Meeting Protocol for the "Eurasian Community for Access to Treatment" with "Viatris" company

September 29, 2023

Representatives of the organization: Abhishek Datta - Head of the ARV Drug and Infectious Disease Division in the EMEA region

Meeting Commencement.

Introduction of Participants.

Question: Please explain the difference between Mylan and Viatris.

Answer: Approximately 2-3 years ago, Mylan merged with Upjohn, a generic drug company owned by Pfizer. Viatris can be considered as the new name for Mylan, although, in essence, it is the same old company with new name. Even on our logo, it says: Upjohn + Mylan = Viatris.

Question: We previously inquired about Mylan's diagnostic test kits. Is there a division of responsibility between the brands? For instance, is Viatris responsible for tablets, and Mylan for tests? Can you provide information about the rapid HIV test under the Mylan brand? Does Mylan work in the field of diagnostics? We used to know your company as a manufacturer of pharmaceuticals.

Answer: Any products that were under Mylan's purview, including those related to HIV, HCV, and the like, now fall under Viatris. This pertains to both medications and test kits. During the rebranding process, some products are still being marketed under the Mylan brand, while others have started being produced under the Viatris brand. Gradually, we are transitioning our entire product line to the Viatris brand.

Question: Do you have other diagnostic products?

Answer: Currently, the rapid HIV test is the only product we have in the field of diagnostics. We are discussing the possibility of introducing tests for hepatitis C, but it's still a project in progress.

Question: Why did you change the name? It involved changing the logo, packaging, and so on. These expenses could impact the final product cost for consumers.

Answer: During the merger, we had two options: either merge with Upjohn under the Mylan brand or create a new brand. To avoid confusion with the Upjohn brand, we decided to choose a new brand. If we had undergone a complete rebranding from the beginning, it would have been very confusing for partners & costly for all. Therefore, we are rebranding gradually. Viatris is derived from the names of several Upjohn company products.

Question: When the new name emerged, community organizations, including international ones, began to say that Mylan had become an originator company because it was acquired by Pfizer. Are you still a generic company in terms of philosophy, or are you now positioning yourself as an innovative company? Who has the final say: Mylan or Upjohn?

Answer: Pfizer and Viatris are two different companies. Mylan acquired Pfizer's subsidiary, resulting in the creation of Viatris through the merger. Pfizer was involved in this process. You

are correct in saying that Pfizer is an innovative company, while Viatris remains a generic company and continues the business model that Mylan adhered to. Robert Coury, who was the head of Mylan, now leads Viatris.

Question: In 2023, a representative of Viatris in Kazakhstan offered the combination of sofosbuvir/daclatasvir at a price four times higher than what was previously stated by Viatris headquarters. Why didn't Viatris headquarters intervene, despite multiple invitations to participate in negotiations for this procurement? Do you have a pricing control algorithm for countries, and if not, do you plan to create one?

Answer: When the Ministry of Health of Kazakhstan announced this tender, our partner approached us, and we responded that we were ready to supply the product. As far as we understand, both the budget and prices were determined by the Ministry of Health of the Republic of Kazakhstan. We provided our price to our partner, and they added their markup and participated in the tender. Of course, the price increased, as you noted. However, by the time we received this information, the tender had already taken place. We, as manufacturers at that time, could not participate in negotiations with the Ministry of Health because our partner was involved in the bidding. We don't want the Ministry of Health to think that we are intervening as a third party in this process, as that would be incorrect. As you know, our prices for HCV treatment medications have historically been the best in the region.

Comment: That's not a fact. Hetero also competes with you quite well.

Answer: Yes, the prices of Hetero and Natco are very close to ours, but if you look at the actual results of procurements, our price was the lowest. Naturally, there is competition, and in some situations, their prices may be lower, but in most cases, we strive to offer a lower price.

Comment: I have dedicated ten years of my life to making the hepatitis C elimination program work in Kazakhstan. Three of those years were spent trying to convince Gilead to include Kazakhstan in the voluntary license. I want to remind you that the elimination program for viral hepatitis C in Kazakhstan started with Mylan's pharmaceuticals. You initially sold drugs in Kazakhstan for $80 per course of treatment, then for $70. And suddenly, someone came along and disrupted everything. Hetero supplied us with a three-month course for $60. Thanks to this partner, the price of the treatment course has now risen to $240. When this situation was unfolding, your representative was repeatedly invited to negotiations, as you know from the correspondence. The situation could have been changed during these negotiations. Initially, there were negotiations with "SK-Pharmacy," where everyone, including your representative, declined to participate. Then there were negotiations with the Ministry of Health, and again, we received no response. In the end, thanks to you, this person joined the correspondence, but he started with threats of legal proceedings. I would like to continue to believe that Viatris is a socially responsible company. I know that the price for the sofosbuvir/daclatasvir combination is $80 or lower, not $240. I don't want to delve into this now. Instead, I will ask a **Question** that we have raised several times in meetings. When will Viatris have a full-fledged representation in Kazakhstan or a Kazakh company with which you have good relations and with whom we could work? The person we were just talking about is not available; he doesn't **Answer** phone calls from "SK-Pharmacy" and the Ministry of Health; he ignores our attempts to contact him. This is not how business should be conducted. In Kazakhstan, the healthcare budget is limited, so a low price is very important for expanding access to treatment.

Answer: Thank you for your comment. We hope you consider Viatris a socially responsible company. We agree that $240 for a course is an entirely unacceptable price. Recently, we issued a joint press release with the Clinton Foundation, stating that the price of HCV therapy will be reduced to $60 per course. This partnership with the Bill Clinton Foundation (CHAI) includes

Hetero as part of the agreement. We commit to offering a price of $60 per course for any government procurement. Currently, this agreement applies to four countries: Cambodia, Indonesia, Rwanda, and Vietnam. New countries will be added to this agreement in the future. The price of $60 per course for the sofosbuvir/daclatasvir combination is what we will offer to all countries included in the CHAI agreement. We agree that the previous year was a bad year for prices. In the future, we plan to continue supplying HCV treatment medications (sofosbuvir/daclatasvir, sofosbuvir/velpatasvir, and sofosbuvir/ledipasvir) at low prices.

Comment from a patient community representative: I informed Abhishek about the tender for sofosbuvir/daclatasvir in Kazakhstan, and Abhishek said he would work on this issue with the local representative. The procurement volume is small because the tender is aimed at patients who are already receiving this combination. Later, there will be a tender for sofosbuvir/velpatasvir. We ask Viatris to participate in both tenders, and I hope that in 2024, you will provide us with low prices.

Answer: We will do everything within our control.
Comment from a patient community representative: We urge you to work on mechanisms so that such situations do not happen in Kazakhstan or other countries in the future. As a manufacturer, you should have leverage over intermediaries whose behavior contradicts your mission and policy.

Answer: We agree. This is the first time we have encountered such a situation when working with partners. Usually, we learn the price directly from our partners, but this time I learned the price from Sergey Biryukov after the fact, and it was a shock for us. We will try to be more cautious in the future.

Comment: What happened in Kazakhstan tarnishes your reputation. How do these risks compare to the costs associated with your presence in the markets of our region? If you work directly, you have control over everything. If you work through partners, you can hope to control everything. Due to legislation that is more or less the same in Eastern European and Central Asian countries, local distributors cannot add a significant markup. In my opinion, on average, it ranges from 10% to 20% in the region. Given that you sold at a price not higher than $80-90, the maximum price should be $100-110. Where does $240 come from? Often, distributor companies import drugs through firms registered in the United Arab Emirates. Perhaps Viatris should trade directly rather than through intermediaries. Then the price will be what the law sets, and the company's reputation will not suffer.

Answer: We have taken note of your comment, and we consider it a good suggestion. The challenge lies in constantly changing national legislation, as in Uzbekistan, for example. In Uzbekistan, we have obtained approximately 10 to 15 registration certificates, but we cannot bring the products to market despite tenders and commercial interest. In this situation, we rely on local partners who operate within the national regulatory framework. In Kazakhstan, pretomanid has been registered for two years, and we still cannot bring it to market due to specific requirements. Consequently, in this case, we rely on local partners who discuss, for example, issues of drug inclusion in recommendations with health ministries or other stakeholders. If there is an opportunity to participate in tenders directly, we will gladly take advantage of it.

Comment: It's important for you to understand that the choice of partners is your responsibility, and your reputation can depend on the partners. What's done is done, but we will still view this situation as a mistake by Viatris. In the future, for example, in Uzbekistan, the responsibility will also be on you. We understand that national legislation can change, but your reputation as a socially responsible company that provides a certain price remains your reputation.

Answer: This situation has occurred for the first time. We have been participating in tenders in the region, including through partners, for quite some time, and this is the first time we've encountered such a problem. We have participated in procurements in Moldova, Belarus, Ukraine, and there have been no complaints about prices. We certainly take responsibility for this, and we will strive to ensure that such a situation does not happen again.

Question: What specifically does your company plan to do in the region to prevent this from happening again? Will you implement new procedures or annually review your partnership relations?

Answer: In our current agreements, partners have an obligation to ensure transparent pricing. We have been working under this model in the region for 4-5 years, and, as I mentioned, this situation has arisen for the first time. On our part, we would like to request that if you see cases of an initial price increase, including in the Ministry of Health tenders, please inform the ministries about it. It may not be an effective solution, but we, in any case, cannot control the prices set by the Ministry of Health.

Question: Your products have limited presence in Kyrgyzstan. Nevertheless, pretomanid is registered in Kazakhstan and Kyrgyzstan. How did you manage to obtain a registration certificate for pretomanid without the results of Phase III clinical trials?

Answer: When we registered in Kazakhstan, pretomanid already had a WHO prequalification certificate. Pretomanid was registered in all countries – Kazakhstan, Uzbekistan, Kyrgyzstan, Moldova, Belarus, Azerbaijan, Ukraine – based on the WHO prequalification certificate.

Question: Without a complete registration package?

Answer: This is a technical

Question: and our regulatory department will be able to provide a more detailed

Answer: But in general, all research related to pretomanid has been completed.

Question: In Kyrgyzstan, there are plans to expand the use of pretomanid. Will you continue to work only through the GDF, or is direct supply of pretomanid to the government possible? What will be the price in this case?

Answer: We can sell pretomanid not only through the GDF but also directly to governments. For any purchases in the world, we provide a price of $34.59 per pack. This was a voluntary decision on our part to expand access. The price was reduced from $60-80 per pack to $34.59.

Question: So, the price in government procurement will be $34.59 per pack? Including the distributor's margin?

Answer: $34.59 per pack is the price on an ex-works basis.

Question: Can the low price for pretomanid be linked to the price for bedaquiline (BPAL regimen) in GDF purchases? Suppose pretomanid is purchased through the GDF at a reduced price, and bedaquiline is procured directly by the government. In this case, the combination can be problematic.

Answer: As you know, the patent for bedaquiline expired on many markets this year. We have developed a generic version of bedaquiline, and it is currently going through the WHO prequalification process.

Question: When will it be completed?

Answer: We should receive the prequalification certificate in this quarter (Q4 2023). We are working with the Medicines Patent Pool (MPP) and are ready to supply bedaquiline to markets where it will be possible, considering license terms, patent availability, etc.

Question: Will secondary patents from Janssen be an issue?

Answer: The Medicines Patent Pool (MPP) provides a license that covers all patents. If a country is included in the MPP license, we can supply there regardless of the presence of secondary patents.

Question: Are you continuing negotiations with Pharmstandard? If you plan to conclude an agreement with them regarding pretomanid, we are strongly against it, as such agreements have already led to problems with drug accessibility in the region.

Answer: We have not yet signed an agreement with Pharmstandard. Currently, we are working in each country of the region separately, and we do not plan to enter into a licensing agreement with the Russian company that would apply to the entire region. I assume you are referring to the situation with delamanid and the license granted to R-Pharm. We will not use that model. We already supply pretomanid within the framework of the GDF mechanism. I am aware that there have been difficulties, but by September of this year, we have resolved these issues by increasing production capacity to 100,000 packs per month. If a country has a need, we are ready to supply.

Question: What is the estimated price of your bedaquiline?

Answer: The price will be known after WHO prequalification. But you can be sure that, as with pretomanid, the price of bedaquiline will not be as high as the original drug.

Comment from a representative of the patient community: Price information is important for people on the ground to discuss potential volumes with governments.

Answer: We will try to discuss this with senior management, and if possible, we will share an estimated price for future calculations.

Question: There were difficulties with the delivery of pretomanid in Ukraine. Was it possible to deliver everything?

Answer: By September, we had fulfilled all deliveries not only to Ukraine but to other countries as well. If the demand increases, we are ready to supply, as the production capacity issue has been resolved.

Question: Your new price for pretomanid is almost half of the price through the GDF. Taking the GDF price of $364 for a course, it is nearly double the $34.59.

Answer: I think you are referring to the old price. The price has recently been revised and now stands at around $35 on an ex-works basis. Most likely, the cost of logistics will be added to this price. This information is public.

Question: Do you have plans to produce pediatric versions of the BPAL combination and fixed-dose combinations?

Answer: We have pretomanid and bedaquiline as separate drugs. We plan to develop a combined option, but we cannot say how long this will take at the moment. The same applies to pediatric forms. First, we need to obtain WHO prequalification for the adult form, and then we can work on other forms.

Question: Based on incoming orders, do you need to increase production capacity further? How long might this take if necessary? This question is relevant because almost all countries in the region have requested information about supplies.

Answer: Yes, there were delays in deliveries, but we have resolved this issue and increased production capacity to 100,000 packs per month. If demand increases further, we will increase capacity as needed. This process typically takes from 3 to 6 months. However, based on the requests we receive, our current capacity seems to be sufficient.

Question: How many requests do you receive per month, and what is their volume?

Answer: It is a cyclical process that depends on the timing of tenders. Based on the current requests, we do not anticipate delays like we had in the past. We would like to ask you that if you see a need in a country, please inform us. We are ready to supply pretomanid without delays.

Question: Are you discussing with the TB Alliance the possibility of renouncing patents or secondary patents on pretomanid, given the pressure that the global community is currently putting on pharmaceutical company Johnson & Johnson to withdraw secondary patents on bedaquiline?

Answer: As you know, the TB Alliance was responsible for developing pretomanid. Pretomanid needs to be combined with bedaquiline. We are currently negotiating with the Medicines Patent Pool regarding a license for bedaquiline. The terms of the license will determine which countries are included in the access program. From our side, we are trying to obtain a waiver or some form of intellectual property license that allows us to bypass all secondary patents. Our mission is to ensure that as many people with tuberculosis as possible receive the therapy.

Question: Thank you for your efforts to make pretomanid accessible. Do you have data on children and pregnant individuals, and do you have plans to develop pediatric forms?

Answer: I do not have information on data related to pregnancy. I will check with my colleagues and provide you with the information. Pediatric forms are included in the research and development plan.

Question: Are you negotiating with the Medicines Patent Pool regarding a licensing agreement for pretomanid?

Answer: When we talk about a license, it primarily concerns bedaquiline. As for pretomanid, we can supply it to any country because there are no patent issues with this drug.

Question: What difficulties do you observe in the EECA region, including EAEU countries, when it comes to drug registration?

Answer: A significant barrier in the Eurasian procedure is the large volume of documentation and the requirement to translate many modules into national languages. Such requirements do not exist in the national procedure. This is a new process, and experts who prepare dossiers in countries are learning as they go. Representatives from countries occasionally approach our regulatory department, requesting new information that was not previously required. Correct me if I'm wrong, but if we, for example, want to register the TAF/emtricitabine/dolutegravir combination in the EAEU territory, we must conduct studies in one of the countries in the region according to the requirements. Even a bioequivalence study requires time and expenses. Consequently, the registration timeline is extended.

Question: In 2023, the Eurasian Economic Commission allowed countries to register drugs according to national procedures. Belarus and Kyrgyzstan issued relevant resolutions, and until the end of the year, they are accepting dossiers via the national procedure. Has your company submitted documents for registration via national procedures in any EAEU countries? These procedures do not have requirements for bioequivalence studies, etc. The EEC is currently considering the possibility of returning all national procedures until 2030. Have you adapted dossiers for national procedures?

Answer: We learned about the extension of national registration procedures to 2030 recently. According to the information we had, by 2025, countries were supposed to transition to registration according to the EAEU rules. We contemplated which registration procedure to choose. In Kazakhstan, for example, we decided to submit dossiers for dolutegravir and dolutegravir/tenofovir/lamivudine for registration under the national procedure before the EAEU rules came into effect. This happened during the Covid-19 pandemic, and we couldn't send the necessary samples due to flight disruptions. As a result, our dossier was returned for revision. Subsequently, the Medicines Patent Pool expressed dissatisfaction with our failure to register the drugs within the given timeframe and even threatened to revoke the license. However, the problem was with the registration procedure under EAEU rules.

Question: Our partner informed us that it is now possible to register drugs in Kazakhstan using the national procedure, and we are registering TLD and dolutegravir using the national procedure. We have also submitted the same products for registration in Belarus using the Eurasian procedure. We are registering our products using both national and Eurasian procedures. Fifteen days ago, we received a registration certificate for tenofovir in Kyrgyzstan using the national procedure. We try to choose the optimal approach. To be honest, the requirement for bioequivalence studies is a significant issue, not only for us but also for all companies that register drugs using the Eurasian procedure.

Answer: Yes, that's true. There's no requirement for bioequivalence studies in national procedures, and it's a major challenge to conduct such studies. Our partner in Kazakhstan mentioned that they have now started using the national procedure because it is more straightforward than the Eurasian one. You need to adapt to the specific requirements of each country and select the most efficient approach for registration.

Question: So, you receive Eurasian registration certificates in Belarus?

Answer: Only for these two products.

Question: What about the rest of your portfolio?

Answer: Not necessarily. If we submit 10 dossiers to one country, it will take a lot of time. We diversify the process: we submit, for example, three dossiers in Belarus, three in Kazakhstan,

and so on. The process runs in parallel because the Eurasian registration procedure takes a lot of time, and we try to distribute the workload among countries.

Question: Is there any logic in your choice of products and countries?

Answer: We chose Belarus because these products were already registered there under the national procedure, and we use that as a basis for further registration under the Eurasian procedure. We choose the country for Eurasian registration depending on whether our products are registered there under the national procedure.

Question: In the Kyrgyzstan market, you have primary registration certificates for sofosbuvir and daclatasvir. According to our rules, after primary registration, we need to undergo re-registration after five years, following which we receive an unlimited registration certificate. We now have fewer drugs because some companies refuse to re-register certain drugs. Do you plan to re-register dossiers for HCV drugs? Additionally, do you plan to register sofosbuvir/velpatasvir? We currently have a large volume of government procurement.

Answer: Yes, we will renew all registration certificates. The process is already underway. We have submitted a dossier for the registration of sofosbuvir/velpatasvir. You can check the registration status of drugs in the table in Appendix 1. Please note that in some cases, there are indications of an extended shelf life or changes in packaging. In particular, we have changed the package size for TLD from 30 tablets to 90 and 180. In Ukraine, we have applied for the registration of packages of 90 and 180 tablets using the national procedure, and we may need the support of Ukrainian colleagues for their registration. We see that, at present, preference is given to the 90-tablet packaging, and no one wants to purchase the 30-tablet version. In essence, instead of three bottles, you get one.

Comment: Currently, medications are dispensed for a three-month supply, so it's not a problem.

Question: Do we understand correctly that Gilead does not agree to include HIV infection in the TAF product label, only hepatitis B?

Answer: TAF, as a standalone drug, is indicated for the treatment of HBV. When used in combination with emtricitabine and dolutegravir, it is used for the treatment of HIV.

Question: In Belarus, a range of ARV drugs manufactured by Viatris is registered: DTG, TDF/FTC, TDF/FTC/EFV600. In 2022, an unregistered drug, TLD (Acriptega), was procured, and in 2023, registered drugs DTG and TDF/FTC/EFV600, as well as unregistered drugs TLD and EFV600, were procured. Do you plan to register TLD and EFV600 in Belarus? If not, can you provide medical usage instructions in one of the official languages of Belarus (Belarusian or Russian)?

Answer: TLD has recently been registered in Belarus using the national procedure. Therefore, both dolutegravir and TLD are currently registered. We have also registered tenofovir/emtricitabine/efavirenz and a range of hepatitis drugs. Belarus is a priority market for us, and we aim to register all the products we supply.

Question: In August 2023, MinskPharmacia (Belarus) announced a tender for the supply of naloxone, but Viatris did not participate. Were you unaware of this, or was the potential contract value unattractive to you?

Answer: I will contact colleagues responsible for this medication and provide their response.

Question: Given Belarus's switch to the WHO recommendation for the use of EFV at a dosage of 400 mg, we would like to clarify the price difference between TDF/FTC/EFV600 and TDF/3TC/EFV400. We are talking about a similar procurement volume of up to 50,000 packages per year.

Answer: We have a combination with efavirenz 400 mg, which is the preferred dosage compared to 600 mg. We supply approximately 50,000 packages per year. We consider this to be a good volume, and we are ready to continue supplying if the demand persists. The 400 mg dosage is 10% cheaper. We supply the 600 mg dosage on request, but most purchases are for the 400 mg dosage.

Question: Are you ready to confirm your readiness to supply a generic of a drug produced under a voluntary license to Belarus if the government issues a compulsory license? In Belarus, the issuance of compulsory licenses has recently become possible by government decision.

Answer: Everything related to the issuance of compulsory licenses in countries and the possibilities of supplies must comply with the terms of the Patent Pool license. This applies to patents not only in the destination country but also in the country from which the drug is supplied, in this case, India. If the agreement terms and patent holder's rights are not violated, we are ready to supply if there is a request from the Ministry of Health.

Question: When can we expect a generic version of cabotegravir in Ukraine?

Answer: Cabotegravir is still in development and is expected to take approximately 3-4 years.

Question: What is the price for entecavir and liposomal amphotericin B for EAEU countries?

Answer: We have recently encountered some difficulties related to the quality and stability of entecavir. We are not currently supplying this product to the market as we are working to address these issues.

Question: Have you already supplied this product somewhere, but later discovered issues with quality and stability, or were these issues discovered during the development process?

Answer: We had previously supplied entecavir mainly to Taiwan, and we sourced the substance from another company. During our own testing, we found that the stability of the product was 18 months instead of the claimed 24 months. We are currently addressing this issue.

Question: How often do you find that the shelf life of a product is shorter than what your partner has claimed? This is a concerning issue.

Answer: We procured the substance from a third-party company, while the tablet itself was manufactured by us. At present, this situation is isolated. As an American company, we have to adhere to certain procedures. We conduct proactive checks and continuously monitor to ensure the product complies with requirements. Even after shipments, our compliance department continues to perform checks, and if instances of non-compliance are identified, we inform all relevant parties. There have been no such problems in EAEU countries, and we hope there won't be.

Question: How often are you contacted from EAEU countries with complaints about side effects of HIV, hepatitis, and tuberculosis treatment drugs through the existing pharmacovigilance system? Are there any "problematic" countries?

Answer: We have a global pharmacovigilance system, and there are no "problematic" countries in the region. Currently, there is a global study aimed at assessing the link between dolutegravir and the development of diabetes. We understand that dolutegravir is the most effective option today, but people at risk of diabetes and hypertension may require different options. Our pharmacovigilance team receives and processes all signals.

Comment from a representative of the patient community: If there are topics in the list of questions that fall under the competence of other specialists, please also invite them to the Zoom meeting or provide their responses in written form before or during the meeting.

Answer: We will take this into account.

Question: Considering the upcoming transition of Belarus and other EAEU countries to the WHO-recommended HIV testing algorithm, which includes three rapid tests, we are interested in the price of the Mylan HIV Self Test. The volume of national procurement is around 70,000 tests per year. Is this product part of Viatris' portfolio? If not, who is responsible for this product?

Answer: This self-test for HIV self-testing is a partner product. It was developed in collaboration with an Australian company called Atomo, and we are the exclusive distributor. The HIV Self Test is currently registered in Ukraine, and we are working on registration in Belarus. According to the requirements, the applicant must be the manufacturer, not the distributor, and the registration process in Ukraine took a long time because we needed to conclude a three-party agreement. There were many delays, including due to military actions, and the registration process took from two to three years. This year, there was the first delivery to Ukraine, with around 5,000 tests purchased through the Global Fund. We can meet the volumes you mentioned. We are ready to supply the product to any country that expresses a need. We have established relationships with Atomo, and we have production capacity in South Africa.

Question: Do you supply the product to South Africa, or do you only manufacture it there?

Answer: We manufacture the product in South Africa, and it is already available in the South African market. In addition, the test has been introduced to the markets in Zambia, Zimbabwe, and Mozambique. It is also available in Southeast Asia, such as in Vietnam, and in Middle Eastern countries, such as Qatar. We are currently entering the North African market, specifically Egypt. The price is $1.99 USD per test. This price is valid for government purchases and for donors, not for the commercial market. We are ready to supply to any country in the EAEU region upon request. We are in constant communication with Ukrainian procurement officials, the Ministry of Health, discussing our readiness to supply additional volumes if needed. This is our first diagnostic product, and we aim to make it as accessible as possible. We believe it's one of the best products in its segment, and we are willing to provide more detailed information about it.

Question: What is the sensitivity and specificity of the test? Should such Questions be addressed to you or Atomo?

Answer: The sensitivity and specificity of the test are 99.6%. You can ask these Questions to us.

Question: Does the product have WHO prequalification?

Answer: It has WHO prequalification and CE marking for the European Union.

Question: How long have you had this product?

Answer: Approximately 2-3 years.

Question: Do you plan to undertake joint projects for testing the general population with Ministries of Health?

Answer: Yes, we have such plans, and we have already started negotiations in some countries. If governments are interested, we are ready to partner. We like the number 70,000, and 10 markets with 70,000 each would be even better.

Question: Do you plan to expand your activities in Kyrgyzstan? According to the table with the registration status (Appendix), there are few registered certificates in Kyrgyzstan.

Answer: Currently, we have six registration certificates in Kyrgyzstan. Initially, the local team handled registration, and then the global office took over this function. As of today, the following drugs are registered in Kyrgyzstan: dolutegravir/lamivudine/tenofovir, dolutegravir, lopinavir/ritonavir, pretomanid, TAF, and TDF. Daclatasvir is also registered, and we are currently undergoing the re-registration process. We had difficulties aligning the dossier with the requirements of the Ministry of Health, but we have resolved them and do not expect further problems, especially with the registration of sofosbuvir/velpatasvir.

Question: To use the national procedure, you need to file a registration dossier for sofosbuvir/velpatasvir and sofosbuvir/daclatasvir in Kyrgyzstan this year. Resolution No. 136 of March 7, 2023, is valid until December 31, 2023, and your products have WHO prequalification. Hetero is losing to you, as they do not have WHO prequalification. We need to implement a humanitarian program. Will you be able to do this, and what is needed to assist with this? You need to at least submit an application, not necessarily the complete document package.

Answer: Assistance is always needed. We have informed our regulatory department about the need to submit the documents.

Comment: National registration is currently being extended through a separate resolution of the Kyrgyzstan Cabinet of Ministers. To issue such a resolution, it takes 4-6 months. If you do not manage to submit the registration documents before December 31, 2023 (even if the EAEU decides to extend national registration until 2030), there will be a gap of 4-6 months.

Answer: Let's assume we manage to submit the dossier. Will the effect of this dossier cease when the resolution expires?

Comment: No, it will be registered for five years. We need 3,000 courses to treat all patients at a low cost next year. If you don't manage to submit the dossier through the national procedure in this year, you won't be able to do it later.

Question: Do you plan to open drug manufacturing plants in other countries?

Answer: Regarding drugs for HIV, hepatitis, and tuberculosis, our manufacturing facilities, three plants, are located in India. All three plants are WHO prequalified and FDA approved, and they cover the current demand. In particular, we produce 2 million packs of TLD per month.

Question: Are there plans for production in our region, such as Uzbekistan?

Answer: Not at the moment. If the demand increases, we will consider this possibility, as we did in Africa. Such decisions are made at the management level.

Question: Are there plans for the production, promotion, or localization of specific products in other countries in the EAEU region?

Answer: We will plan this as our activities expand. Currently, we have no plans for production in the region.

Question: Then why do you need "Pharmstandard" as a distributor? It is one of the largest Russian drug manufacturers.

Answer: The agreement with "Pharmstandard" has not been finalized yet; it is currently under evaluation. Russia has specific localization requirements that we need to consider. That's why we have a local office with employees in Russia. We don't know how the situation will develop.

Question: Does the company plan to enter the commercial sector with its products?

Answer: Yes, we have not worked in this segment before. We are currently gathering information about potential local partners' needs. The first market we will work in is Uzbekistan. Depending on demand, we plan to expand to the entire region. As we understand it, hepatitis, not HIV, will be the primary concern.

Question: Can we request an updated list of partners in the countries of the region with contacts?

Answer: Yes, we will provide it.

Question: What are the difficulties in translating instructions and other materials into national languages in the EAEU countries?

Answer: We only use specialized translation companies. This applies not only to the region but worldwide. We approach translation very carefully because we cannot allow patients to receive incorrect information.

Question: What is the average time for translating one set of instructions? Have there been cases where the translation affected the registration timeline?

Answer: No, not for national registration procedures. As for the Eurasian registration, the volume of translation has increased with the increasing information in the dossier. Consequently, this has extended the registration process.

Comment from a representative of the patient community: There is no information about ARV drugs on the viatris.com website. We suggest improving the section that describes the drug portfolio.

Answer: Thank you for your comment. We have contacted the department responsible for updating the website, and information about ARV drugs will be added to the web site.

Question: Do you have initiatives aimed at supporting public health and well-being?

Answer: Our corporate social responsibility projects are listed on our website. For example, in Mexico, we recently made a donation to the ambulance service. We had programs in India.

During Covid-19, we supplied medicines at reduced prices, and we also made donations during times of conflict.

Question: Do you have drugs for the treatment of hepatitis D?

Answer: They are not in our portfolio; we would need to find out if there are plans to develop them.

Comment from a representative of the patient community: The drug for hepatitis D is owned by Gilead. Do you not want to take this drug away from them?

Answer: If we could, we would have done that already (jokingly).

Question: Over the past 10 years, there was the company Matrix, which was acquired by Mylan. Then Mylan merged with Upjohn, and Viatris was formed. An Indian company turned into an American one. There is a trend towards larger companies. More and more bilateral exclusive agreements are being formed between originators and generics. Can we say that generic companies are becoming huge conglomerates that find it easier to make agreements with originators rather than compete with them, as it used to be? Should we expect that generic companies will take fewer revolutionary measures to improve access to therapy? What is your expert assessment?

Answer: The trend of larger companies acquiring smaller ones exists. But governments must realize that if only innovators remain in the market, the prices will be very high. In India, for example, there is currently a regulation that mandates the supply of generic drugs to government hospitals. I agree that generic companies 10 years ago and today are different companies. But to remain generics, we need the support of governments and your support.

End of the meeting.