Minutes of the meeting of representatives of the Medicines Patent Pool (MPP) and the EECA community

December 4, 2024

Organization: **Medicines Patent Pool**

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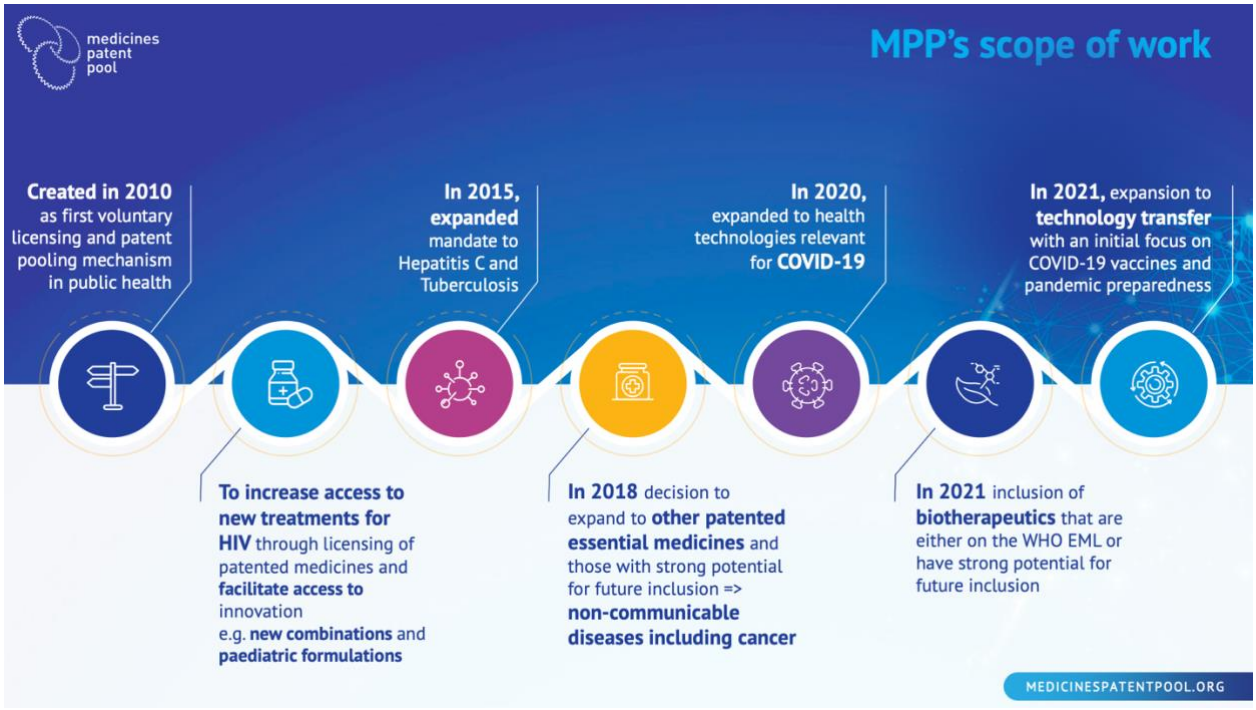
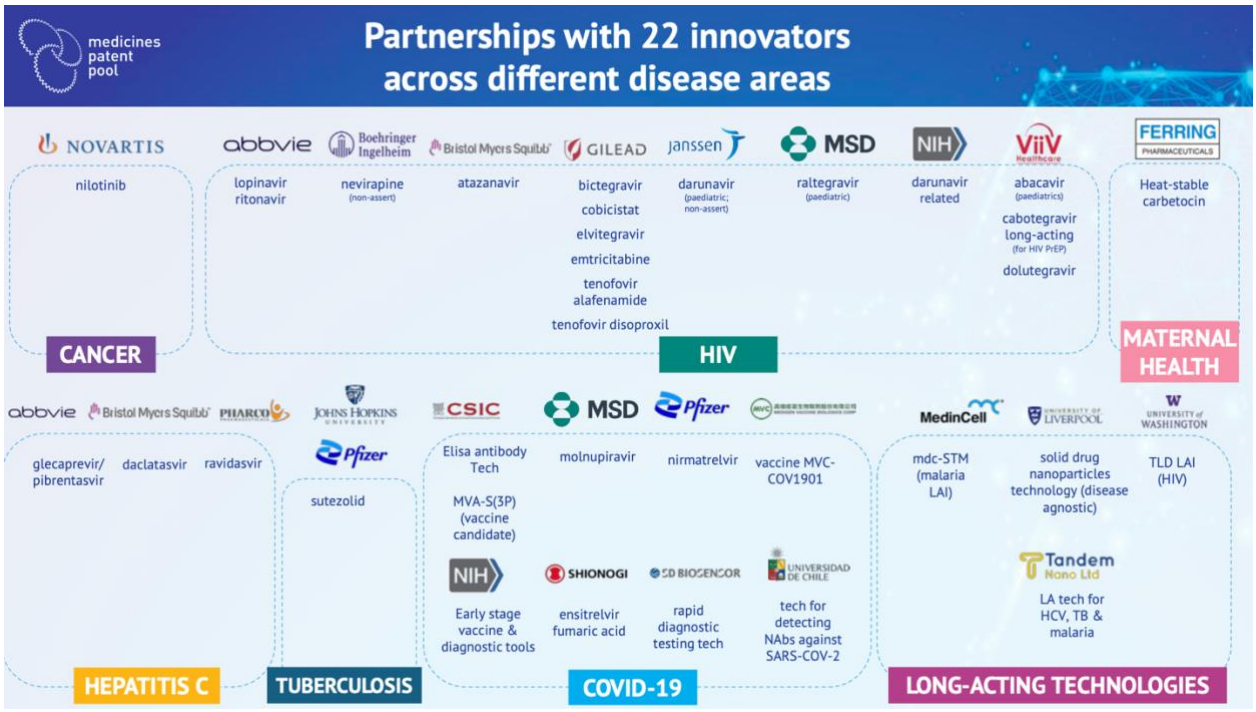
Start of the meeting. Introduction of participants.

Presentation of the Medicines Patent Pool.

Good afternoon, we will start with a presentation about our organization. The first slide shows how our organization has evolved since 2010. In 2010, the Medicines Patent Pool (MPP) was founded by UNITAID, with the support of the UN, as the first health-focused voluntary licensing mechanism. The original idea was that we would work to improve access to HIV treatment. And this is not just talking about existing treatments, but also new pediatric forms and new combinations, such as the tenofovir/lamivudine/dolutegravir (TLD) combination. As this model has proved to be working well in HIV, in 2015, at the request of WHO, governments and civil society, the model of work was expanded to include viral hepatitis C and tuberculosis. And also in 2018, at the request of policy makers, our mandate was extended to other patented drugs that are either already on the WHO Essential Medicines List (EML) or have the potential to be included on the WHO EML. Our mandate now also includes non-communicable diseases. In 2020, our mandate was expanded to COVID-19, and in 2021 to biotherapeutic drugs that are on the WHO EML or have the potential to be included in the EML. Also, our mandate has been extended to technology transfer. In terms of technology transfer, the primary focus has been on COVID-19, but we are now also prepared for the challenges of future pandemics.



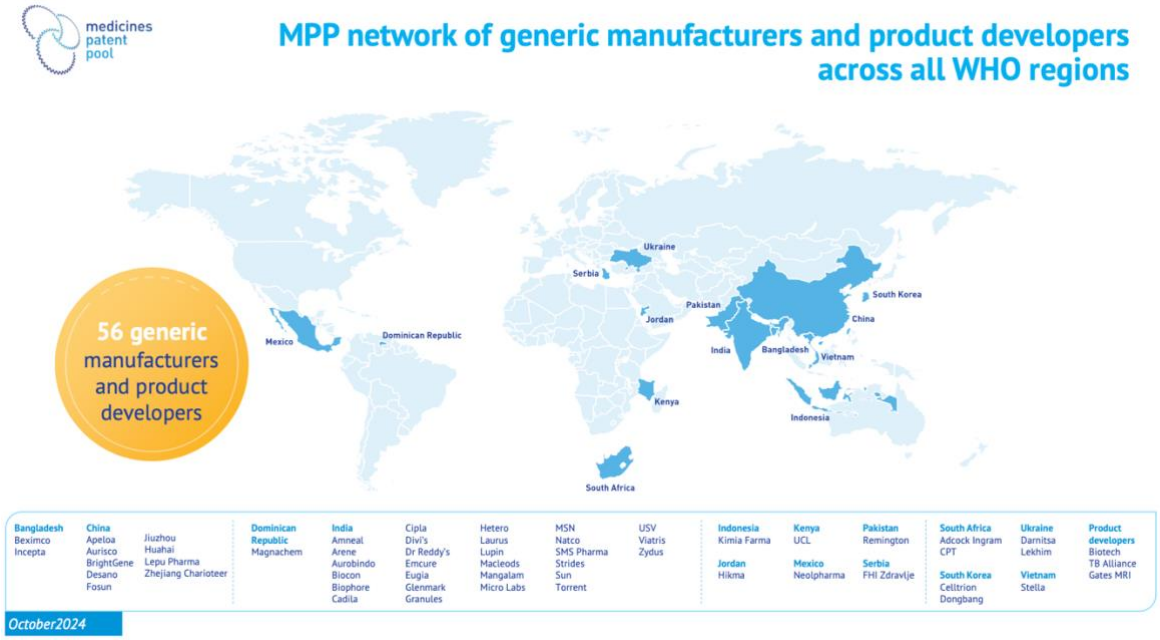
On this slide, you can see all the innovator pharmaceutical companies that we are currently working with.



On this slide, you can see our generic producer network, which includes 56 companies located in all WHO regions. At the bottom of the slide, you can see information about how many generic manufacturers are represented in each country and region.

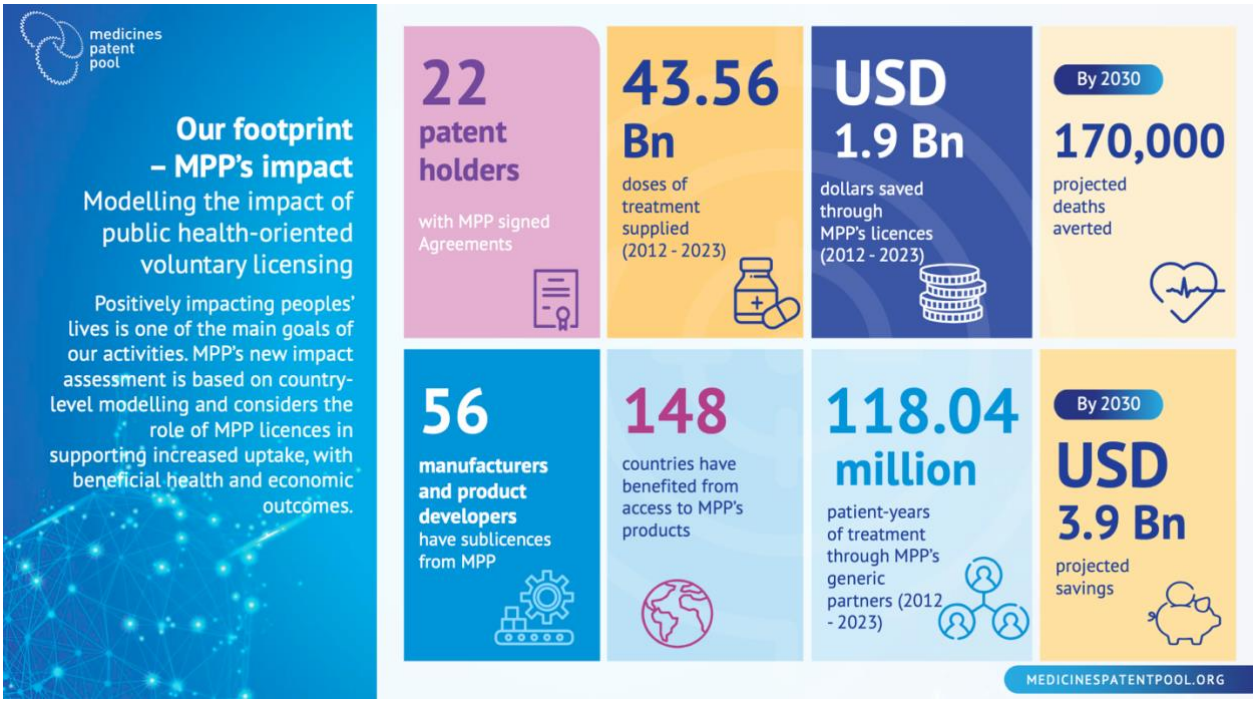
Question: As far as I understand there are two companies in Eastern Europe: Darnitsa and Lekhim in Ukraine?

Answer: Yes, that is right. They are also listed at the bottom of the slide.



And we are very often asked "Why is the approach to access through MPP a win-win solution for everyone?". Because it is a win-win approach for all parties of the process. For example, for patent-holding companies, it's a very good opportunity to ensure that drugs are available in low- and middle-income countries (LMICs). Also, our organization does all the license management, which means that the companies holding the patent do not have to deal with these issues. The costs associated with the distribution of the drugs are borne by the generic manufacturers. Also, patent holders targeting markets in high-income countries can expand the availability of drugs in developing countries. For 56 generic companies, it is an accelerated way to produce affordable versions of drugs. Our licenses also enable us to make the necessary forms, such as pediatric forms, which are often not produced by the original manufacturers. As well as fixed-dose combinations, such as TLDs. And for governments, working with MPP is an opportunity to treat more people with WHO-recommended and prequalified drugs for the same amount of money. For communities, it means better and faster access to drugs. For example, in situations where middle- and low-income countries have to wait until the patent expires before they have drugs that have been on the market for a long time in high-income countries, the MPP is a mechanism that allows medicines and other health products to get to markets in LMICs faster.

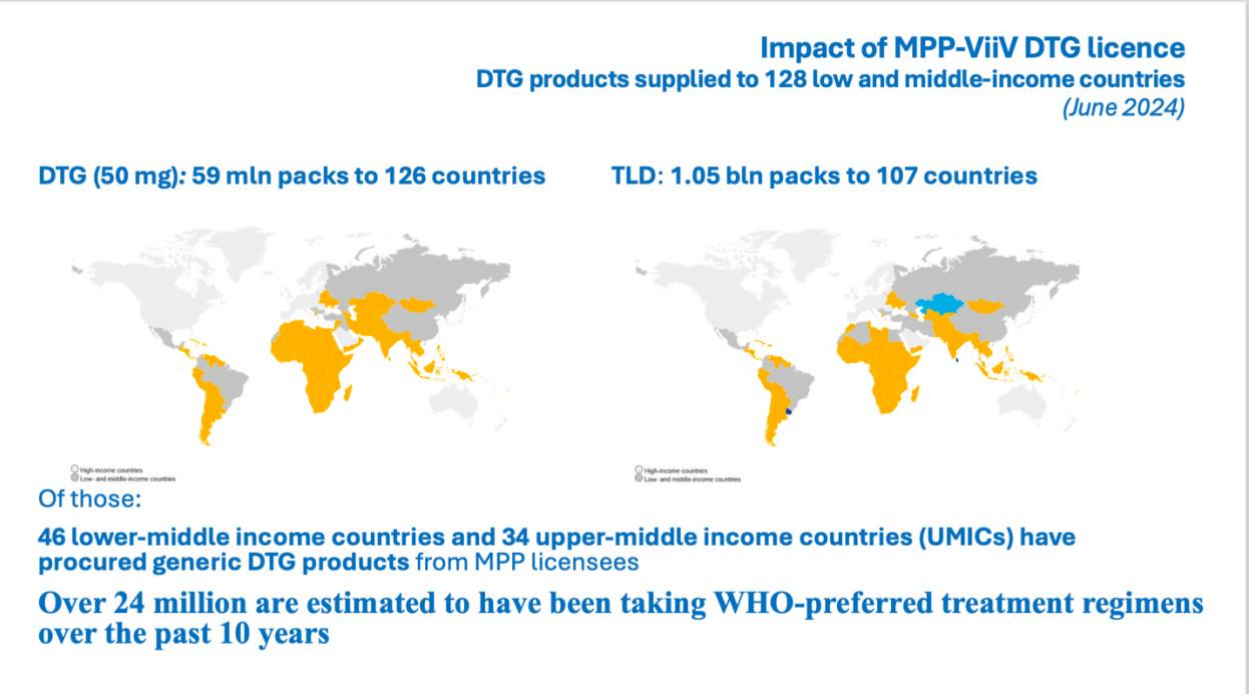
On this slide, you can see our impact on public health.



As I said, we work with 22 patent holders and 56 generic manufacturers. By the end of 2023, more than 43 billion doses of different treatments were delivered to 148 countries. Through the MPP licences, the global health community saved about $2 billion by the end of 2023. These figures are already much higher today, and new data will be published in 2025 when all the results have been compiled. We will inform you about that as well.

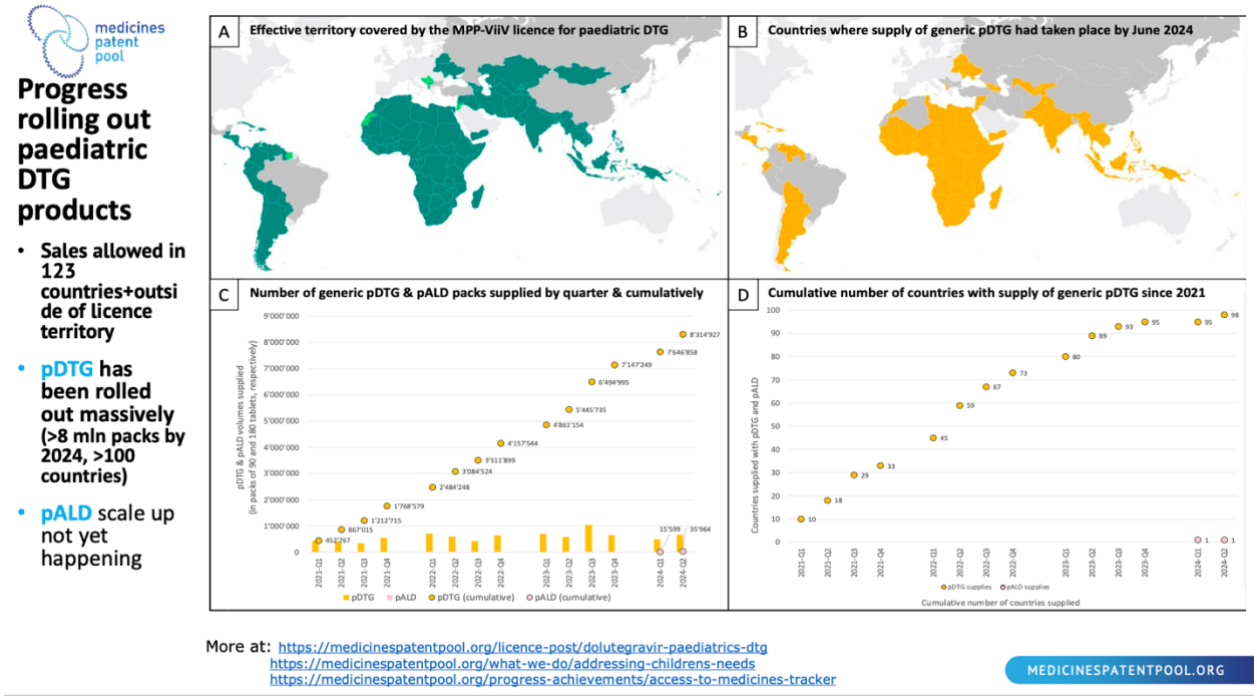
Now we want to talk a bit more about how our model works in practice. For example, the licence for dolutegravir, which is now 10 years old. The licence was obtained in 2014, right after dolutegravir was approved by the FDA (short for Food and Drug Administration). The switch to dolutegravir began after the WHO included the drug in its guidelines as first-line therapy. Since then, the procurement of dolutegravir and its combinations has been gradually increasing. And as of June 2024, 128 countries were procuring the drug from MPP licensees, the generic companies you saw on the map. It's not necessarily the case that all 56 companies are manufacturing and supplying dolutegravir, but many of them are doing so in LMICs. And of those 128 countries, there are 34 upper-middle-income countries. And as of June 2024, more than 24 million people are being treated with dolutegravir or dolutegravir-based products. Well, and as you probably know, the patent on dolutegravir expires in 2026, which means that after that point, all countries will be able to procure generic dolutegravir and DTG -based combinations.

Then on this slide you see two maps that show that 59 million packs of dolutegravir were supplied to 126 countries and more than 1 billion packs of the TLD combination were supplied to 107 countries. 34 of them are upper-middle-income countries and 46 are lower-middle-income countries.



Another license for dolutegravir is a separate licence for pediatric form of DTG (pDTG) . This licence allows 123 countries to procure generic pediatric dolutegravir and combinations. In addition, the remaining countries that are not included in the license, and that either do not have a patent on the pediatric forms or have a challenged or compulsory license, also procure the drug from MPP licensees. Generic manufacturers such as Mylan and Macleods supply the pediatric forms of dolutegravir in these countries. In all MPP licensees, quality assurance is provided by WHO prequalification and approval by regulatory agencies.

On the slide, you can see that the green color on the map shows all the countries that are included in the MPP license for pDTG. And on this map, the light green map shows those countries that are not included in the MPP licence for paediatric DTG but, same as in adult DTG licence, the paediatric DTG licence provisions enable procurements of generics from MPP licensees as there are no patents in place.

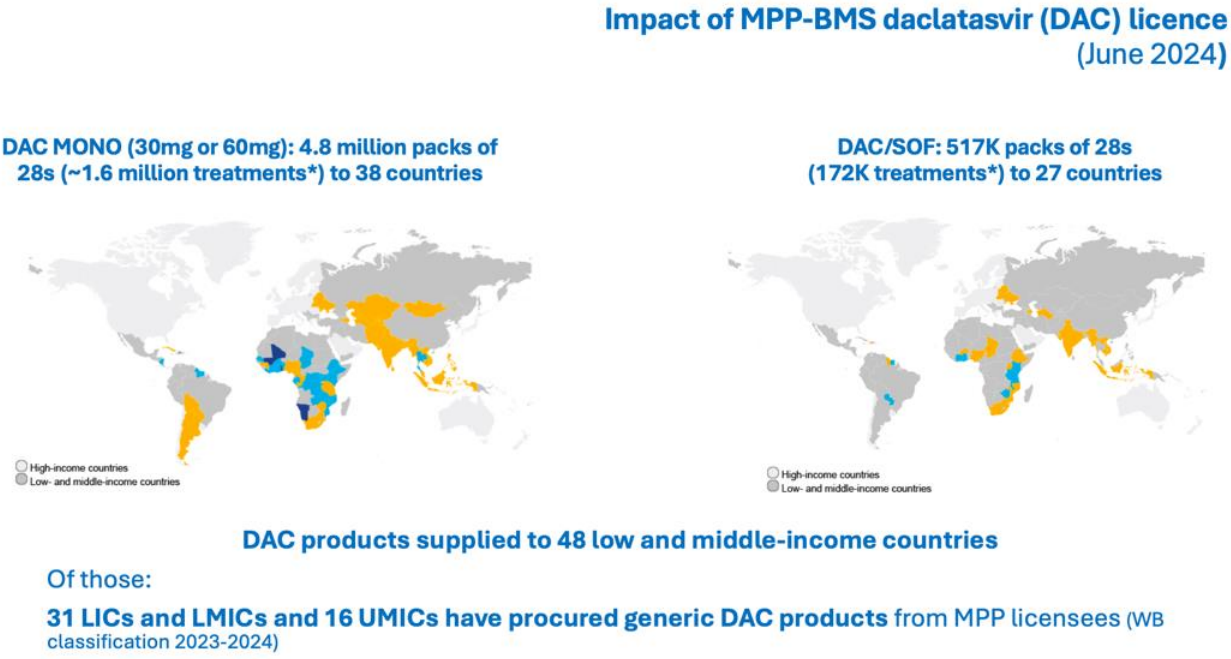


The yellow color on the map shows all countries that have procured more than 8 million packs of pDTG as of June 2024. So, we can see a massive transition to pDTG.

And the other good news is that the pediatric abacavir/lamivudine/dolutegravir (pALD) combination has now been developed and approved. There is not a massive transition to this new combination yet, because countries are still in transition to pDTG. But WHO and us, in our turn, regularly inform countries that this combination is available and, if necessary, can be procured. You, as a community, are more than welcome to inform countries about the availability of this new combination.

Another example is daclatasvir (DAC) and the daclatasvir/sofosbuvir (DAC/SOF) combination. The license was concluded in 2015 by MPP and BMS. This license did not include royalties and the quality was guaranteed by WHO prequalification and strict regulatory agencies. The license initially covered 112 countries and was later expanded to 39 countries. In total, the license currently covers 151 countries. Now generic daclatasvir should be available worldwide, as BMS has abandoned the patent. In Russia, there is a bilateral agreement between BMS and a Russian company to produce generic daclatasvir (DAC) in Russia. Until recently, a benchmark price for the DAC/SOF combination per course of treatment was $72 ($24 per pack). In April 2024, a new benchmark price of $60 per course of treatment (three months) was announced at the Global Hepatitis Summit in April 2024. We also know that in some countries, such as India and Pakistan, the price might be even lower.

On the maps, you can see that daclatasvir and its combination have been supplied to 48 countries. We can also see that the procurement volumes are not as big as in HIV. They are gradually increasing, but still, they are not as large as the procurement volumes of HIV medicines.



At a recent event, we were asked, "What does MPP bring to the global health?". The first thing we bring is our experience in voluntary licensing, which is focused on public health needs. There is an organization called ATMI (Access to Medicine Index) that evaluates different access models. This organization has recognized MPP licensing model as the one most focused on access and the needs of public and global health. Our licenses are transparent and they are published on the MPP website. They are also non-exclusive, which implies a large number of licensees to ensure competition driving the prices further down. We have two networks of generic manufacturers: one network is the one I have already mentioned (56 generic manufacturers and product developers) and the other is the 15 manufacturers of the mRNA Technology Transfer Program that is implemented with WHO.

We are open to expanding our manufacturing networks in the regions and strengthening regional production. In our work, we engage with global organizations such as WHO, WIPO, WTO, UNAIDS, UNDP, MSF and others. Also, engagement with governments and civil society as well as procurement agencies plays a very important role in our work. We also have experience in such consortiums as ATOM (cancer consortium), H-TAP, GAP-F, LA PrEP Coalition and others. In addition, we have the MedsPal database, which is a database on patents on medical products, as well as LA PAL, which is a database on patents on long-acting technologies, and VAX PAL, which is a database on vaccines.

I would also like to mention that cooperation between ECAT and MPP has been going on for several years, and the results of this cooperation are improved access to HIV and viral hepatitis treatments in the EECA region.

Question: What new drugs or technologies have recently been licensed through MPP, and what are the expected benefits to global health?

Answer: On this slide, you can see all the products and technologies that we have licenses for. All diseases are represented here.

As you can see, we have quite a large list of HIV medicines, including abacavir (pediatric), atazanavir, bictegravir, long-acting cabotegravir, cobicistat, dolutegravir, elvitegravir, emtricitabine, lopinavir/ritonavir, nevirapine, pediatric darunavir, pediatric raltegravir, tenofovir alafenamide, and tenofovir disoproxil fumarate. For hepatitis, we have daclatasvir, glecaprevir/pibrentasvir, and ravidasvir. For tuberculosis, we have sutezolid.

We also have in our portfolio products for maternal health, one product for cancer and some technologies for long-acting therapeutics.

I want to elaborate on the long-acting technologies. There is one item there, which is related to the technology for the production of a prolonged-acting TLD drug. This is a technology that we are now investing in and consider promising. It is being developed at the University of Washington with the support of UNITAID. It will take us many more years to develop, but in the long term it could become a full-fledged three-component prolonged drug.

There is another important long-acting technology that is being developed in therapy for viral hepatitis C, it is a long-acting glecaprevir/pibrentasvir-based drug. This is planned to be a single injection to treat viral hepatitis C. The long-acting technology will be based on the glecaprevir/pibrentasvir (G/P) combination. If successfully developed, the long-acting drug will be administered once and there will be a cure effect due to a prolonged release. The technology is being developed in collaboration with the University of Liverpool.

And another long-acting technology to prevent latent TB infection is being developed with the University of Liverpool. The idea is also to replace the daily pill with a single injection.

The other part of your question was related to the expected benefits that global health will see due to the licensing of these products. That is quite difficult to predict because the products are different and

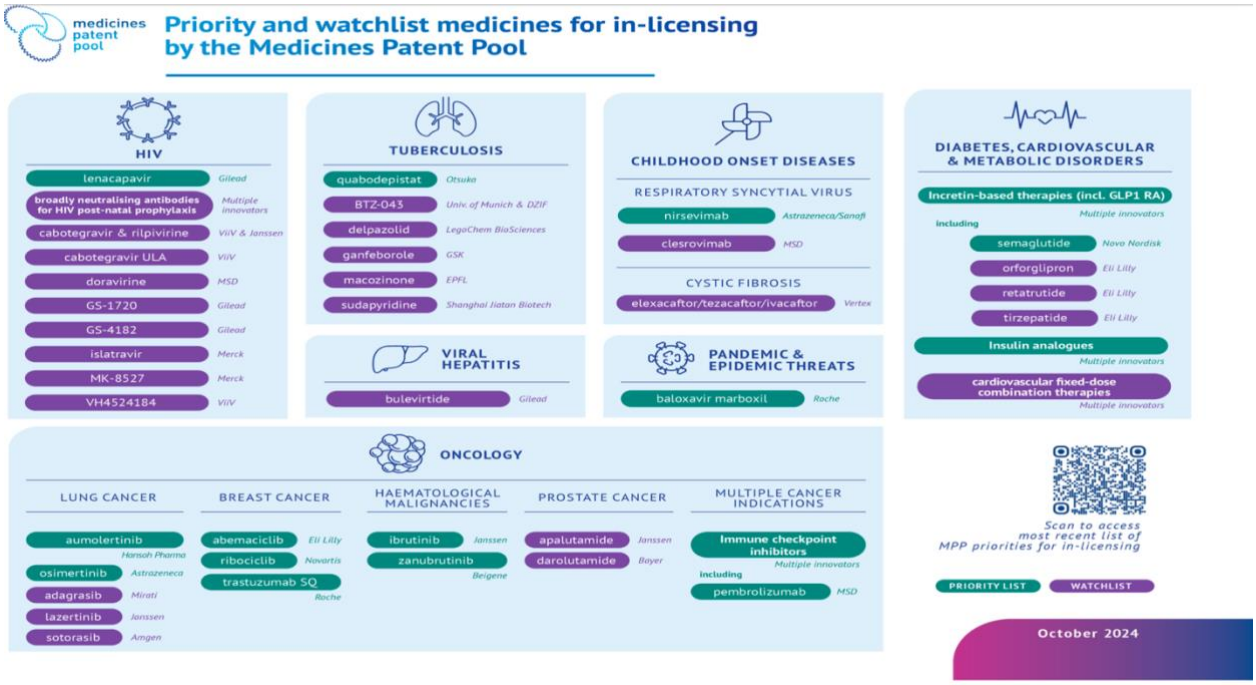
the benefits can vary. But a lot will depend on how an epidemic develops and the extent to which governments take proactive steps to promote and use certain technologies.

For example, in the situation with pre-exposure prophylaxis (PrEP), a lot will depend on the position of the community, and how much the product will be demanded by the community. For example, everything may look great on paper, but we will have to look at how much communities will want to use it, how much it will be included in programs, and how much donors will want to fund it, and so on.

A lot will also depend on the development of the countries' healthcare system, including how well developed the diagnostic network is, and whether healthcare programs are willing to cover the costs. A lot also depends on how much clients themselves will be willing to pay from their own pockets. And the situation is very different depending on the disease. For example, if we take HIV, we have strong national programs and government funding. We estimate that we have supplied 43 billion doses of drugs, under the licenses that we have now. And as mentioned earlier, we've achieved almost $2 billion in savings in various programs. We're expected to achieve $4 billion in savings by 2030.

Question: What drugs, vaccines, and diagnostics is MPP considering for licensing in the coming years, especially for HIV, TB, and viral hepatitis treatments?

Answer: On this slide, we have a complete list of the drugs that are prioritized and for which we are tracking progress. They are in two colors: green and purple. The green ones are those that are prioritized for us, and the purple ones are those that we are monitoring and trying to see how much they might be prioritized in the future. Of course, the list may change and we may add new drugs.



I will mention the priority drugs for some diseases. For HIV, long-acting lenacapavir. For tuberculosis, quabodepistat. For diabetes, semaglutide. Also, on the list of what we plan to monitor:

broad-neutralizing antibodies, cabotegravir/rilpivirine combination, ultra-long-acting cabotegravir, and bulevirtide for hepatitis D.

Question: What should happen to move a drug from the "watch list" to the "priority list"? Can you tell us more about the criteria you use to put a drug on the priority list?

Answer: We use several criteria. The first criterion is disease burden, and it is the most important. The second criterion is the current intellectual property environment. The third criterion is whether there is a clear regulatory pathway for approval of the drug. Another criterion is whether the drug has prospects for widespread market distribution. And yet another is the production cycle, and how difficult it will be to produce the drug, and how quickly generics manufacturers will be able to produce and bring the drug to market. There is also the issue of making the product available in programs, for example, whether there is a diagnostic network for the disease, or how the drug is available in the healthcare system. And finally, the clinical perspective, which is how the product will benefit patients compared to existing options on the market. We usually include a drug into the watch list for the following reasons: the first reason is that there is insufficient data to make a definite conclusion on the product assessment. Secondly, there may be challenges with the product in terms of the product not being able to be used with any other co-infections, or it might not be possible to make the product available to the end user. And the third reason is that we, in our turn, may not have completed a full product assessment. That is, we have already identified it as one of the priority drugs, and while it is in the process of full assessment, we have put it on the "watch list".

Question: How long can a complete assessment of bulevirtide take?

Answer: We are closely watching this drug because we realize that this is currently the best option on the market. But right now, we do not have enough data to say whether the drug will be effective enough or not. We have had discussions with experts who have also expressed great expectations about bulevirtide, that it will end up being a very effective drug. We expect that by the end of next year, we will have more data. We also have information that more data will be presented at the EASL conference. Again, the drug is seen as promising, but since there is not enough data, we cannot move it to the "priority list". We would also like to know your opinion on this drug, namely: how much of a priority is this drug for your countries? Although we are consulting with experts and WHO representatives, it is very important for us to know what the community thinks about this drug.

For example, some of the drugs on the slide must be stored in a refrigerator. Do you think there will be difficulties with the delivery and use of bulevirtide?

Question: Are there any preliminary negotiations with the patent holder on the possibility of concluding a license for bulevirtide? As far as we know, Gilead is not the only patent holder. Hepatera is also involved in the production and marketing of the drug in the EECA region. We would also like to add that there is already enough data on bulevirtide based on studies conducted in Russia.

Comment from a representative of the patient community: The fact is that the issue of transportation or storage is not of particular importance now, as the drug is life-saving. It is currently the only drug that can save the life of a hepatitis D patient.

Answer: At the moment there have been no formal negotiations with the companies. Usually, as long as a drug is on the "watch list", we do not have sufficient grounds to make a full-fledged proposal to a patent holder. There may have been informal discussions, but I need to clarify this with our team.

It was extremely important for us to hear your opinion about the drug, and the need for it for patients.

Because bulevirtide is an injectable drug and must be administered by a healthcare professional. How difficult do you think it will be for patients to visit a healthcare facility every day to receive injections?

Comment from a representative of the patient community: For example, in Kyrgyzstan, the community succeeded in having bulevirtide included in the national clinical protocol. In our country, the healthcare system is ready to ensure that patients receive the drug and set up a system if its affordability is ensured. And people with hepatitis D are willing to take injections every day to save their lives. There are no other treatment options for them right now. Many patients from Kyrgyzstan moved to Russia to participate in clinical trials and receive the drug.

Answer: Are there other countries in your region that are now showing interest in this drug?

Comment from a representative of the patient community: Yes, all countries in the EECA region are interested in this drug. And in our region, Hepatera holds the rights to the drug.

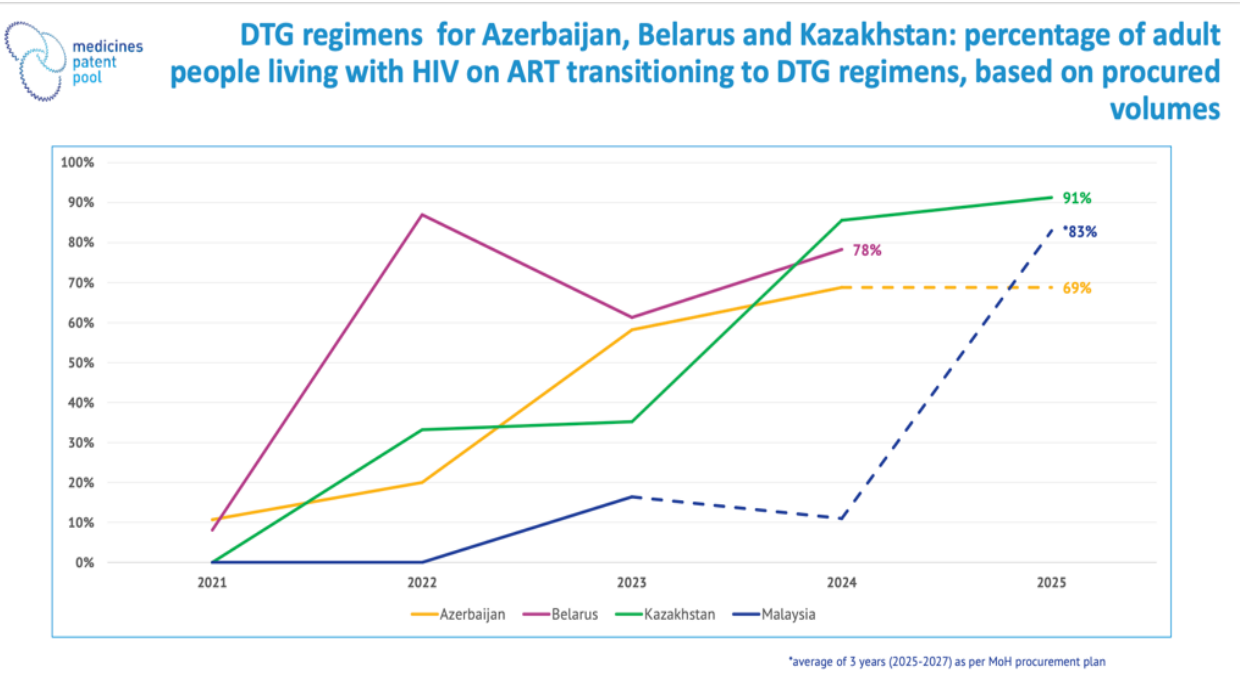
Comment from a representative of the patient community: If we talk about storage and cold chain, we should remember that pegylated interferons also required a cold chain. As we can see, any drug can be stored by the patient in the refrigerator. For example, in Kazakhstan, the first two injections of pegylated interferon were administered in a medical facility under supervision, and the subsequent injections were stored and administered at home by the patient himself.

Comment from a representative of the patient community: I have a suggestion: let us schedule a separate meeting on bulevirtide for all interested parties. This way we can have a more detailed discussion on the drug.

Answer: Yeah, that is a great idea.

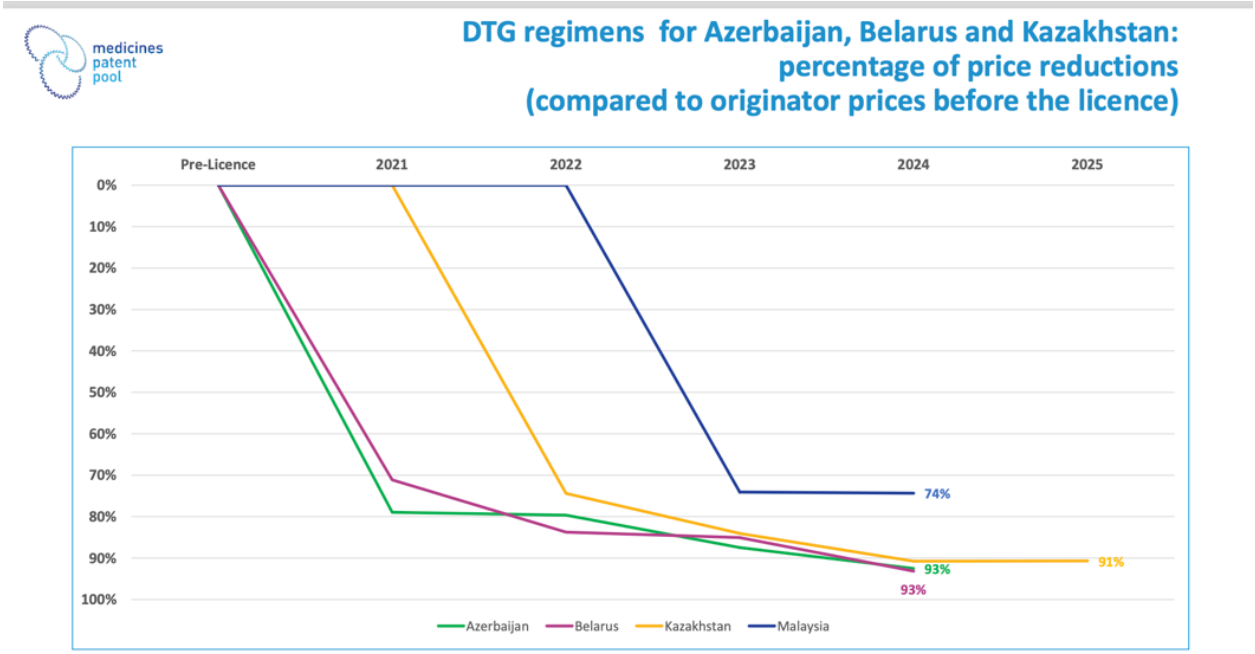
Question: In Kazakhstan and Belarus, there is an active transition to treatment regimens containing dolutegravir. Do you have any work/discussion on royalty reduction due to significant expansion of treatment coverage of patients?

Answer: You all know the terms of the license agreement, so we will not go into details. On this slide you can see the latest data on procurement volumes as a percentage of the number of people receiving treatment in the four countries that were included in the special license.



Once again, I would like to emphasize that the figures on the chart represent procurement volumes, and this does not mean that the drugs have reached the patients. These are the procurement volumes that are stated in the procurement contracts. And in the graph, you see the total quantity that includes the combination of TLD, ALD and dolutegravir as a mono-drug. This graph also does not include the pediatric forms.

And on the next graph, you can see the price decrease.



A request for additional royalty reduction due to increased volumes was submitted to ViiV. To date we have not received a response from the company. As part of the ECAT meeting, you will be meeting

with ViiV and we believe this is a good opportunity to also discuss with them on the royalty reduction request and why it is important.

Question: Yes, we certainly believe that lowering the price is a good thing. But can we talk about cancelling the special license and including these four countries in the main license? We have already negotiated with you and with ViiV, but we see no progress in reducing the price.

Answer: The issue of revoking the special license is not under discussion as we are seeing sa significant transition to dolutegravir in these countries following the licence and the price reductions . As mentioned, there is a request for further price reductions under this license and that is being discussed.

Comment from a representative of the patient community: We think we need to work with country legislations to prevent the patent on DTG from being extended.

Question: Will your organization make any statements on the need for changes in country legislation on its part?

Answer: I think our role is to work in the context of existing legislation. There are UNITAID-funded projects that aim to change legislation in countries.

Question: What prevented an agreement on lenacapavir between you and Gilead?

Answer: It is better to address this question to Gilead, not to us. We made our offer to them, but they had already entered into bilateral agreements for COVID-19 and hepatitis C before that offer, and the company chose this approach again. The point is that unlike other companies, Gilead has a whole structure tfor managing the licences and this may also be a reason why they choose this approach.

Question: In that proposal that you came out with Gilead, was lenacapavir only considered as a pre-exposure prophylaxis drug, or for HIV treatment as well?

Answer: Our proposal included all of the indications that lenacapavir could have.

Question: And your license proposal only included low- and middle-income countries? As you know, Gilead's current license does not include Latin America.

Answer: As is always the case in our initial ask, our request to Gilead was to discuss a possible licence in relation to all LMICs from low-income to upper-middle-income countries. We did not reach negotiations with Gilead. They received our proposal, decided to conclude the license on their own, and there were no negotiations.

Question: Will you continue to take any steps to negotiate better terms with Gilead?

Answer: As you can see, this drug has not been removed from the "priority list". It is difficult to say here, but we agree that the terms of this license could be improved.

Question: If we talk about tuberculosis, there are practically no anti-TB drugs on your priority list. Perhaps we should start prioritizing some drugs now, before they appear on the market?

Answer: I completely agree with you. We are discussing with several companies that have potentially promising molecules in development. But they all give us the same answer, which is that they don't have the funds to conduct full clinical trials in all three phases. Perhaps this is just an excuse. But they assure us that if we can help them find those who will fund their clinical trials, then they will be willing to discuss bringing the drugs to market as well. We can also discuss this in more detail with everyone who is interested.

Question: What is the current situation with cabotegravir? As you know, lenacapavir will already be on the market in the next few years. Have you negotiated with ViiV to expand the license for cabotegravir?

Answer: There are several ideas for cabotegravir that we would like to explore. First, to see whether we can expand the indications for the use of cabotegravir as a treatment that are included in the license. Second, we would like to explore whether possible to include the private sector in the license. Third, we would like to expand the list of countries in the treatment license. In terms of PrEP, this may be less relevant because your entire region would be covered under the voluntary license for lenacapavir. We would like to see an expansion of the list of countries in terms of treatment, but there are no negotiations underway. As you know, certain countries are not covered by the license for cabotegravir. But the most important thing for us at the moment is to see whether it would be possible to expand the indication for cabotegravir for treatment. It's important because now generic manufacturers around the world are hearing that "lenacapavir is the best option for PrEP," and expanding the indications for cabotegravir for treatment may be an additional motivation for generic companies to prioritize cabotegravir.

Question: Long-acting injectable cabotegravir is used together with injectable rilpivirine for treatment. What can you say about the availability of rilpivirine? And we would also like to know more about the tablet form of cabotegravir, as it is necessary to start treatment.

Answer: The patent for rilpivirine expires in 2027, and generics manufacturers will not be able to produce it until the patent expires. And if the global community has an interest in this product, we believe that we need to send a clear message to WHO and the international community that there is a need for rilpivirine.

Comment from a representative of the patient community: In our turn, we are ready to start negotiations with generic companies to bring cabotegravir to the market as soon as possible, if our countries, for example Kazakhstan, are included in the license. As you understand, we cannot do anything as long as the country is not in the license.

Comment from a representative of the patient community: If we talk about rilpivirine, the primary patent expires in 2027, but today in many countries patent applications for secondary patents have been filed. For example, in Ukraine, secondary patent applications have been filed for both pediatric rilpivirine and another form, which we are now actively challenging. And as you understand, secondary patents will also block access to the drug.

Answer: Thank you for your comments, it was important for us to hear that. We would be very interested to see also clinical trials of the cabotegravir/lenacapavir combination, which have not yet

been conducted. But at this point, there are already a few people who have received this combination off-label. It seems to us that it would be extremely important to have data from such clinical trials.

Question: Every year the question of the need to introduce additional (parallel) criteria, in addition to the World Bank classification, for inclusion of a country in the list covered by the MPP license becomes more and more acute. One of the latest notable examples is Ukraine. A country at war and totally dependent on external tranches, with a health budget that cannot cover needs without the help of partners and donors, has been classified as an upper-middle income country (due to the same tranches) since mid-2024. When will MPP start to apply more flexible approaches to assessing the needs of countries when deciding whether to include them in the license area?

Answer: We agree that the World Bank criteria are not perfect. We have tried to convince pharmaceutical companies to use more health-oriented parameters. Pharmaceutical companies in turn argue that countries themselves should prioritize healthcare and invest more in it, i.e. the higher the country's income, the higher priority should be given to healthcare.

End of meeting.

Additional questions.

Question: How does MPP work with WHO, the Global Fund, national governments and others to maximize global access to drugs?

Answer: MPP works closely with WHO, having official partner status. MPP experts are involved in drug prioritization, forecasting and advisory activities within the framework of relevant committees (e.g. STAG on HIV, viral hepatitis and STDs, GAP-f). MPP contributes to the development of global strategies and action plans (HIV, viral hepatitis, non-communicable diseases) and helps shape key WHO documents such as the Roadmap on Intellectual Property and Access etc. Quality control of products manufactured by MPP licensees is carried out through WHO prequalification mechanisms, SRAs or other competent authorities (WHO Listed Authorities). Together with WHO, MPP initiates and coordinates the mRNA Technology Transfer Program, acts as an implementing partner in the Health Technology Access Pool (HTAP), and collaborates with WHO units at global, regional and national levels to inform them about current and future opportunities for access to essential drugs.

In addition, MPP has strategic partnerships with the Global Fund and UNDP, including participation in the LA PrEP (Long-Term Pre-Exposure Prophylaxis for HIV) coalition, as well as regular interactions with regional and country teams at the Global Fund and UNDP. The organization provides information on available generics and procurement options in low- and middle-income countries, helping to optimize planning and improve access to drugs. MPP also works with governments to get information on the needed medicines and other health products and providing governments with information on the current and upcoming opportunities to procure licensed drugs at favorable prices and facilitating supplies through generic companies/MPP licensees.

Question: Explain the advantages of MPP patent agreements as opposed to bilateral patent agreements between pharma companies?

Answer: Licenses negotiated by the Medicines Patent Pool (MPP) are more focused on expanding access to medicines than bilateral agreements between commercial companies. For example, the Access to Medicine Foundation (ATM Foundation) notes that MPP licenses contain the most "pro-access" criteria for maximum flexibility and transparency. Dolutegravir (DTG) license is a notable example.

Unlike bilateral agreements, which often remain confidential, MPP licenses involve transparency and encourage greater competition among manufacturers, which in turn leads to significant price reductions. MPP considers important public health considerations, not just commercial interests, when designing and negotiating such agreements. In addition, the organization's involvement in license management allows it to have full access to information on all challenges related to the development, registration and supply of generics.

With MPP licenses making products more affordable and bringing them quickly to markets in low- and middle-income countries, more than 40 billion doses of medicines have already been supplied to 148 countries, much faster than without MPP's involvement.

Question: Is there a direct mechanism of interaction between community organizations and MPPs (not through CAP)? Who can we contact with?

Answer: Many CAP (Community Advisory Panel) members also participate in community or NGO delegations to Unitaid, UNAIDS, the Global Fund and represent other groups (e.g. AVAC, EATG, AfroCAB), as well as collaborate with community or non-governmental organizations working in different countries. Engagement with communities occurs directly, including through in-country meetings, conferences and other events.

Communities play a central role in increasing access to medicines and supporting people in need by identifying needed medicines and health products, identifying existing gaps and opportunities for access, and advocacy campaigns. They provide feedback on the availability of licensed products, inform about barriers that limit access, and actively engage in addressing them. In addition, community members help people directly obtain required drugs and other essential health products.

Question: For example, the license for biktarvy was signed in 2017. In 2019, additions were made. At the same time, as of today, the generic drug is not registered in Armenia, Belarus, Kazakhstan and Kyrgyzstan. How is the issue of entry of pharmaceutical companies into the markets of the countries included in the license agreement controlled?

Answer: Biktarvy is a combination of bictegravir (BIC), emtricitabine (FTC) and tenofovir alafenamide (TAF) developed by Gilead and approved by the US Food and Drug Administration (FDA) in 2018. The drug has not been included in the World Health Organization (WHO) guidelines, nor has there been any expressed interest from other stakeholders. Until recently, there were no FDA-approved generics of biktarvy, but some manufacturers have now received approval. If there is further interest in this drug, the issue could be explored in more detail.

Question: Gilead and Merck have published the results of phase II clinical trials of the oral combination of lenacapavir/islatravir (ISL/LEN). Does MPP have plans to work on an agreement for this combination?

Answer: Gilead has a bilateral license for lenacapavir. Although the substance islatravir itself is not patented in low- and middle-income countries, there is a secondary patent on the use of islatravir that could potentially limit its use. This drug is on the watch list.