Charles Gore â?? Executive Director, Medicines Patent Pool (MPP)

> What we are trying to do is to get new drugs that are patented into low- and middle-income countries as soon as possible â?? trying to essentially shrink the gap between when they are available after they first become available in high-income countries

09.02.2023

Tags:

Global, Switzerland, Medicines Patent Pool, Intellectual Property, Generics, HIV

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Executive Director Charles Gore outlines the MPPâ??s goals, how it interacts with an industry â?? innovative pharma â?? known to jealously guard its intellectual property, and why voluntary licensing has the potential to foster mutually beneficial outcomes, not least access to medicines for patients that would otherwise go without.

Can you begin by introducing the Medicines Patent Pool, the roots of its conception, and the goals the organisation is trying to achieve?

The Medicines Patent Pool (MPP) was set up in 2010 by Unitaid, an organisation housed within the World Health Organisation (WHO) that focuses on innovation in the public health space. MPP was established as a solution to get affordable drugs for HIV to low- and middle-income countries. It did this by going to the big pharma companies that had new, patented drugs and asking them for a license that could then be sublicensed to generic manufacturers to produce affordable versions for a wider population. For various legal reasons it was decided that rather than being a project within Unitaid, MPP should be set up as a separate Swiss foundation in Geneva with its own board.

For the first couple of years, it was difficult to persuade companies to participate. It was a new idea and companies felt they were giving away intellectual property (IP). Therefore, we had to communicate that it was not about them giving away IP, but instead, reaching people they otherwise would not reach with a version of their product that has the same quality but is made much more cheaply by generic manufacturers without the overhead costs of developing the drug. Furthermore, the products are for markets that do not compete with the originatorâ??s primary commercial market. Overall, there are good reasons why the program makes sense for the industry, but it has required us to educate pharma companies as to the advantages.

The eventual success of MPP with HIV drugs suggested that it could be useful in other disease areas. For example, hepatitis C immediately came up because companies had wonder drugs that for the first-time cured people rather than merely managed the disease. The board therefore expanded to hepatitis C (and also TB), but unfortunately, it took a while to do this. During this time, Gilead, a leader in this disease area, set up a similar internal version of the programs themselves. More recently, we felt this model could also be used in even more areas, and we expanded to include nearly everything on the WHOâ??s Essential Medicines List or likely to be included in the future, in other words, key medicines that every country should have.

What role does the MPP play in delivering improved access to drugs compared to the normal life cycle of exclusivity and loss of patent?

For the MPP, the speed at which we can license drugs is a critical factor. If it takes a long time to put new products on the Essential Medicines List, they often do not have much patent life left and the generics can begin producing soon anyway â?? so the initiative becomes less useful. What we are trying to do is to get new drugs that are patented into low- and middle-income countries as soon as possible â?? trying to essentially shrink the gap between when they are available after they first become available in high-income countries. Otherwise, there is an illogical situation where a drug exists, it saves lives, but patients cannot get it because it is either not available in their country or it is not affordable. Through this idea of sublicensing to generic companies that will sell in those countries, we aim to change this system and make sure that medicines are both available and affordable.

When we do this, it saves the originator company from doing all the registrations and efforts that come with selling in those countries. Furthermore, those countries are simply not going to be able to afford the price at which the originator would like to sell their drug. We are effectively doing something that they are not able to do and therefore expanding the reach of these drugs.

Especially in the highly regulated pharmaceutical industry, originators hold their accomplishments closely. R&D costs are high and bringing a new drug to market is a lengthy process. What are the main concerns of industry players when it comes to voluntary licensing given that their business model relies on the commercial success of their products?

If a company has not previously interacted with us there are questions we have to answer. The first is very often key â?? if they grant a license to sell in low- and middle-income countries, how can we ensure that the drug does not end up being sold in key markets like the US or Europe? To tackle this, we have developed an advanced alliance management system. We monitor every single pack using export and import databases as well as direct reporting from the generic companies on a per pack basis to determine where everything is going. The MPP has delivered close to 30 billion pills to

date, mostly in HIV. This equates to about 1 billion packs we have successfully tracked. It is a huge amount of work and we have an office in India entirely devoted to tracking this. In general, the generic companies tend to operate according to these terms, but they may partner with a distributor who might then try to sell outside the designated market. In this case, we alert the manufacturer and they either stop working with the distributor or tell them they cannot sell into other areas.

Next, the quality level is very important, especially in infectious diseases where substandard quality could lead to antimicrobial resistance. Therefore, our generic companies need to get approval from a stringent regulatory authority for the product. This might include WHO pre-qualification or the US FDA when appropriate.

There is also this idea that they are giving away IP which is not the case. The originator company is only giving us a right in the form of a license, which allows us to reach high-need populations rather than their method of tiered pricing, donations, or bilateral deals, and much more efficiently. For example, if they do a bilateral deal with a generic company to provide for these countries, they have to manage the generic. Meanwhile, the MPP does all this for free.

How significant is the impact of these licensing agreements on the pricing mechanism for drugs in the target markets the MPP is focused on?

As these are now generic products, what we do is give licenses to several manufacturers so that they compete against each other. What typically happens in many high-income markets is that the originator has a monopoly, making it very difficult for a government to negotiate. However, if we have five generic companies producing the same drug, that gives authorities a lot of power to push the prices down. In HIV, where we have the longest track record, a course of treatment costs roughly USD 10,000 a year in high income markets. Our licenses allowed us to develop a product that is not even available in high income markets using a mixture of three drugs which is now the WHOâ??s first line recommended treatment. There are similar treatments available, but what we have put together is not available in many higher income markets because it comes from a regimen of drugs across different manufacturers. With the licenses granted to generic companies through the MPP, they have been able to do the science and come up with a series of combined drugs into new fixed doses.

When this was first launched into the market, it was USD 75 a year compared to the USD 10,000 for a similar treatment. Competitive pressure has now pushed that down to around USD 50 per person per year for HIV treatment. That really shows what we can do given the right circumstances. However, HIV is special because there are global procurers and most countries have significant HIV programs with diagnosis and treatments in place, along with guidelines from WHO. This is a lot simpler than for noncommunicable diseases, but nonetheless, it shows the benefits that can be achieved with this model.

You mentioned that Unitaid and the MPP started with HIV as the main therapeutic focus. Why was this particular disease chosen to be at the center of this model and what was it that made the effort so successful?

HIV was and still is a huge concern because of the burden of the disease, particularly in low- and middle-income countries, not just in Sub-Saharan Africa. Furthermore, the fact that society was so mobilised by HIV helped put pressure on the pharmaceutical industry to start thinking about new models for improving access. The MPP being a new model at the time, having that kind of pressure

was very useful in getting companies to consider the importance of our mission. Even so, today maybe only two thirds of the people living with HIV are being treated. We have not reached enough people through diagnosis or treatment and new infections continue â?? nearly 1.5 million a year.

Furthermore, there are countries that for political and philosophical reasons are opposed to HIV prevention. Pre-exposure prophylaxis is becoming an area of great importance, but there are drugs that could be taken daily or up to every two months. Adherence is essential for prevention, but it is often difficult to manage. Thankfully, there continues to be groundbreaking work done in this area resulting in drugs with longer lasting protection and there is exciting work happening around vaccines, such as using the mRNA platform.

MPP is involved in a project with WHO to set up mRNA manufacturing, by establishing the vaccine development platform in South Africa, and then transfer that technology to 14 other countries. In addition to the benefit that this would bring in pandemic preparedness, it will also potentially help to discover a vaccine for HIV. When the next pandemic comes along, we can hopefully get an antigen, slot it into the platform, and we will have local and regional production that will prevent the massive supply issue we faced with COVID. We are building this mRNA platform to be multi-disease enabled so that it can be used for diseases like HIV.

High-income countries are finally managing HIV rather well. Do you see any risk of the larger players perhaps losing interest in this disease area?

From an industry perspective, they have got to look at the best investment of their time and there is an opportunity cost for everything they do. In the last couple of years more and more companies have been divesting out of a lot of other areas to concentrate on cancer. The question is not just about HIV, but also major areas like antibiotics where we have the same question â?? how do we get players to continue to invest here? Luckily, there is still investment in the science of HIV, and I do believe advocacy plays an important role in motivating the world to continue tackling the challenge through innovation.

Aside from the mRNA platform project you have taken on with WHO, what is next on the MPPâ??s agenda?

Of course, I want to continue finding new partners while highlighting that our model can work in almost every situation. Currently, each of our licenses is bespoke â?? reflecting the commercial requirements of the originators, the burden of disease, and the specificities around each particular drug. From here, our big move is towards expanding the use of voluntary licensing because it has been underutilised up until now. We recently got our first cancer license, but we should be getting more licenses in noncommunicable diseases, as well as for the new patented drugs in other areas that are likely to end up on the WHO Essential Medicines List.

COVID has highlighted the need for equity and access; low- and middle-income countries cannot continue to go on like this. In my view, it is no longer morally acceptable to have a product that is priced out of the reach of the people who absolutely need it unless the cost of manufacturing is too high. There are always big questions about therapies like CAR-T and whether it is going to be available in low- and middle-income countries at least in the foreseeable future. This has also the approach with biologics; however, I think things are changing.

We need to be looking at how we can get some of these new biologics into low- and middle-income countries at affordable prices and I believe we can. Generic companies are becoming much more sophisticated in their ability to produce biosimilars and the regulatory environment is changing for the better. It is less likely to require phase III trials, which are expensive, and the cost of production is likely to come down.

Our aim is for every company to have an access program in place when they launch a new drug. Ideally, these programs should mean that access can be delivered within a year, not as an afterthought or ten years later when sales are starting to drop off in the high-income countries or competitors have entered the market.

What is important for pharmaceutical companies to know about MPP and voluntary licensing? What message would you like to deliver to the industry?

As a partner, MPP offers a lot of value to the pharmaceutical industry. Not only can we do a lot of things for the industry for free, increasingly, investors are looking closely at environmental, social, and governance (ESG) components and want to see these kinds of actions. In other words, having a good access program creates dollars and cents value in addition to having an impact on things like recruitment and staff turnover. I met someone recently that told me they chose to join their current company because it is number one on the Access to Medicines Index.

These things are of value to pharmaceutical companies, but I am not sure they have completely taken that on board yet. Still, the pressure that came out of COVID with respect to equitable access, combined with the realisation that there are dollars involved will shift the paradigm. The MPP model is not the only answer to this, but our program is sustainable in the long run unlike donations because generics make money out of it. Additionally, it is better than doing bilateral licensing. While tiered pricing is possible, the prices may be so low that it is of no interest to pharma.

In countries where they do not have a presence, an access program with generic versions could open up the market for the future. For example, in a country where the government does not buy cancer drugs through a universal healthcare scheme because they are too expensive, an affordable generic version can help create a budget line for these kinds of treatments. In this way, as countries become richer and move up into a new category, they have already opened the market.

As I have said, we are underutilised and there still lacks a real understanding of what we do or of the advantages we offer. I hope and believe this is going to change.

Part of the demands to the World Trade Organisation for a waiver of intellectual property were based on the fact that a lot of countries felt there was not enough access. One way of looking at it is, if the industry delivered better access, there would be less demand for waivers. By giving MPP a license, we may be protecting IP because if they share it, people will not be upset that the originators are keeping it all to themselves.

At the moment there is intractable opposition between countries that are saying there is no access and IP should be waived and the high-income countries that feel they must protect their industry. MPP can be a solution in the middle. Because our licenses are bespoke, we can make them work in a whole variety of different circumstances.

Originators keep asking if voluntarily licensing could work, and it is the wrong question. The question is, how, in a given situation, can we make voluntary licensing work? There in an excellent opportunity to find win-win solutions. It requires a lot of negotiation and it is not always easy, but it can be done.

See more interviews