price is €2,875,000 (2,787,571 USD) per dose. Paying for three children would have a budget impact of 9 million. [As one health economist pointed out](#), this amount is the equivalent of paying a year's salary for 250 community nurses. The health minister rejected the reimbursement and the Beneluxa initiative (a joint health programme involving Belgium, the Netherlands, Luxembourg, Austria and Ireland) negotiated for a year to reach an agreement with the manufacturer. The agreement was [announced](#) in January of this year; unfortunately, the price agreement has not been made public.

## Covid-19

The Covid-19 pandemic has again put the spotlight on the need for better mechanisms to ensure equitable access to vaccines and therapeutics. But also, the need for greater transparency of prices and cost. Prices of Covid-19 vaccines in Europe only became known through an accidental tweet by a health minister. This information also [revealed that South Africa was paying twice as much for the same vaccine](#). Equitable access to vaccines and other pandemic countermeasures is a central theme at the negotiations for the WHO pandemic accord and at the WTO, where proposals to manage IP on pandemic products have been discussed since October 2022. Recent news from the WTO General Council that the agenda item on the TRIPS Agreement and Covid-19 will be closed without a resolution on therapeutics and diagnostics only increases the pressure on the WHO talks to come up with ambitious provisions.

## What conclusion can be drawn at the 4th Fair Pricing Forum?

A fair price is a price the individual and the community can afford; a price that covers the cost of production, offers a reasonable profit for the manufacturer and the opportunity to recoup development costs. (A razor thin margin may not be advisable to secure supply of generic essential medicines.)

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High medicine prices - divorced from the cost of development and production - are sustained through monopolies that are granted through the patent and regulatory system. Without addressing monopolies in medicines supply, it will remain difficult to reach fair pricing levels. Countries can intervene and lift the monopoly, as they did for HIV. But it is not happening as much in other areas.

Pharma companies will be quick to point out that without monopolies, incentives to invest in the development of new medicines are lacking. This is probably true. However, there is insufficient transparency to assess how much exclusivity is actually needed. Where the data is available, an interesting picture emerges. [The WHO report of 2018 on cancer drug pricing](#) showed that the median time to generate revenue to fully cover risk-adjusted R&D cost is between 3 and 5 years of sale. The report concludes that “cancer medicines, through high prices, have generated returns for the originator companies far in excess of the R&D cost and financial rewards to finance and incentivise future R&D.” A [recent study published in the Journal of the American Medical Association](#) concluded that of the “60 new therapeutic agents approved by the US Food and Drug Administration from 2009 to 2018, there was no association between estimated R&D investments and treatment costs based on list prices at the launch of the product or based on net prices a year after launch.” The authors recommend that drug companies make further data available if they want to use the R&D cost argument to justify high prices.

Monopolies are granted without assessment of need. We advocate for the introduction of a sufficiency principle in the grant of regulatory exclusivity linked to the actual R&D expenditure to ensure this can be recouped but not exploited beyond need at the expense of the health care system. Further essential medicines should be licensed to the MPP.

Addressing monopolies requires addressing how to pay for the cost of R&D. This could be done through de-linkage models, where paying for the R&D is no longer dependent on the ability to ask high prices but done directly. Groups of countries could get together and start pilot projects. The area of antibiotic drug development would be a good place to start.

Drug and vaccine development benefits from significant public investment and this investment should be leveraged to create greater public good. Failing to do so was a huge missed opportunity in the development of the Covid-19 vaccines, which was largely de-risked by the public sector, but the know-how and resulting profits were privatised.

Governments and other funders of health innovation should attach conditions to ensure reasonable pricing and licensing requirements to increase equity in access globally and insist on a public stake in the control over the innovations. (A recommendation also made by the [WHO Council on the Economics for Health for All](#).)

Increasing transparency in the markets for medicines, vaccines, and other health products is crucial to making progress in fair pricing. The need for greater transparency was recognised in [2019 World Health Assembly resolution WHA 72.8](#) (which was adopted by the WHO member states with the exception of Germany, the UK and Hungary in 2019). The resolution [set new global norms](#) for transparency in particular for pricing information. In addition to net price transparency, it is also crucial that transparency of the cost for R&D be increased. Progress in the implementation of the resolution has been slow but [some countries are beginning to take legal action as is shown in a report published by the WHO European Regional Office](#). It is time for the World Health Assembly to assess global progress towards transparency in pharmaceutical markets and agree on a better way forward.

I thank you for your attention.