**Minutes of the Meeting of the Eurasian Community for Access to Treatment with Gilead Sciences, October 1, 2022**

Representatives of the pharmaceutical company:

- Larkin Callaghan, Senior Director, Public Affairs, Gilead Sciences
- Alexey Brevnov, Director, Public & Government Affairs, Gilead Sciences Russia

Representatives of non-governmental organizations:

| | First and last name | Organization |
|---|---|---|
| 1 | Denis Godlevskiy | ITPC EECA |
| 2 | Tatyana Khan | ITPC EECA |
| 3 | Aleksey Mikhaylov | ITPC EECA |
| 4 | Maria Shibaeva | ITPC EECA |
| 5 | Sergey Golovin | ITPC EECA |
| 6 | Darya Mikulich | ITPC EECA |
| 7 | Yuliya Vereshchagina | "Patient control" |
| 8 | Morgan Akhmar | ITPC Global |
| 9 | Detrich Peeler | ITPC Global |
| 10 | Ajbar Sultangaziev | Association "Partner Network", Kyrgyzstan |
| 11 | Ekaterina Novikova | Association "Partner Network", Kyrgyzstan |
| 12 | Evgeniy Goloshchapov | Positive Initiative, Moldova |
| 13 | Elena Rastokina | Answer, Kazakhstan |
| 14 | Pavel Savin | Central Asian Network of PLHIV, Kazakhstan |
| 15 | Sergey Biryukov | NGO AGEP'C, Kazakhstan |
| 16 | Lasha Tvaliashvili | NGO Real people real vision, Georgia |
| 17 | Medeya Khmelidze | NGO Real people real vision, Georgia |
| 18 | Anatoliy Leshenok | Public Association "PeoplePLUS", Belarus |
| 19 | Shorena Nazraidze | TB-people, Georgia |
| 20 | Mari Chokheli | TB-people, Georgia |
| 21 | Sergey Dmitriev | Health Advocacy Coalition, Ukraine |
| 23 | Anastasiya Gomenyuk | Health Advocacy Coalition, Ukraine |

Beginning of the meeting. Introduction of the participants.

Company presentation.

Briefly about the company: the company has been already operating for 35 years and 17 million people have access to the company's drug products. It has already been 10 years since the first regulatory approval (by the FDA in the United States) for the use of tenofovir disoproxil fumarate and emtricitabine (TDF / FTC), for use in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. We would definitely not have achieved these goals without close cooperation with public organizations and patient communities.

More than four thousand people work in the area of virology. All this includes research, development, production, commerce, and so on. The main focus is on small molecules, including the development

of combinations, and, as you all know, Gilead was the first company that launched combination drugs for the treatment of HIV infection and viral hepatitis C to the market.

Individuals in more than 125 countries are using Gilead virology therapeutics and Gilead works with partner organizations around the world. Gilead focuses on solving issues or closing gaps in the following areas: HIV, viral hepatitis, and other viral diseases.
HIV - the company is working in the field of treatment, prevention and cure of HIV. Viral hepatitis - elimination of viral hepatitis, in other words a cure strategy. Hepatitis B cure and hepatitis D treatment are also in focus. Today we are not going to talk about Covid and other viral diseases, but Gilead is working in this direction as well.

**HIV infection:**

An estimated 37 million people worldwide still live with HIV. 32% of people living with HIV have not achieved viral suppression, and still 1.5 million people contract HIV annually. The need for pre-exposure prophylaxis is very high. According to UNAIDS estimates, more than three million people could benefit from pre-exposure prophylaxis (PrEP). Less than a million people are using PrEP, and the use of PrEP could double by 2030 with collective efforts.

Today Gilead focuses new therapeutic developments on different dosing options and routes of administration for people living with HIV (the development of a dosage regimen when people wouldn't need to take drugs every day), and for people who would benefit from PrEP.

There is a need to reduce the dosing frequency of ARV drug. 60% of people living with HIV say they would like to take drugs less often. At the moment, the "once-a-day pill" regimen is considered standard of care, but there are other needs, for example, the desire to take drugs less frequently to cope with emotional, logistical or other issues. Therefore, the company is currently working on long-acting ARV options for treatment or prevention, that may be taken orally or administered by injection.

The company has three focus areas. The first area is the focus on the specific patients' needs. These are treatment and prevention strategies, drugs with less frequent dosing, and the search for strategies to cure HIV infection. Gilead is actively moving in this direction with the participation of partner organizations. The second area is the promotion of equal access to health services worldwide, and this is about capacity and knowledge increase, stigma and discrimination reduction, elimination of inequalities in access, and community support. The third area is partnerships, including with community organizations.

**Question**: Please provide new information on logistics and prices, taking into account the military operation in Ukraine.

**Answer**: There were some issues with getting supplies into the region at the beginning of the war, but now there are no such issues, and we do not foresee any serious impact on our ability to supply drugs to Ukraine and surrounding markets. For Ukraine, our main focus was, and remains that people who depend on Gilead's medicines continue to receive them. Our team is working with partners, including community-based organizations, in the region to ensure that people continue to receive the support and treatment they need. As we know, Ukraine is the country with one of the highest HIV prevalence rates in the Eastern Europe, Caucasus and Central Asia (EECCA) region. We are working with partners to solve the drug access issues for HIV-positive people in Ukraine and those in surrounding countries, including Poland, Moldova, the Czech Republic, Romania, and Russia. Gilead has been present in the EECCA region for a long time in the field of HIV and hepatitis, and now Covid-19, and now we are doing everything possible to ensure that supplies are not stopped or discontinued. If there is a risk of supply interruptions, our partners, including logistics ones, notify us. In general, we are focused on ensuring that nothing stops, and the work goes on as before. Currently, PEPFAR is helping the PLWHIV in Ukraine. The only product that is being shipped to Ukraine [directly] from Gilead is Viread at this time, for Hep B. The majority of PLWH in Ukraine are on a TLD regimen.

We also made a one time donation to the Ukrainian Ministry of Health, upon receiving their request, on October 26th, 2022, of twelve (12) bottles of Harvoni@ (sofosbuvir and ledipasvir (200mg/45mg)); and thirty-nine (39) bottles of Epclusa @ (sofosbuvir and velpatasvir (200mg/50mg)).

**Question**: Please provide a little more information about logistics issues at the very beginning and why the company is not experiencing them now?

**Answer**: The issues were mainly related to the fact that we have a key logistics partner, which is located in the Netherlands and has certified warehouses. At the beginning of the military operation, issues naturally arose due to the fact that the situation was very unstable in Kiev and the normal supply routes and the logistic chain were also unstable. The issues were resolved within a few weeks by our distribution partners, and the work continues.

**Question**: The question was about these specific countries, such as Poland, Moldova, the Czech Republic, Romania, and Russia, where there are a large number of refugees. What kind of assistance does the company provide?

**Answer**: TLD is the primary regimen used by HIV positive people in Ukraine, but neighboring countries do not have this medication. Later in 2022, the WHO provided guidelines for the treatment of HIV for displaced populations. Gilead facilitated the care of displaced population in two ways. The first was through product donations to address the immediate needs at the start of the military operation. The European Union (EU) consequently granted the right to access care to the displaced population across EU countries. The second way Gilead aims to support people in EECCA is through its work with multiple partner and grantee organizations in the region that are dedicated to removing societal barriers to care. This includes Gilead's RADIAN partnership with the Elton John AIDS Foundation, for example, which works to raise awareness about HIV, reduce stigma and link people to testing and care. None of us wants to see any setback in progress for this critical work because of the war. Gilead is in ongoing contact with the various community-based organizations we support to see what additional resources or help they might need. To support the broader humanitarian efforts in Ukraine, Gilead employees donated more than $860,000 and Gilead committed an additional $53M to support relief efforts in the region including programs focused on services to PLWH and those in need of prevention services.

**Question**: A question about Gilead's plans in the field of tuberculosis, including as part of a complex approach.

**Answer**: Research in the field of tuberculosis (TB) is not a focus for Gilead. Here the company relies on partnerships; we cooperate with organizations that work in the field of R&D for TB, knowing that many communities are affected by both TB and HIV, but tuberculosis is not a part of the key work areas of the company.

**Question**: A question about logistics, regarding two countries - Belarus and Russia. The recent situation when FinnAir refused to import drugs to Belarus - does your company have such difficulties?

**Answer**: No, we don't. There are no such issues at the moment. The supplies of our drugs for HIV and viral hepatitis treatment to Russia do not come through FinnAir. These supplies go through Dubai. This is a well-functioning supply chain identified and quickly set up just after the beginning of the military operation by our logistics team. This was done quite effectively, and did not lead to any interruptions regarding supplies to the Russian market. Regarding supplies to Belarus, this issue is automatically solved: if there are no difficulties with supplies to Russia, then automatically there should be no difficulties with drug supplies to Belarus.

**Question**: The second question is about donations.

**Answer**: Gilead considers product donation requests as and when they are received, and now special attention is paid to such requests from Eastern Europe and Central Asia regions. In addition to drug provision, Gilead supports various organizations, including community organizations. To support the work and efforts to eliminate the crisis consequences, Gilead donated 3 million dollars as financial grants to three organizations: UNHCR, UNICEF, the American branch, and the International Medical Corps.

In addition, there is a donation program within which if a Gilead employee donates a certain amount within this grant, Gilead will add the same amount. So if a person donates 100 dollars, Gilead also adds 100 dollars. At the present moment 785,000 dollars have already been collected within the framework of this program.

**Comment of the patient community representative**: Thank you very much, first of all, for donations, but on the other hand, Gilead is a huge company, and three million dollars does not look like a significant amount.

**Answer**: I understand your comment. But, in addition to the mentioned donations to the three global organizations, we also continue to support a variety of community across the region.

**Question**: What is the most popular drug product for donations?

**Answer**: Gilead has a variety of access strategies for numerous products across regions. Our medication donations are based on need, location and timing. We have a variety of access strategies that also focus on sustainability to ensure access continues uninterrupted.

**Question**: Thank you for the donation and the help provided by Gilead for the Ukrainian refugees, including those who are in the Russian Federation, but the question is that you give money, not drugs. What is the reason for the position not to give drugs to Russia, I don't know about other countries, but what is the issue? Since we have to buy your drugs for money anyway; if we are talking about Russia, yes, these are refugees from Ukraine and, mainly, they have Truvada in their regimen, Truvada in Russia costs 200 dollars, because it is still under a patent, and a lot of money is spent on the purchase of this drug.

Answer: As it has been already mentioned, Gilead donates a drug product in some cases, sometimes Gilead donates funds. This instance in Russia, we made donations for purchasing for refugees living with HIV, and not drugs. Mainly because the situation was quite urgent, and funds were faster and more efficient. Secondly, in Russia Gilead's drugs are supplied by Pharmstandard, which would add further delay. Additionally, the share of Gilead's antiretroviral products is not significant in Russia, and the number of patients receiving this product is relatively moderate. Lastly, the majority of people living with HIV from Ukraine are on TLD as a regimen. Accordingly, it is more efficient to give the right to determine the needed drugs by the partner party, and our funds donation allows for further purchase of drugs.

**Question**: If anything, is it possible to get a drug donation?

**Answer**: In theory, yes.

**Question**: The next question is about Russia and the sanctions.

**Answer**: There are several important points that I would like to highlight here. First of all, as a company, we are committed to making it easier and expanding access for our patients to our innovative, life-saving drugs. This is the objective that we always pursue. Since the beginning of the military operation in Ukraine, nevertheless, the company has decided to suspend that all non-essential business operations in the country – and they have been suspended. This means, first of all, the suspension of any investments in the Russian market. The second point is that any profit from the drug sales in Russia will be used for humanitarian aid to Ukraine. This is what Gilead announced shortly after February 24, it is public information. The CEO of our company Daniel O'Day, actually stated the company's position in detail in his two open letters, which are published on the Gilead's website.

The launch of new clinical trials in Russia and Ukraine was suspended. The company is currently working with investigators involved in ongoing clinical trials. Those clinical trials that had started before February 24 are not suspended. They continue, despite of logistical difficulties, nevertheless, everything is going well here. We are fully committed to supporting all patients in the region. This applies to patients in Russia, patients in Ukraine, and patients in neighboring countries. Also, as we have said before, the company is making certain, and, as it seems to me, significant efforts to support patients and non-patients who have suffered as a result of this military conflict. We are working in this mode so far. We monitor what is happening in Ukraine, what is happening in Russia on a regular basis; depending on this, the company will take some new steps in the future.

**Question**: I have a clarifying question about those clinical trials that had begun before February 24. As far as I understand, a number of companies, leaving the clinical trials market, made statements that this was not so much due to the fact of the military operation, but to the fact that the logistics had changed - it was difficult to deliver samples within the time frame established by the new legislation, to the sites; check all this, and so on. How do you deal with these difficulties, how do you manage to keep it?

**Answer**: This question is probably not to be addressed to Gilead, because Gilead is a sponsor of the clinical trials, while the implementation of these clinical trials is carried out by special organizations and medical centers. But we can actually clarify this. The issue of logistics is really a key point here because any clinical trials are always connected with biological samples, the regular sending of these biological samples, the information exchange, etc. and during military operations and significant closure of airspace and transport communication may be critical. Anyway, those clinical trials that have been in progress are continuing. And, in fact, there are no particular issues there.

**Question**: When and what must happen in the current military history so Gilead decides to return to Russia completely?

**Answer**: Currently the situation remains very tense, so it is difficult to say anything now. The decision of the Gilead's leadership will depend on many factors.

**Question**: But will this decision be made quickly? So, it won't be six months…

**Answer**: I do not know.

**Question**: The question concerns Bulevirtide for hepatitis D.

**Answer**: Gilead announced MYR acquisition in 2020, and it was completed in 2021 (keeping in mind Myrcludex). Gilead does not have marketing rights for this product in most Eastern European countries, but at the same time, Gilead is currently working on the improvement of the product's supply. Since the acquisition, the company has been working to get the product registered in a number of key countries with a high prevalence of hepatitis D. One of such countries in the region is Mongolia. We do not have more information on the plans about hepatitis D at this stage, but this is what we are doing.

**Question**: The first question is who has rights if not you? Are there any plans for clinical trials taking into account the side effects and considering that interferon is required there? Will there be any more convenient dosing regimens and so on?

Answer: The company Hepatera is one of the drug developers. This is the company that owns the rights, at least, for the Russian market. And it represents the product at some of markets neighboring Russia.

**Question**: Is it planned that Hepatera will continue to own the rights? This question is about the fact that we know from the experience of other tuberculosis drugs, in particular, Pharmstandard, R-Pharm, that there will be great difficulties in entering the market. Roughly speaking, hepatitis D will not be covered in the region, taking into account the fact that this is a Russian company with small logistics capacities. Is it Russian or German Hepatera, which they created to promote the product?

**Answer**: This is the Russian "Hepatera", and the question as to whether they will always own the rights, or whether there are any time restrictions, should be addressed to "Hepatera".

**Comment of a patient community representative**: Your presentation is very similar to UNAIDS presentation, as if Gilead is a non-profit company. It would be interesting to hear about the sales and profit levels in the EECA region for each drug and the share of so-called donations from this profit level, for example, sales level of sofosbuvir in the Russian Federation. If there were abandonment of patents and a 10 or 5 times drug cost reduction, this would bring much more benefit to the region than all the summarized donations. Sorry for being straightforward.

**Question**: Now there is a question about Bulevirtide. The situation is very similar with sofosbuvir, when a finished molecule was purchased and, technically, Gilead did not bear the costs for trials, which are attributed to the high price of the drug. And now the people's longevity with hepatitis B and D will be in the Gilead's hands worldwide. Do we understand correctly that a patent will be, or it has already been, whether the licenses will be transferred, or how quickly it will happen, what is the price policy for

Bulevirtide, because the Gilead's declared policy is to expand access and sell for 80,000 per course that was for sofosbuvir, - this is not access.

Answer: Firstly, I will answer the question related to side effects. The molecule improvement is still in progress. The information about side effects, adverse events is collected and, if necessary, we are ready to organize even a separate meeting on this issue to present all clinical data that we have and discuss any necessary improvements.

**Question**: Are the improvements made by Gilead or Hepatera?

**Answer**: There is a Gilead clinical team that is engaged in this. As for the price policy, we will touch upon this issue a little further, but in general, the answer is that we do not have a ready-developed price strategy for this product at the moment. We are in the process of discussing both within the company and with all involved parties, the community, various stakeholders, etc. to aid in our pricing strategy.

**Question**: What can you say about the license and the patent?

**Answer**: We have no policy on this part, as well as a ready solution for product promotion, but we know that a voluntary license is an option that can be considered.

**Question**: I would like to clarify the question about Bulevirtide. Is there any division of responsibilities between "Gilead" and "Hepatera"? Over the past three years, we have not had a constructive dialogue with Hepatera concerning this product. We can ask questions several times, but we get the answer once a year. In the recent times we have not received any answers to our questions at all. If there is any division, what questions should Gilead be asked, and what should be addressed to Hepatera? Can I have any contacts?

Answer: Gilead cannot facilitate communication between or on behalf of Hepatera as they have exclusive marketing rights in Russia.

**Question**: The question is about TAF for the hepatitis B treatment.

**Answer**: As you know, Gilead has signed a voluntary license agreement with generic manufacturers. This is a one-on-one agreement with different manufacturers - it is not a common one. In total, these agreements covered 116 low- and low-middle-income countries. And these licenses made it possible to make TAF more accessible for the hepatitis B treatment in these 116 countries. Here is a link to the list of license agreements - not the texts themselves, of course. But, as you know, these are Cipla, Dr. Reddy's, other Indian companies that are responsible for different countries. This is one component of our access strategy.

**Comment of the patient community representative**: The previous day we talked with other companies, and we faced the fact that TAF, despite it is included in the combined forms for the HIV infection treatment, it is a monocomponent and used only for hepatitis B. And the question is, or it's more a wish, that the company – in cases where it issued a license – expands the use of TAF for HIV infection.

**Question**: Less as about TAF, than as about voluntary licenses, since they have been mentioned here. Could you clarify whether this is only a list, or we can still find the texts of voluntary licenses at this link, if they are not published, can you provide them to us by request?

**Answer**: VL agreements can be found at Gilead.com (https://www.gilead.com/purpose/medication-access/global-access/access-partnerships)

**Question**: A question about lenacapavir for the HIV treatment.

**Answer**: We know that there is a lot of interest to Gilead's plans to expand access to lenacapavir, especially since it has recently been approved by the European Commission for the use of this drug in combination with other ARVs. Let me remind you that this product is recommended for adults with multidrug resistance to HIV-1. And this is a very specific, niche product especially in the situation when other groups of drugs don't work. We understand that lenacapavir is an important agent in filling the niche for people with multidrug resistance against HIV. Accordingly, we have hope, and we need to promote this product in order to end the HIV epidemy in low-middle-income countries. We have no ready

plan for the lenacapavir promotion. And here we are ready to listen to your suggestions, vision, specific requests that you have. We are ready to engage the Lenacapavir community representatives in a dialogue.

**Question**: Two questions. What is the current recommended regimen? The second question is about cooperation with MSD on islatravir.

Answer: In regards to cooperation with MSD on islatravir, we are open to continuing our engagement.

Currently, LEN is only approved for highly-treatment experienced individuals. We are still exploring appropriate combinations for LEN for treatment for broader and naïve indications. Our LEN for PrEP studies are ongoing.

**Question**: What is the minimum possible price for sofosbuvir-based regimens for the hepatitis C elimination in the Russian Federation?

**Answer**: I would prefer to speak here with facts and discuss what we have now. In this sense, two of the three drugs for the hepatitis C treatment, registered in the Russian Federation, are included in the Essential Drugs List: Sovaldi and Epclusa. The maximum price for each of these drugs is registered in the Essential Drugs List. Sovaldi price is 74.5 thousand rubles per package, Epclusa - 114.5 thousand rubles per package. As it is known, Harvoni is not on the Essential Drugs List, therefore, price regulation does not apply to it, and its maximum price is not registered. Regarding the national program for the HCV elimination, as we know, it has been developed by the Russian government for the last few years, particularly, by the Ministry of Health in cooperation with other relevant government authorities. As far as we know from public sources, this program may be already launched next year. Although delays are possible, and it may happen that this program will not start next year. Our company is engaged in a rather substantive dialogue with the Ministry of Health. But we cannot provide any details of this communication due to confidentiality.

**Comment of the patient community representative**: I think everyone understands the point about the prices. The last thing about Harvoni is that it is not included in the Essential Drugs List, and that is why its price is not regulated by anything.

**Question**: What is the actual commercial price level for Harvoni sales in the commercial market?

**Answer**: It is difficult to say.

**Question**: Sofosbuvir in Russia. Taking into account that all the profits from the Russian market are used to support the citizens of Ukraine, the market is temporarily unprofitable for the company, with clouded prospects. And here is the question - haven't you considered the option to work the agreement back with the local manufacturer, Pharmstandard, which is involved in the drug promotion in Russia. To issue a voluntary license, for example, or to say that we generally refuse a patent in Russia so that we can equal the prices with countries such as Kazakhstan, where you can buy a course with sofosbuvir for $ 60.

**Answer**: The question, as I understand it, is mostly about sofosbuvir. One by one. Regarding the fact that the Russian market is becoming unprofitable, I would not assess it in terms of profitable or unprofitable. These are Russian healthcare system, Russian patients and there are great needs in medicines developed, manufactured and supplied by Gilead. This is the key factor in this case. The patient and his / her interests are to the most degree at the center of this. Regarding the cooperation with Pharmstandard. This is our partner; we did not revise this partnership and we have no plans to do this because we consider this cooperation and partnership as very effective and productive. So we have no such plans. Regarding the Gilead's price policy: there is one main approach to the price policy of Gilead's products: the cost of Gilead's products is always determined by three factors: the required level of product access in a particular country or healthcare system; the disease burden in a particular country or healthcare system, in this case, in the Russian Federation, and, actually, the treatment goals set in the country by the government, public health authority. Based on these three key parameters, Gilead determines the cost of its products in certain markets, including Russia. Regarding the revision of the drug cost to significantly reduce it or exit from the market, or the transfer of a voluntary license to other manufacturers, we do not consider such a scenario.

**Question**: I have listened to you carefully, but I have no clear picture. You are constantly talking about caring for patients. As far as I understand, the hepatitis C burden in Russia is not just great, it is huge, and at the same time, you are not going to revise the cost. Please explain to me how this can be correlated.

**Answer**: If we are talking about Sovaldi, as well as Epclusa, their cost has already been revised at least once, when these products were submitted for inclusion in the Essential Drugs List; and, basically, the procedure for drug inclusion in the EDL and discussion during the inclusion procedure led to a rather significant reduction in the cost of these drugs. The second point is that if we are talking about Sovaldi, even without the drug inclusion in the Essential Drugs List, the company reduced the cost. We are all talking about the fact that the Russian national HCV elimination program has to be launched, and of course, it will include a significant number of patients who will be treated under this program. And this, I think, will be one of those clear indicators that will show the disease burden. Because at the moment the hepatitis C burden is not precisely set for Russia, there are different expert assessments, different calculations, but there is no Registry. Accordingly, when the government approves this national program on HCV elimination, and it is launched, then the company will take decisions on the access based on the disease burden and the number of patients to be treated under this program.

**Comment of the patient community representative**: We understand and know that the national program has been approved for several years, and it is not clear how long it will last. Wouldn't it be easier to give the license? So you understand that a person comes and can buy the product on the same day without waiting for the program? Let the program go on as usual, but so that a person can come and buy the product in the pharmacy at a price much lower than it is now. In Kazakhstan you can buy a treatment regimen with sofosbuvir + daclatasvir for 250 dollars. But this cost, excuse me, is not about caring for a Russian patient, and I think the situation is the same in many countries. That's why I would still suggest considering the voluntary license issuing, bringing generic companies to the market. We know very well, we understand what a good step you have taken. But in this case, this scheme just does not wrap my head around.

**Comment of the patient community representative**: This is a comment that needs to be said, although everyone knows and has heard it many times. As for the elimination program, our position as a patient community is to keep the price as low as possible. Ideally, close to the price in Kazakhstan and the prices repeatedly announced by Andrew Hill. And of course, on the one hand, we understand the company's strategy, the time is now, to put it mildly, not Russian-friendly, but our position and another appeal is that it would be interesting for the company itself to create not a Georgia model, when there is just a free drug distribution, but the drug distribution at enough low price; perhaps, to create a general elimination program that would use mainly sofosbuvir and daclatasvir or sofosbuvir and velpatasvir, those drugs which were licensed to Pharmstandard at very low prices, and such an adjustable program - a lot of patients and the hepatitis elimination during three-four years in Russia.

**Answer**: Our company is ready for a dialogue and we are in this dialogue already. But, unfortunately, as I said, I cannot reveal the details here. In any case, the elimination program, which drugs will be used within this program and in what proportion, how many patients will be treated - these are all the regulator responsibility, the responsibility of the Ministry of Health; these are aspects that are directly related to the budget capabilities of the Russian Federation. In this sense, we are ready to become a partner of the Russian government in implementation of the program. But to reiterate, the initiator and the main owner of this process, is, of course, Russian government.

**Question**: As far as I understand, you have not received patents for tenofovir / emtricitabine (Truvada) and Descovy in all countries. How do you decide in which country to get a patent and in which not? Why do you get patents in some countries, particularly, if we are talking about pre-exposure prophylaxis? A question without linkage to Russia

**Answer**: We work with government and regulatory agencies of countries to communicate the value of the innovation of our medicines. Occasionally the decision is made to not register a drug in a country if regulatory and government bodies do not agree on the value of the therapeutic.

**Comment of the patient community representative**: The first important clarification. Unlike the previous question about TAF, here we are talking about TDF, the patent of which will expire soon, but from our

point of view, if the company decided to refuse and issue such a letter of patent non-prosecution, this could expand access to treatment. We can see that the company does not submit the product to the Vital and Essential Drugs List. The company will obviously prioritize other combination drugs. There is a generic drug product that is already being produced, it is not a secret. As far as I understand, despite the original plan to sue in the situation with remdisivir, the court proceedings have not started yet.

**Answer**: No. The remdisivir case is a compulsory license which we challenged. The decision to issue a compulsory license for remdisivir was made by the Russian government, we challenged it at court, but the decision was to refuse.

**Comment of the patient community representative**: Why I provide an example with remdisivir, because now there are, roughly speaking, at least two strategies: for example, the patient community addresses to you and says that one and a half or some other amount of time before the patient expiration is left. The product is obviously not a priority for the company, you have said about it many times that there are other more modern drugs, and it is important that patients have access to them. Roughly speaking, smaller losses strategy for both parties, so called win-win strategy is to ask you to abandon the patent. Or there is the second strategy where the patient communities prepare patent opposition, bring case to court, and start spending money on lawyers; Lawyer budgets are a much larger expense item for patient organizations than for Gilead in percentage terms. Taking into account the ten-billion-dollar budget deficit, there is a generic product that can enter the market and cover needs. I understand that you can't solve this issue, but you can inform about our position and appeal to issue such a letter rather than go to the courts again - it is very serious to consider access expansion issues at the level of the global office.

Answer: Thank you for your comment, we will bring it to our colleagues. Just in case, I would notice one more time that once we submitted this product for inclusion in the Essential Drugs List in 2018, and the price quotation was about $35 per pack at that time. Unfortunately, it was rejected. I say this to put it on record. We did everything possible and offered a very low price at the certain stage. Thank you for what you have just said. We will definitely inform our colleagues about this.

**Question**: Will there be the pre-exposure prophylaxis national program in Russia, from the point of view of Gilead? The second question is about Descovy. At one time, European activists were very indignant that Gilead had decided not to commercialize Descovy (TAF/FTC) for PrEP. It turns out that the Truvada generic is practically available everywhere, Descovy is practically not used for PrEP anywhere except for the USA, and what product does Gilead actually use to achieve the goals that were presented to PrEP access expansion?

**Answer**: The short answer to the first question is no, no one asked about our participation in a certain pre-exposure prophylaxis national program, and if we had received an invitation to such a dialogue, we would have discussed it with interest. Registration of PrEP indication of Truvada on the Russian market meant various investments from our side, so this topic is very important for us. But again, there is no discussion of this issue with the Ministry of Health.

**Question**: If this is proposed either from the regional or federal level, are you ready to consider it?

**Answer**: Absolutely. Regarding the answer to the second question. Regarding Descovy, yes, this decision was made a year ago, and we really had a conversation with European activists about it. The situation was that the European regulator position in our discussions was that Descovy did not offer additional value compared to Truvada, taking into account its price, a position we disagree with. But it will be possible to return to this discussion later. As for lenacapavir, we are currently in a dialogue with multiple stakeholders to consider how to improve access since it is a long-acting product; it may be seen as more convenient for patients and the healthcare program.

**Question**: The last question is about voluntary licenses for Bulevirtide, Lenacapavir. If there are such licenses, what will be the geographical coverage?

**Answer**: At the moment we are at the nascent stage of an access strategy so now the door is open, and we are discussing what the optimal strategy will be in terms of improving access to these drugs with the community representatives within this and other meetings, and we will continue this practice in order to understand how to improve access - by issuing a voluntary license or by some other means.

**Comment of the patient community representative**: If a decision is made due to the agreement with the Lenacapavir Patent Pool, please do not conclude special licenses for countries with an upper-middle income level.

**Question**: Please tell me if there is an early access program for lenacapavir?

**Answer**: As with all countries where a product is not registered, we evaluate these requests on a case-by-case basis. Individuals seeking lenacapavir for its approved indication for highly treatment experienced individuals are able to request access through their healthcare provider for Gilead to evaluate.

**Comment of the patient community representative**: I would like to start with the background of the Truvada procurement for children of the Republic of Kazakhstan, which was carried out in 2021 for 2022 through the international organization. Unfortunately, the procurement procedures went very badly. Even our partners from a single distributor asked us to help in resolving this issue. So on February 24, the international organization UNICEF provided a letter in which it clearly justified the refusal to supply the drug Truvada for children by the reason that Gilead had changed its plans in relation to Kazakhstan. I read directly from this letter, here they write: "Gilead Science reports that at the present moment it is impossible to provide a price quote with the terms of drug supply for the following reasons. Drug manufacturers are not interested in product supply due to very small volumes. Gilead has refused to supply the product on the terms of 2021. The manufacturer is looking for a distributor in the Republic of Kazakhstan. And the option of drug supply through an European distributor also does not guarantee a positive result and leads to the price increase at least twice. " So they propose to consider the possibility of a generic drug purchasing, but, unfortunately, according to the orders of the Ministry of Health, only the original product is purchased for children with HIV infection. I want to pay your attention to the fact that the letter was already provided in February, when all the purchases were almost completed and finished. Instead of receiving the product in January 2022, they received it at the end of August 2022.

**Clarifying question from Gilead**: But the product was purchased but later, correct?

**Response of the patient community representative**: We have a dialogue with Karl Johnson on this topic. We sent three letters with a request to hold a zoom meeting on the direct Truvada purchase for children of the Republic of Kazakhstan. We have not received a response on this issue to this date. I have been authorized by our partner, the single distributor in the Republic of Kazakhstan, to hand an official invitation over to hold a zoom meeting to resolve the issue of direct Truvada supply for children of the Republic of Kazakhstan. I can preliminarily say that this will be a three-year contract, but with an annual confirmation of the quantity. Again, the conditions are preliminary, since we hope that you will enter into these negotiations. Your expenses will be only up to the border of the Republic of Kazakhstan - all the rest is covered by a single distributor. I am handing these letters over to you. I also have such information: the drugs tender for 2023 has already been announced. There is an understanding that UNICEF will not manage to deliver the drugs on time, so I ask you to make a certain priority in resolving this issue.

**Question**: I would still like to return to biktegravir. Maybe you donate a bit of Bictegravir, as Pharmstandard is not in a hurry, and in general, no one is in a hurry to bring it. The drug is very necessary, and it would help us a lot. Maybe will you donate it for 10,000 patients? The drug is in the protocol in the Republic of Kazakhstan, in the first line, there is a need for it. We are waiting for a very lively dialogue with Karl about this. We know that Hetero has this product, but, unfortunately, they always tell us that it is very expensive to conduct a bioequivalence analysis. The latest information received from Karl was the following: we (Gilead) cannot place pressure upon generic drugs manufacturers. We suggested him to consider the issue of the original drug registration in the Republic of Kazakhstan. He asked for additional information on the quantity - we gave it to him. We understand that this issue is not quick, it will be solved for some time, that's why I would like to consider the drug donation to our country.

**Clarifying question from Gilead**: Do you mean bictegravir as a mono-component? So, is it a Biktarvy's generic?

**Answer**: Hetero has a generic Biktarvy, three-component, and it is mainly a three-in-one pill, one per day.

**Question**: Registration in the EAEU. Who will register your drug products due to EAEU and do you plan to do this?

**Answer**: In the case of drugs that we plan to submit under the Eurasian registration, this will be handled by the Russian office, the Moscow office of Gilead, and the Gilead regulatory team. I want to make a remark: it is necessary to understand that this will be done by the regulatory team of Gilead in Russia, but the product can be submitted both in Russia and in Kazakhstan.

**Question**: Why are you not promoting bictegravir in the WHO protocols? I understand that the question is old, but it would help us a lot. Despite the WHO protocol, we still included it in the first line in Kazakhstan. Why don't you count on it? We understand that everyone uses dolutegravir, but anyway. I do not know, if raltegravir, one of integrase inhibitors is outdated or not, we just did not see it in Kazakhstan. And we are really looking forward to BIC. And why is that?

**Answer**: The lack of WHO guidelines inclusion is primarily bc Gilead did not conduct research in the key areas for inclusion (i.e. TB co-infection, women of childbearing ages/pregnant women). We are looking to address this via some recent study publications that will soon be released. This in addition to the positive results from recent studies in HIV/HBV and low dose pediatric approval will help us re-engage on this front.

**Question**: Since you have mentioned the EAEU, do you take any actions to make it not so difficult to register under the EAEU procedures? As you do not practically enter the EAEU countries for registration, I mean in 2022. Does the company do anything to influence the registration rules in the EAEU countries?

**Answer**: No, if I understand the question correctly. The company does nothing to influence the regulatory process, which is established by the relevant supranational legislation.

**Comment of the patient community representative**: This applies to everything, all diseases. We have the same position on this issue. If possible, please use the country registration, and not the EAEU. So we mean national registration - it has already been in place in Belarus, it will be soon in Kazakhstan and Kyrgyzstan. An attempt to enter through the Eurasian registration is automatically a block, the registration does not work according to the mutual recognition procedure for all other countries. We are now telling all pharmaceutical companies: you probably know about the EAEU decision that countries can take some anti-crisis measures by the end of 2023, and now there is a return to national registration procedures in the EAEU countries. In Kyrgyzstan all drugs included in the Essential Drugs List can participate in tenders without registration until the end of this year, if they are pre-qualified by the WHO. Do you have any strategy if countries return to national registration procedures?

**Answer**: I have one clarifying question and a comment on the question you asked. When you recommend pharmaceutical companies to follow the national registration track, and not the Eurasian one, and then you talk about the mutual recognition procedure; isn't the mutual recognition procedure activated when the product is registered according to the national procedure, and then the company that owns the marketing authorization submits this product for the mutual recognition procedure in another EAEU country?

**Comment of the patient community representative**: It is submitted for initial registration according to the supranational procedure, taking into account GMP and everything else, but not according to the national procedure. It is much easier to register according to the national procedure, for example, in Kyrgyzstan. A number of the supranational drug policy requirements are not provided there.

**Answer**: As far as I understand, there are no requirements for local clinical trials.

**Comment of the patient community representative**: Yes. In particular, and not only this.

**Answer**: This is one of the key ones.

**Comment of the patient community representative**: This is a very important point. I do not know how it is in other countries, but now we have a resolution of the Cabinet of Ministers awaiting signature, according to which all pharmaceutical companies can be submitted under the country regime until the end of 2023, it is simplified. It is possible to register the product under the compact procedure in forty days.

Here are two examples. I will not tell the company names. Relatively speaking, when a company enters through Kazakhstan, and submits according to the Eurasian procedure, the Eurasian centralized procedure and not according to the mutual recognition procedure, although this is also a Eurasian procedure, but a bit different. The company X enters through Kazakhstan, submits and receives the file there, enters to conditional Russia under the mutual recognition procedure. It obtains registration and enters Russia, there they question the result of the examination of the Republic of Kazakhstan, ask questions, return the file. This can last years.

**Comment of a Gilead representative**: Thank you, this is valuable information.

**Comment of the patient community representative**: In support of Kazakhstan, I would like to say that we are the largest market in the EAEU after the Russian one. That's why if you apply, for example, for registration to Armenia, you will not enter Kazakhstan very soon under the mutual recognition procedure. We also have such an example with a drug from another company. We cannot see the product, although we have a larger market. So this is not an indicator that it is bad in Kazakhstan. This is an indicator that the procedure is imperfect.

**Question**: Have you submitted any request to the Eurasian Commission in this regard?

**Answer**: Many times, we even organized a large meeting with all the countries in December last year, and the answers, received at it, overset. As we understand that no one is going to solve any issues. That's why your decision to register under the national procedure is very important.

**Comment of the patient community representative**: I will try to say it as politically correct as possible: the Eurasian Economic Commission does not care. Unfortunately, the position, as we have seen, is absolutely not intended for any kind of cooperation.

**Comment of the patient community representative**: Yesterday we had a meeting with another company, which actually talked about the recognition procedure. They are trying to go through the mutual recognition procedure and constantly come across some kind of ping-pong, and this has been going on for a very long period.

**Question**: This is a traditional question about procurement. Do you have any experience in mutual or consolidated purchases organized by the authorities of several countries? I am not asking about international agencies, but about purchases by the authorities of several countries.

**Answer**: This is very uncommon – it may have been done through a multi-lateral or an NGO but not via Gilead.

Question: If yes, where is it delivered - to a central warehouse in one country or directly to warehouses in different countries, is the price different, and so on? Let's suppose that the drug price is set, and then does an additional cost depend on the logistics? We would like to understand if there is such practice in principle.

**Answer**: We are unaware of any such practice.

End of the meeting.