Minutes of the meeting of the Eurasian Community for Access to Treatment with Viatris

May 24, 2024

Company: **Viatris**
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***Data on drug registrations for all countries is summarized in a table in the Appendix.**

Start of the meeting. Introduction of participants.

Question: What are the company's plans to register pretomanid in Azerbaijan? What price is planned in this country?

Answer: Pretomanid is already registered in Azerbaijan. The registration expires in 2028. Our company is interested in making the price for pretomanid for a course of treatment for one patient in public procurement 240 US dollars (Ex-Works).

Question: As far as we know, pretomanid is not publicly procured in Belarus. Is there any information about the estimated price of your drug product for Belarus?

Answer: Pretomanid is registered in Belarus and the registration expires in 2026. The price will be the same as in Azerbaijan, i.e., 240 USD (Ex-Works).

Question: Are there any procurements in Belarus at the moment?

Answer: At the moment, the Ministry of Healthcare does not procure pretomanid. We have been negotiating with the National TB Program (hereinafter – NTP), including addressing their concerns about our product. We are working on this issue, but at this time we have not received any confirmation regarding the procurement of the drug. If you can help us in this matter, we would be happy to do so. Well, the price will always be the same, i.e., 240 US dollars (Ex-Works). As we see, the only barrier to procurement in Belarus is the Ministry of Healthcare. We are ready to continue to negotiate on this issue.

Question: Is pretomanid registered in Kazakhstan? What is the situation with the availability of the drug?

Answer: The drug is registered there. The registration is valid until 2026. The situation in Kazakhstan is similar to Belarus, that is no orders have been received and no procurement has been made. We also met with NTP, and they know that we are ready to supply the drug. As soon as an order is received, we will be ready to supply the drug.

Question: Is the process of obtaining WHO prequalification for bedaquiline completed? We talked about it at our last meeting.

Answer: We have submitted a dossier for WHO prequalification. We expect to receive WHO prequalification this quarter or next quarter.

Comment from a representative of the patient community: If we talk about pretomanid in Kazakhstan, to procure the drug, it has to be included in several registration lists. Therefore, as long as the drug is not included in these five lists, it will be impossible to procure it.

Answer: Thank you for your comment. We have a local partner who is working to ensure that the drug is included in all the necessary lists.

Question: Can you tell us who your local partner is?

Answer: Yes, for the time being the distributor is APC Healthcare Limited but we are partnering with others too.

Question: Do you plan to enter the Kazakhstan market through the Global Drug Facility (GDF) or via direct supply?

Answer: We are ready to use both of these mechanisms. We are partners with GDF, and as you know, many countries in the EECA region procure drugs through GDF. But if there is a requirement from the Ministry of Healthcare that the drug should be procured directly, we are ready to supply directly.

Question: If the drug is procured directly, will you stick to the GDF price of 240 USD? Or will the price be higher?

Answer: If the drug will be procured directly, the price will be 240 USD plus logistics costs, including transportation, taxes, etc.

Question: What are the logistics costs?

Answer: It depends on the country, but it is usually around 10–15%.

Question: As we know, you only do the logistics yourself up to the country's border, but within the country, is the logistics handled by a local distributor?

Answer: Yes, that is correct.

Question: What TB drugs does the company plan to register in Kyrgyzstan?

Answer: Pretomanid is approved in Kyrgyzstan. The marketing authorisation expires in 2027. We plan to expand the use of bedaquiline in the region, and we are working with partners in the region to prepare documents. Our local partners are now working on filing the registration dossier for bedaquiline. In addition, we have registration dossiers prepared for linezolid, moxifloxacin, etc.

Comment from a representative of the patient community: Kyrgyzstan is currently considering a decree that will extend the possibility of using the national drug registration procedure until the end of 2024. We kindly ask you to submit registration dossiers for your drugs until the end of 2024.

Question: As you know, Kyrgyzstan has a two-step registration procedure: the first registration of a drug is valid for 5 years, and then the drug must undergo a re-registration procedure. After this procedure, the drug will receive indefinite registration. Do you plan to submit pretomanid for re-registration under the EAEU procedure? Is it possible to undergo re-registration under the national procedure?

Answer: We registered the drugs in 2023 under the national procedure. And we plan to continue to use the national registration procedure. But we also realize that registration under the EAEU procedure is a long-term prospect, and we are already working on further registration of our products under the EAEU procedure.

Question: Two years ago you also said that you were working on registering under the EAEU procedure. Do you have any experience of registering drugs under the EAEU procedure?

Answer: Yes, we have already received approval under the EAEU procedure.

Comment from a representative of the patient community: I would like to add that in Kyrgyzstan, drugs that will be included in the list of strategically important medicines or in the list of medicines for the treatment of socially significant diseases will be registered according to national procedures.

Answer: Thank you for the information. I understand that it is important to act according to the national registration procedure, and we will do so.

Comment from a representative of the patient community: There is also information that in a few months in Kyrgyzstan the zero VAT rate for all medicines will cease to apply. This means that the price of all medicines will increase by 12%.

Answer: This is the first time we have heard about this. Unfortunately, our company can do nothing about it.

Comment from a representative of the patient community: We, as a patient community, are trying to solve this problem. For example, yesterday we had a round table on this issue in Kyrgyzstan. But so far there have been no results.

Question: Have you received a marketing authorization for the sofosbuvir/velpatasvir combination?

Answer: We have not received the approval. We do not have an approval at this time.

Question: Last year you registered pretomanid in Kyrgyzstan in the dosage of 200 mg, however, according to clinical protocols other dosages are allowed. Do you plan to register other dosages in Kyrgyzstan?

Answer: At the moment we are working on registration of pediatric dosage of pretomanid. As soon as we get approval from TB Alliance, we will submit the registration dossier.

Question: Are you ready to enter direct public procurement in Kyrgyzstan? At the moment all supplies in our country are made through the Global Drug Facility and UNDP, but NTP has funds for procurement of drugs. Can your distributors ensure your participation in tenders? Have you negotiated with the single Kyrgyz distributor Kyrgyzpharmacia about supplies?

Answer: At the moment we are communicating with representatives of Kyrgyzpharmacia. They asked us about the price, and we have provided them with prices for our drugs. We have informed them that we are ready to make direct shipments.

Question: What was the outcome of the discussion with Pharmstandard on the production of drugs in Russia?

Answer: We are still in negotiations with potential partners. Once the process is finalized, we will let you know our partner.

Question: Has the registration process for pretomanid started in Russia (it was planned to start in mid-2022)?

Answer: The registration dossier was submitted on March 31, 2023, and we expect approval by the end of 2024.

Question: Does your registration agreement with Pharmstandard cover only pretomanid or all your drugs? Do you plan to produce your entire product line at Pharmstandard's production facilities?

Answer: At the moment pretomanid is a priority drug, but we also have plans to register other products. We have a fairly broad line of HIV drugs, and we have already received several approvals. I have information that there are preferences in Russia for local manufacturers, but first we need to complete the registration process for pretomanid.

Question: We know that your company has an office in Russia. We would like to know what strategy you use when registering drugs? What principle is applied to select the drugs that you register through Pharmstandard and those that you register on your own?

Answer: Our office in Russia will handle drug registration and hold the marketing authorizations. The ARV & TB supply for all diseases is planned from India. We may change this model in the future, but at the moment we are working according to this strategy.

Question: What TB drugs does your company plan to register in Tajikistan?

Answer: Pretomanid is already registered. The dossier for registration of isoniazid 100 mg and 300 mg has been submitted.

Question: When was pretomanid registered? When does the registration expire?

Answer: If I remember correctly, pretomanid was registered at the end of 2023 and the registration expires in 2026.

Question: Does your company plan to participate in small tenders?

Answer: Yes, all tenders are important to the company regardless of size.

Question: As a patient community, we are aware that Macleods' price for pretomanid is 238 USD. In addition, Otsuka is offering 1190 USD for a treatment course of delamanid. What are your plans for lowering the price?

Answer: As for delamanid, we do not have a license from Otsuka to manufacture and supply delamanid in the EECA region. Coming back to pretomanid, as you know, previously the price of pretomanid was 362 USD. We have reduced the price to 240 USD (Ex-Works). Macleods is competing with us. It depends on the market, but Viatris is always trying to make the drug more affordable for patients. We will try to be the best in the market, and do everything we can to make sure patients get the drug.

Question: Have you reached a plateau in the price of pretomanid? What would the volumes have to be for the price to change? Experts have estimated that the cost of producing pretomanid is 50–100 USD, which means that there is still room for price reduction. What is your strategy in this matter?

Answer: It is true that volumes do matter in determining the price. But beyond that, there are many other factors to consider when lowering the price. As I said, we have already reduced the price. If there are any opportunities to reduce the price, we will do so.

Question: Can you still tell us the volumes?

Answer: It is difficult for me to answer this question because I cannot calculate this. There are a lot of associated costs.

Question: As we can see, your distributor in Belarus is working well and filling out all the documents in a proper manner. But you also need to write an application to the Unified Republican Scientific and Practical Center for Medical Technologies to include the product in the drug formulary. We checked and noticed that pretomanid is not in this list (formulary). At the moment supplies are made through the Global Drug Facility, but if the drug is not included in this formulary, the state will not be able to procure it directly. We have provided you with this information so that you can inform your distributor.

Answer: Thank you for the information, I will pass it on to the distributor.

Question: When is it planned to bring bedaquiline by your company to the Ukrainian market and at what price?

Answer: We plan to bring bedaquiline to all markets, and Ukraine is one of the key ones. Our partner in Ukraine has already submitted a registration dossier, and we have received feedback on this issue. We are getting closer to the fact that the drug will be registered soon. In October 2023, we submitted the dossier for prequalification of the drug to the WHO. We will work on pricing after WHO approval. The price will be influenced by a large number of factors and I cannot announce a price at this point in time. But I can assure you that our price will be lower than that of Janssen. We know that the price was quite high, and we will try to make it much lower.

Question: From which Janssen price will you reduce your price? From the original price, or already from the price that was reduced by 55% last year?

Answer: Janssen's original price for bedaquiline was very high. We hope that our price will be lower than the current Janssen's price. Once we calculate it, I will definitely share that information with you.

Question: Last year, the first procurement of pretomanid was made in Moldova. As you know, Moldova is a small country, and accordingly, the volume of the drug is also small. We have experience of procurement of bedaquiline for public funds, and the price was 6 times higher than in procurement through GDF. Does your company have a strategy to control prices at the local level? We understand that at the moment we have one price through GDF procurement, but when the state will procure the drug directly, it will be a different price. Does your company plan to control the price for the local market and local distributors?

Answer: The company has made a commitment that it will sell pretomanid at a price of 240 USD (Ex-Works). And when we negotiate with distributors, we tell them what price should be offered during the tender. And if you look at the procurement of HIV drugs, there is no significant difference in price there in GDF procurement and direct public procurement. We want to make sure that our drug is affordable, but we cannot control other players in the market. We do hope that competition will bring prices down, but we cannot tell on behalf of our partners.

Question: We have heard reports from independent researchers who have said that they estimate that the cost of producing bedaquiline plus profit is between 50 and 100 USD, depending on production volumes. We realize that you cannot talk about prices, but we would like to hear your personal opinion. Do you agree with this estimate?

Answer: I don't think I'm the right person to answer the question about how pricing is done. I'm sure there are a lot of factors that researchers can look at from different angles.

Question: Will registration dossiers/applications for re-registration under the new EAEU rules be submitted in these countries? How will the registration of drugs previously registered by the company under the former name, Mylan, be extended?

Answer: Yes, we have already started to submit dossiers under the Eurasian registration procedure. We are submitting a dossier for registration in one of the EAEU markets, and then we will replace the marketing authorization with a new one under the mutual recognition procedure. We will gradually go through the process of validating the company name change, but at the moment we continue to operate under the legal name of Mylan from the point of view of the marketing authorization holder.

Question: I would like to go back to the issue of the mutual recognition process. For example, Russia refuses to accept a marketing authorization for a drug registered in

another country. Have you encountered such a situation? What is your strategy in such a case?

Answer: I have got an example: we have received approval for the abacavir/lamivudine combination in Russia, and now this drug is going through the mutual recognition procedure. In a few months I will be able to let you know whether this procedure is working.

Comment from a representative of the patient community: There are some changes in the EAEU legislation. The mutual recognition procedure has been slightly simplified. Perhaps you need to choose a few countries, excluding Russia, register a drug there, and then Russia will be forced to recognize the drug according to the procedure. But, given that there are different options in the EAEU legislation that refer to the national registration procedure, it may be necessary to use this option.

Question: I would like to clarify who will apply for registration of pretomanid in Russia? Is it your company or Pharmstandard? And under which procedure, Eurasian or national?

Answer: In Russia, we have started to register pretomanid under the national procedure. And when we submit pretomanid for registration under the Eurasian procedure, we will do it independently by the local office of Viatris. We will not submit the registration dossier through Pharmstandard, and the holder of all marketing authorizations will be Viatris.

Question: So, Pharmstandard will not be the holder of any marketing authorizations for your products?

Answer: Mylan and Viatris is the marketing authorizations holder in the countries where we register the products.

Question: Do you have any data on registration of pretomanid in Uzbekistan? Is the drug procured in this country?

Answer: Yes, pretomanid is registered in Uzbekistan. The registration expires in 2026. Pretomanid is procured in Uzbekistan only through GDF. It is not procured directly by the Ministry of Healthcare. And please note that we have two products registered in Uzbekistan, namely pretomanid and moxifloxacin.

Question: Are you planning to reduce the price of pretomanid with the increased use of BPaL regimen?

Answer: As I said, the price of pretomanid was reduced from 360 to 240 USD (Ex-Works). We want to make the price as affordable as possible, and will let you know as soon as we are able to do so.

Question: What would the production volume have to be in order for the price to be reduced? What is your strategy for expanding production volume, given that there are other companies with a license from TB Alliance in the market?

Answer: Viatris mainly supplies pretomanid through GDF. Some countries ask us to supply the drug directly. The volumes of these countries are added to the total requirement and therefore, the more countries come to us with requests for direct supplies, the more opportunities there will be for price reductions. I will not be able to tell you the exact figure for the volumes, but I can assure you that for our part we are constantly working on our production costs to make them as efficient as possible.

Comment from a representative of the patient community: We understand that the price is also affected by the royalty you pay to TB Alliance. We may be able to influence TB Alliance to waive the royalty as a non-profit organization.

Answer: Let's have that conversation later. I'm sure the price of pretomanid will come down soon.

Question: Are there any plans to reduce the price of bedaquiline manufactured by your company?

Answer: Yes, as I said, we are planning to set the price of bedaquiline below the current price. As soon as we finalize the prequalification and registration procedures, we will be ready to give you the price within a few months.

Question: How do you plan to decrease the price of bedaquiline? What is your strategy for lowering the price?

Answer: The price is primarily driven by the cost of the active pharmaceutical ingredient, i.e. its synthesis. We try to work on reducing the cost of these manufacturing processes to reduce the price of the tablet itself. In addition, we have a large number of suppliers who give us the resources to synthesize the active pharmaceutical ingredient, and through this we can also reduce the production costs. Each company has its own strategy to reduce prices, but now we see that everyone is coming to about the same price level. And, as we have already said, volume is a very important factor that affects pricing.

Comment from a representative of the patient community: As far as we know, there are plans to include bedaquiline in the regimens for drug-sensitive TB, which means that the demand may increase, which will lead to an increase in volume.

Answer: Yes, we are aware of that. Taking that into account, as well as the BPaL regimen, we are expecting high volumes. And that's why we are planning that the price will be reduced even more.

Question: What are your plans for the production of delamanid? Do you plan to produce the pediatric form of the drug?

Answer: Unfortunately, we do not have the rights to promote the drug in the EECA region. We can promote the drug in Africa and some other countries. We would be interested in promoting the drug in your region, but we do not have authorization from Otsuka.

Question: Do we understand it correctly that in 2019 only Viatris received a license to manufacture and supply pretomanid from TB Alliance, and in 2023 the license was granted to the rest of the companies?

Answer: You are right, that is correct.

Question: What lessons have been learned from the situation where you were the only licensee and you failed to manage the production volumes of pretomanid, causing a large number of people to have their treatment postponed? What steps are you going to take to ensure that this situation does not happen again? TB Alliance shared with us that they will use a strategy of issuing licenses to multiple companies to prevent disruptions.

Answer: First, we have quadrupled our production capacity. Naturally, with this production capacity, this situation should not happen again. We realized that it is necessary to have a reserve of production capacity. And it seems to me that now there are no situations when people postpone treatment because there are no drugs available.

Question: What do you think about TB Alliance's strategy of issuing licenses to multiple suppliers? Is this a problem for you? There are currently 5 companies that are licensed.

Answer: Initially pretomanid was a new molecule and we ourselves, as a company, did the work to promote the drug into the clinical guidelines of the countries and worked to get doctors to prescribe the drug more. And by the time other companies entered the market, pretomanid was already being actively procured and prescribed to patients. And with regard to the licenses that have been issued to other companies, our strategy is that we will register the product wherever there is a potential need for it. This will be done so that if there is a situation where there is a need for the drug, we will be able to supply it promptly. The other companies are now at a different stage of the manufacturing process. We know that they are negotiating for procurement, but at the moment they are increasing their volumes, because they do

not have the production volumes that we have. At the moment we are in a better position. If we get an order, we will be ready to supply it immediately, and we will not need a long time to scale up production.

Question: How does your company ensure availability and affordability of TB drugs in different regions, especially in low-income countries?

Answer: For us there is no difference if it is a low-, middle- or high-income country, because all countries and all patients are important to us. As you know, globally, we work with the Global Drug Facility, and we are ready to supply our products to any country that the Global Drug Facility works with. And we have local offices and partners and distributors through whom we provide drug registration in all the countries where it's needed. And through our network of distributors, we try to meet the requirements of any market and supply the drug wherever it's needed.

Question: When is pretomanid expected to be available in pediatric and soluble forms? And when will it be registered in different countries?

Answer: I think TB Alliance was able to give you more information on this. At the moment they are doing studies and under a conservative scenario we expect the pediatric form of pretomanid to be released in 2 or 3 years.

Question: Will your company be the first to get a license from the TB Alliance for this drug?

Answer: I really hope so, but they are an independent organization and make their own decisions. If you are willing, you can let them know that Viatris would be a good partner.

Question: Given the fact that pretomanid and delamanid are part of TB treatment regimens, will your company be able to ensure a stable and constant supply chain of active pharmaceutical ingredients needed to produce the drugs?

Answer: The good news is that we synthesize both active pharmaceutical ingredients ourselves, and they are our product. This allows us to make sure that we have an uninterrupted supply chain. We make sufficient amount of the active pharmaceutical ingredient that we need to produce the tablet.

Question: The cost of delamanid was quite high because the drug was manufactured in Japan. As we know, the production is to be moved to India, which will reduce the cost and the price of the drug itself. But as we see, your company has been experiencing delays in production. What is the situation now? Will the price be reduced?

Answer: Initially we were getting the active pharmaceutical ingredient from Otsuka, but now we are synthesizing it in-house. We have a license from Otsuka, so we have to pay royalties, which affects the price significantly. And I repeat that we do not have a license to promote the drug in your region, so it is difficult to speak specifically about it.

Question: According to the MedsPal website, there is no patent for delamanid in Kyrgyzstan, Kazakhstan and Armenia. It turns out that you do not need a license to supply the drug to these countries. Or are there patents that we just don't know of?

Answer: Under the bilateral license agreement with Otsuka, we are not permitted to manufacture the drug for these countries at our sites. The license restricts the territories where we can sell the product produced at our plant. If we try to supply drugs to Kyrgyzstan, for example, it would be a violation of our territorial license agreement.

Comment from a representative of the patient community: This situation shows us that the parallel import mechanism does not work because the license agreement may have territorial restrictions.

Answer: Yes, parallel importation is no longer a legal working mechanism of TRIPS flexibilities. This is why, for example, barcodes are introduced in countries. Avoiding parallel import is the reason why they are introduced.

Question: Is it possible to include your delamanid in the Global Drug Facility procurement that goes through UNICEF or UNDP, so that the drug can get to Kyrgyzstan? Or will you ask them for information about which countries they are procuring for?

Answer: We will not be able to participate in such a tender without permission from Otsuka.

Question: Do we understand correctly that the license area is mainly limited to low-income countries and countries that procure delamanid with money from the Global Drug Facility?

Answer: No, the license is not tied to the economic status of countries or the work of the Global Drug Facility. The license includes a list of countries where we can supply the drug. For example, we supply to Zambia and Zimbabwe. As far as I know, there is a distributor who can supply to the EECA region. You need to check this information. Otsuka has a partner that has a license to distribute delamanid in the EECA region.

Question: We know that Lupin has approached Otsuka to produce a generic version of delamanid. To the best of our knowledge, given the limitations of your license

agreement, Otsuka has directed Lupin to you for reference samples for a bioequivalence study. Can you tell us whether Lupin has contacted you? Have there been any negotiations?

Answer: We have not received any request from Lupin yet.

Question: Is your company interested in developing rifapentine?

Answer: Yes, we have this drug in the pipeline right now and plan to manufacture it.

Question: How much time will you need?

Answer: At least 2 or 3 years.

Question: We had a discussion yesterday on the reproductive safety of pretomanid in boys. Do you have any study results or more information on safety?

Answer: TB alliance will be able to answer this better.

Question: We had discussions with NTPs from different countries and they told us that there are patients with extensively drug resistant TB (XDR-TB) in every country. At the moment, these patients have quite few treatment options. How do you feel about using pretomanid in other combinations to treat extensively drug-resistant TB?

Answer: I am not sure, but I think the World Health Organization (WHO) has given approval for the use of pretomanid for the treatment of extensively drug resistant TB. But I could be wrong.

Question: I may have outdated information, but to my knowledge pretomanid is only used in BPaL and BPaL/M regimens for the treatment of pre-XDR-TB, but there are no data on its use for the treatment of XDR-TB. We would like patients who have resistance to bedaquiline and fluoroquinolones to have the option of using pretomanid for treatment to survive.

Answer: My personal view is that pretomanid is safe for use in patients with XDR-TB, but here we have to wait for WHO consensus on this, as they are the sole regulatory agency. We cannot act without their approval. It seems to me that if this is the last chance for a person who is on the verge of death, then pretomanid should be used. But if WHO has concerns, then at the institutional level we can’t make such statements.

Question: Do you have data on the interaction of bedaquiline and methadone?

Answer: No, we do not have data.

Question: Do you have data on the interaction of bedaquiline with hormone replacement therapy? There has been a case that doctors did not understand how to treat a patient who is taking such therapy.

Answer: As we have not commercialized Bedaquiline so data not available.

Question: Please share about your company's new developments in TB treatment, if any. We already see patients with resistance to the latest drugs linezolid and bedaquiline. Are there any plans to develop new drugs and treatment regimens for such categories of patients? Also because of poor tolerance to linezolid.

Answer: We are developing pediatric forms of the drugs. We are also open to your ideas.

Question: What pediatric forms are you developing?

Answer: For all drugs that are part of our TB portfolio. In some cases, we will need approval from the TB Alliance, and as soon as we get it, we will do so.

Question: At what stage is the development of pediatric drugs?

Answer: It will take us another 2 or 3 years to finalize the process.

Question: What fixed-dose combinations with pretomanid (if any) do you plan to develop?

Answer: We plan to develop a fixed-dose combination of BPa+L.

Question: We know that linezolid is quite a toxic drug and it can negatively impact the quality of life in patients. Is it your idea to do this particular fixed-dose combination or a suggestion from TB Alliance?

Answer: We will not include linezolid in any fixed dose combinations.

Comment from a representative of the patient community: This is the same strategy as that of TB Alliance.

Answer: Yes, maybe it can be their idea

Question: Have you done any consultations with civil society and communities to understand how much this fixed-dose combination is needed by patients?

Answer: We have not consulted with patients, but we know that TB Alliance has done consultations and patients were interested in this combination. Our clinical research team also conducts such consultations in local markets. We get feedback from each country.

Comment from a representative of the patient community: We would like to tell you that we have concerns about this combination, given that the patient may have a change in dosage, which may be inconvenient. We also have questions about the price and volume of this combination. We strongly disagree with TB Alliance on the need to develop this combination.

Answer: We always have an alternative, which is bedaquiline, pretomanid and linezolid separately. The fix-dose combination is an additional option. I have received your feedback and will pass it on.

Comment from a representative of the patient community: We know that TB Alliance is trying to patent a BPaL treatment regimen.

Answer: I was not aware of this. The WHO will make the final decision on the fix-dose combination. We, as a company, will not force patients. If we have a consensus on the need to produce this combination, we will do it. If there is no consensus, then we will not force anyone. And I think TB Alliance also cares about patients' opinions because they are a non-profit organization and their mission is not to make a profit, but to help patients. Please discuss this with TB Alliance because it's important.

Question: What standards and certificates are used for quality control?

Answer: Those of the WHO and the FDA US.

Question: How is the safety of the company's drugs monitored?

Answer: Local partners and distributors are responsible for pharmacovigilance.

Question: Is Viatris involved in any partnerships to improve healthcare infrastructure to help bring medicines to hard-to-reach areas?

Answer: Yes, we are working with partners and distributors to make our product available to every patient.

Question: Are you considering joint development with other pharmaceutical companies?

Answer: We are currently in joint development with Otsuka and TB Alliance.

Question: What additional measures are you taking to improve access to TB treatment in the prison system in the countries you work with?

Answer: Our partners are working with local networks to help reach patients in prisons.

Question: How do you assess the effectiveness of the system of early TB diagnosis among prison inmates?

Answer: We believe that early detection is always better and it helps prevent the spread of the disease.

Question: How do you cooperate with governmental structures to ensure TB treatment in penitentiary institutions?

Answer: We collaborate with governments in case they are planning procurements.

Question: What opportunities do you see for improving the treatment and care of prisoners with TB in the future?

Answer: Early diagnosis and timely procurement and supply of drugs works well in this regard.

Question: To what extent is TB a priority for your company along with other infectious diseases, particularly HIV and hepatitis?

Answer: Tuberculosis is a priority for us as much as HIV and hepatitis.

Question: How is your company working to make TB diagnostic tools more accessible and cost-effective for economically challenged countries?

Answer: We are currently partnering with Qure AI to build a TB AI tool in India that enables TB detection using artificial intelligence. But at the moment the company wants to work independently in the international market.

Question: As far as we know, hepatitis is now included in HIV programs in Tajikistan. What are your company's plans to develop and produce drugs for the treatment of hepatitis C?

Answer: We produce the key drugs for hepatitis C treatment, i.e. sofosbuvir/velpatasvir and sofosbuvir/daclatasvir. If there is a need, we can supply these drugs to Tajikistan. Both of our combinations have WHO prequalification, so you can apply and we will supply the drugs.

Question: We regularly communicate with patients and we know that due to the toxicity of TB drugs many of them refuse treatment. Doctors and patients are asking for the drugs to be less toxic. In addition, patients need to know exactly when to take the drugs and what to take them with. Will there be strict guidelines for the drugs as to what to take them with and at what time?

Answer: We have heard your question and will think about what can be done.

End of the meeting.

Appendix 1

Registration status of drugs

Registration status of the medications

Country	INN/ product name	Dosage	Registration status
Armenia	Pretomanid	200mg	Dossier submitted by EAEU proceedeure. Pending registration. Expected Q4 2025
Azerbaijan	Pretomanid	200mg	Registered. Registration expires 2028
	Isoniazid	100mg	Under approval
	Isoniazid	300mg	Under approval
Belarus	Pretomanid	200mg	Registered. Registration expires 2026
Georgia	Pretomanid	200mg	Registered. Registration expires 2026
Kazakhstan	Pretomanid	200mg	Registered. Registration expires 2026
	Pretomanid	200mg	Dossier submitted by EAEU proceedeure. Pending registration. Expected Q1 2025
Kyrgyzstan	Pretomanid	200mg	Registered. Registration expires 2027
Moldova	Pretomanid	200mg	Registered. Registration expires 2026
Russia	Pretomanid	200mg	Under approval
Tajikistan	Pretomanid	200mg	Registered. Registration expires 2026
	Isoniazid	100mg	Under approval
	Isoniazid	300mg	Under approval
Ukraine	Pretomanid	200mg	Registered. Registration expires 2027
Uzbekistan	Pretomanid	200mg	Registered. Registration expires 2026
	Moxifloxacin Hydrochloride	400mg	Registered. Registration expires 2024