

Minutes of the meeting of representatives of Gilead and the EECA community

November 17, 2025

Company: Gilead

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2. Alexy Brenov, Director, PA
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Start of the meeting. Introduction of participants.

Question: When are PURPOSE 4 and PURPOSE 5 studies expected to be completed? When can we expect the results to be published?

Answer: PURPOSE 4 is estimated to reach its primary endpoint in the third quarter of 2026. PURPOSE 5 is expected to reach its primary endpoint in mid-2026. The plans for data release have not yet been confirmed. However, Gilead plans to present the data at a medical conference after it has been analysed.

Question: Does your company already have information about cases of resistance to lenacapavir? Is such information being collected?

Answer: Lenacapavir (LEN) is a capsid inhibitor and a drug with a mechanism of action that differs from all existing approved drugs for the treatment or prevention of HIV.

In PURPOSE 1 and PURPOSE 2 studies, the development of resistance was generally rare. The issue of resistance is being studied as part of the clinical trial programme.

In the PURPOSE 1 study, no participants developed resistance to LEN. In the PURPOSE 2 study, 2 participants developed resistance to LEN (out of 2,179 participants receiving LEN). It is believed that the resistance was related to de facto monotherapy after HIV-1 infection.

We continue to monitor people receiving open-label lenacapavir for new cases of HIV infection. Gilead publishes relevant information as data from ongoing clinical studies become available.

Question: Lenacapavir has potential for use as a PrEP among people who use drugs. Are there any studies underway or planned on the interaction of LEN with psychostimulants (cocaine, amphetamine)? Are there plans to include information on interactions with methadone and the risks of overdose in training programmes for doctors?

Answer: The combined use of LEN with common recreational drugs has not been studied. LEN is a substrate of P-gp, UGT1A1 and CYP3A proteins. LEN is a moderate inhibitor of CYP3A and an inhibitor of P-gp.

At present, the medical instructions contain the information necessary for safe prescribing, including information on contraindicated drugs.

In addition to our instructions, widely used independent resources such as Liverpool HIV-druginteractions.org also include LEN and help to assess interactions with various medicines and recreational drugs.

Question: Can you tell us more about the agreement with the Global Fund to supply two million doses of lenacapavir? We know that it involves 8–12 priority countries and that the first deliveries are expected by the end of 2025. Can you share which countries will be on this list? Are there any EECA countries among them?

Answer: In July 2025, Gilead announced a strategic partnership agreement with the Global Fund to supply lenacapavir for HIV prevention. Under this agreement, Gilead will supply, on a no-profit basis, sufficient quantities of the drug to cover up to two million people over three years in countries supported by the Global Fund, as well as among 120 high-prevalence, resource-limited countries covered by our voluntary licensing agreements. In September 2025, Gilead announced a partnership with PEPFAR to further expand access to LEN for PrEP in countries supported by both the Global Fund and PEPFAR.

Accordingly, until registered generics become available and can fully meet demand in low- and middle-income countries, Gilead will supply lenacapavir for PrEP to these countries on a no-profit basis through the Global Fund mechanism.

The Global Fund will determine early access countries based on HIV epidemiology, national prevention strategies, and available resources. The Global Fund has indicated that early access countries will primarily be in sub-Saharan Africa and that the first shipment and delivery of the drug will be to at least one African country by the end of 2025.

For more information on which countries will be prioritised, we recommend contacting the Global Fund directly.

Question: Can you now name the price of lenacapavir at which you will supply the drug to these countries?

Answer: This is confidential information. We can only mention that this price is non-commercial for our company.

Comment from a representative of the patient community: It seems to me that a non-commercial price cannot be confidential. Confidentiality implies that the price is commercial.

Answer: All we can say is that the price is confidential and that it is non-commercial for Gilead.

Question: We have heard from various sources that Gilead will now sell lenacapavir for 100 USD per course of treatment. Do you know where this information came from?

Answer: To our knowledge, a third-party press release was written with an estimated price of 100 USD, but this price has not been confirmed by either Gilead or the Global Fund. In our official documents and press releases, we always state that the price is confidential and non-commercial. Therefore, the information about 100 USD is speculative.

Question: Can you provide information on the registration status of the drug in EECA countries? Perhaps one of the generic companies is already in the process of registering it?

Answer: To focus on the regions with the greatest need, Gilead is primarily registering the drug in 18 countries that account for 70% of the HIV burden among the 120 countries listed in the voluntary licensing agreements. These 18 countries include: Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Philippines, Rwanda, South Africa, Tanzania, Thailand, Uganda, Vietnam, Zambia and Zimbabwe.

A number of countries in the EECA region are included in the list of 120 countries, including: Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Mongolia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan.

With regard to the registration of generic versions of lenacapavir, we recommend contacting the voluntary licensing companies for information on the countries in which they plan to register the drug.

Question: Does Gilead plan to register its original drug in the EECA countries included in the voluntary licence, or will this market be completely left to generics?

Answer: We are already registering lenacapavir in the 18 priority countries I mentioned earlier. These countries account for 70% of the HIV burden. Generic companies with voluntary licensing agreements can register and supply the drug in any of the 120 countries covered by the licence.

Question: Once you have completed the registration process in the 18 priority countries, do you plan to register your original drug in the EECA countries? Furthermore, given that generic companies can register the drug in all 120 countries, how does your company plan to address the issue of registration dossier data exclusivity?

Answer: I would like to repeat that Gilead will only register its original drug in the 18 priority countries included in the licence. Generic companies will register in all other countries.

As for the data exclusivity, our licence agreement stipulates that Gilead will not claim data exclusivity in countries covered by the voluntary licence. Thus, in these 18 countries where we have registered our drug, generic companies will also be able to register their drugs. As part of the license, the generic companies also agree not to seek regulatory exclusivity in any countries. This is to allow other generic manufacturers to also register and allow enough supply at a competitive price to each country.

Question: Unfortunately, this is not the first time we have found ourselves in a situation where the company sends us to its licensees to share information about drug registration, etc. But the problem

is that over the past year, the process of communicating with generic companies has become much more complicated. They are reluctant to respond to requests, and it is very difficult for us to arrange meetings with them. Can you somehow influence your partners to be more proactive in contacting us and responding to questions?

Answer: Unfortunately, we cannot speak for generic companies about their plans for their drug registration. We have granted them a licence to enable them to manufacture their own product according to their own plans. As for the communication difficulties, we will forward your request to our partners.

Question: Do I understand correctly that we can contact you if we are unable to establish communication with licensees, so that you can contact them and help promote dialogue?

Answer: Absolutely. Of course, I cannot guarantee that they will respond promptly, but we will do our best.

Question: Is there currently a clause in the voluntary licensing agreement that obliges generic companies to register their drugs in certain countries and within certain time frames? Perhaps the agreement also implies certain requirements regarding production volumes and prices? What is the royalty rate under this agreement?

Answer: Several questions have been raised here, and I will try to answer them one by one. It is important to note that these licence agreements do not include royalties. They are so-called royalty-free agreements. Gilead does not and will not ever receive royalties from our partners under this agreement. This is to allow the price to remain low. As you know, the agreement itself is publicly available; you can download and review it. The agreement also states that we encourage our licensees to register their generic versions of lenacapavir in countries where the need for the drug is greatest.

Question: If you do not profit from licensees, what is your interest? How do you plan to recover the costs of research and development of the drug?

Answer: We have one goal: to combat the spread of HIV infection. We supply lenacapavir, manufactured by our company, at no profit to countries prioritised by the Global Fund until the generic manufacturers become available.

Question: At the end of September, it was announced that Unitaid, CHAI, Wits RHI and Dr. Reddy's had reached an agreement to provide access to lenacapavir for PrEP in 120 low- and middle-income countries from 2027 (price: 40 USD for a year's supply, starting regimen \leq 17 USD). Based on your negotiations with Dr. Reddy's, will the company have sufficient production capacity to supply 120 countries, including the EECA region?

Answer: Dr. Reddy's is one of six generic companies that will manufacture and supply generic lenacapavir to 120 countries included in the voluntary licensing agreement. The other companies are Emcure (India), Eva Pharma (Egypt), Ferozsons Laboratories Limited (Pakistan), Hetero (India) and Mylan (India).

In addition to the agreement with Dr. Reddy's to supply generic LEN at a price of approximately 40 USD per person per year, in September 2025, Hetero also signed an agreement with the Bill&Melinda Gates Foundation to ensure the production of its generic lenacapavir at a price of approximately 40 USD per person per year in low- and middle-income countries, starting in 2027, after receiving regulatory approval.

The six licensees have the necessary technical capabilities, geographic reach, speed to market, and capacity to supply generic LEN for PrEP to the 120 countries covered by the voluntary licensing agreements.

We selected these partners based on rigorous criteria, taking into account the complexities of manufacturing a complex injectable drug, including the need to ensure that all partners are capable of producing sterile injectable medicines in sufficient volumes to meet demand.

Question: Do we understand correctly that all questions regarding availability, promotion, pricing policy, and registration of the drug in the EECA countries should be addressed to the licensee companies, since all countries are covered by the agreement? And your company, accordingly, is not responsible for the drug in the region?

Answer: Yes, you understand correctly. We have provided full support to the licensee companies so that they can manufacture their own generic versions of the drug in accordance with our quality requirements. However, the agreement stipulates that the companies themselves decide when to supply, where to supply, at what price to register their own product, and so on.

Question: So, you cannot exert any pressure on them if generic companies do not register the drugs?

Answer: Generic companies make their own decisions about their own product registration, independently of Gilead. However, if you encounter difficulties in communicating with our partners, please contact us and we will do our best to facilitate communication.

Question: What is the estimated price projected by your licensees for the EECA region, taking into account the agreements with Unitaid, CHAI, Wits RHI and Dr. Reddy's? How will supply volumes for EECA countries be determined?

Answer: Licensees set the price for their generic lenacapavir independently. We expect that they will be able to supply generic LEN in volumes sufficient to meet demand and that competition between them will help to reduce the cost of the generic drug.

We fully welcome the pricing agreements between the Gates Foundation and Gilead licensee Hetero, as well as between the Clinton Health Access Initiative (CHAI), Unitaid, Wits RHI and Gilead licensee Dr. Reddy's Laboratories, which will allow licensees to produce generic lenacapavir at a price of around 40 USD per person per year in low- and middle-income countries.

As for supply volumes for EECA countries, I repeat, we recommend contacting generic companies directly.

Question: As we can see, Dr. Reddy's is one of the licensees and is already prepared to reduce the price to 40 USD. When will your company be prepared to reduce the price of lenacapavir, and what do you need to do this?

Answer: Gilead already provides lenacapavir at no profit under an agreement with the Global Fund and a partnership with PEPFAR. We support access to lenacapavir for PrEP in low- and middle-income countries through a two-pronged strategy:

1. Voluntary licensing to generic companies to manufacture and supply generic versions of LEN in 120 countries with high prevalence and limited resources.
2. Direct supply from Gilead: in countries covered by the voluntary licensing agreement and supported by the Global Fund and PEPFAR, Gilead supplies LEN on a no-profit basis until generics become widely available.

Question: Would you like to expand the number of licensees? For example, in Kazakhstan, we also want to produce lenacapavir, and we have the capacity to do so. We have already discussed this issue with our domestic manufacturers, and they are ready to approach you with an offer.

Answer: We have considered many potential partners for the production and distribution of lenacapavir. We have selected six manufacturers that have the technical capacity, manufacturing experience, high speed to reach the market, and most importantly, the ability to produce generic lenacapavir in the volumes that are currently needed by the markets. At present, we do not plan to change our decision because we believe that these manufacturers are capable of fully meeting the demand. However, if the situation changes, we will reconsider our decision. I would like to draw your attention once again to the fact that lenacapavir is a very complex drug to manufacture, as it is a sterile injectable form that requires special technical equipment and complex skills.

Question: If you are not making a profit from lenacapavir in countries in our region, would you object if a compulsory licence were granted in the country for the production of lenacapavir?

Answer:

Gilead's voluntary licensees are working to get their high-quality, affordable versions of lenacapavir to market as quickly as possible. They are generic pharmaceutical manufacturers with the capacity to synthesize, manufacture and supply high-quality generic lenacapavir at high volume and low cost for 120 mainly LLMICs.

We are confident that it remains the most effective way to expand access. Voluntary licensees are equipped with the necessary technology transfer from Gilead that could support regulatory readiness and manufacturing capacity to deliver medicines quickly and at scale.

Our experience shows that compulsory licenses do not achieve the same results. In at least one case, a country issued a compulsory license despite being eligible under a voluntary licensing framework, yet this did not meaningfully improve patient access. Compulsory licenses are designed as tools of last resort for exceptional circumstances, and particularly where no other access pathway, such as voluntary licensing, exists.

Compulsory licenses also risk disrupting the highly specialized, sterile manufacturing and global supply chains required for lenacapavir, which are planned and invested in years in advance. Such disruption can limit scalability, raise costs, and ultimately delay or reduce patient access.

Question: Who will be responsible for training medical personnel in countries, as the drug is injectable and training is necessary? In our countries, will this be the responsibility of the licensee companies or your company?

Answer: We worked with the WHO to develop an online course for doctors so that they can be trained. This course is already available online, and doctors can start training.
<https://new.express.adobe.com/webpage/c1ob5FqyHxfrE>

Question: How do you plan to ensure access to lenacapavir in Russia? Who do you plan to cooperate with? When do you plan to register the drug in Russia? When registering the drug in Russia, will you register it as two separate drugs under different trade names or as one drug?

Answer: Gilead stays committed to expanding access to innovative medicines worldwide, including in Russia.

Gilead is actively exploring all available regulatory and legal avenues to ensure access to lenacapavir in Russia. This includes evaluating the potential for registering the drug within the Eurasian Economic Union (EAEU), which may facilitate a more streamlined registration process. We believe this is the best approach.

We recognise the importance of collaboration to achieve sustainable access. Gilead is engaging with key stakeholders, including regulatory authorities, healthcare professionals and patient organisations, to better understand local needs and identify appropriate pathways to access. We are also exploring potential partnerships with local organisations to support distribution and supply.

We are not yet able to provide an exact timeline for the registration of the drug. The process depends on a number of factors, including regulatory requirements, coordination with local health authorities and other circumstances. We will keep you informed as we move forward.

The registration strategy for lenacapavir is still being finalised. Under Eurasian Economic Union (EAEU) legislation governing the registration of medicines in Russia, a product can only be registered and marketed under one trade name. Gilead is building its registration strategy in line with this requirement and will act accordingly to ensure compliance with the law.

In this process, we value the involvement of patient communities and remain committed to transparent communication as we move forward. We believe that your input is critical to shaping the best approach to access and support.

Question: Can you already name the country in which you plan to register the drug under the Eurasian procedure?

Answer: At the moment, we do not have a final decision, but as soon as we do, we will be sure to let you know.

Question: Are there plans to continue the hepatitis C programme in Georgia after 2025? At the meeting in December 2024, you did not have any information about the contract extension.

Answer: As you know, our programme began in 2015, and our agreement with the Georgian government will end either when hepatitis C is eliminated or 10 years after the agreement came into force (it was extended by one year, so the deadline is April 2026), whichever comes first.

After the agreement expires in April 2026, responsibility for continuing the programme will pass to the Georgian government. Gilead is prepared to continue discussing this issue with the Georgian government as necessary in 2026.

Question: Has the Georgian government already approached you with any proposals?

Answer: At this point, the Georgian government has not contacted us. Recently, we have been communicating about the delivery of the next batch of hepatitis C drugs to Georgia. They may come to us early next year. We now see that the Georgian government has launched its own programme to eliminate hepatitis B without our support. We can also add that the recent request from the Georgian Ministry of Healthcare to Gilead for the supply of hepatitis C drugs has been fully met, and the delivery has already been made.

Question: Does the current voluntary licence for SOF/VEL include a paediatric formulation? As we have previously informed you, Viartis, for example, denies in its official responses that it can produce a paediatric formulation.

Answer: Our voluntary licence for SOF/VEL stipulates that licensees must follow the approved guidelines in each country (FDA or local regulator), and that dosages and formulation requirements must comply with these approvals. The decision on whether to register a paediatric formulation, as well as when and where to do so, is made by the licensee companies themselves. As you know, we have received requests from a number of organisations for humanitarian supplies of paediatric SOF/VEL for Ukraine and are currently reviewing these requests.

Question: Thank you very much for working on these requests. Please advise when we can expect a decision on this matter. This is very important, as your company is currently the only manufacturer of the paediatric form of SOF/VEL.

Answer: We are working very actively on this issue, and we will get back to you once we know we can give you a final answer.

Question: Is your company prepared to engage in negotiations with the Russian company Hepatera regarding the transfer of rights to the Ukrainian market for bulevirtide, taking into account the inability to use Russian drugs in Ukraine after 2014 and the full-scale invasion of 2022?

Answer: Hepatera has marketing rights for Myrcludex B (bulevirtide) in 11 EECA countries: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan. We are unable to supply bulevirtide to these countries, and do not have marketing rights.

For patients with hepatitis delta who have an urgent medical need, there is an individualised expanded access programme (iCUP) for bulevirtide, depending on origin of request. For more information, please contact: LIVERDISEASEexpandedaccess@gilead.com.

Question: Do we understand correctly that you have not yet had any contact with Hepatera?

Answer: No, we have not contacted Hepatera, as we are currently in the process of developing our strategy internally.

Comment from a representative of the patient community: We encourage you to expedite this matter, as the information provided to us by Hepatera during our communication with them has caused us concern. The fact is that Hepatera plans to register the drug in Ukraine after the geopolitical situation stabilises, which does not seem entirely realistic. It is also important to note that the patent for the drug expires in three years, so you do not have much time to think about it.

Question: We have sent you an independent request from patients to receive a donation of the drug. How long does it take to review such a request? And how will your company be able to deliver the drug in practice, given all the logistical difficulties?

Answer: Gilead recognizes the urgent needs of people living with hepatitis delta virus (HDV) and carefully reviews requests for access to medicines through its expanded access pathways, including the individual Compassionate Use Program (iCUP). Requests are evaluated on a case-by-case basis, and review timelines depend on the completeness of the information provided and applicable to regulatory requirements.

For bulevirtide, healthcare professionals may submit requests through Gilead's iCUP by contacting LIVERDISEASEexpandedaccess@gilead.com.

Question: Gilead is known to have a policy of not participating in public procurement of medicines (i.e., not participating in public tenders) if the patient market in a country is considered small or limited. This policy is particularly critical in cases where Gilead is a monopoly in the production of a particular drug. For example, since 2021, Gilead has not participated in public procurement of paediatric sofosbuvir/velpatasvir in Ukraine, as the demand for this drug is less than 100 patients. Does the company plan to review this practice?

Answer: Ukraine is covered by the voluntary licence for SOF/VEL, so there are licensee companies that are authorised to supply the drug to this market.

In Ukraine, Gilead has appointed a distributor with exclusive rights to distribute some of Gilead's products. In a country where an exclusive distributor has been appointed, Gilead cannot participate in tenders. The decision to participate or not participate in a tender is made solely by the distributor.

In general, Gilead does not engage in direct sales or participate in tenders in countries where the company does not have a presence. Access to medicines in countries with the greatest patient need is ensured in several ways:

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Access to Treatment with manufacturers
of drug products and diagnostic tools**



- through voluntary licensing, which allows generic manufacturers to produce and sell generic versions of our medicines;
- through procurement by non-governmental organisations;
- by appointing exclusive distributors for individual countries or regions.

Question: Can you name this exclusive distributor?

Answer: Yes, it is Delta Medical.

End of the meeting.