Minutes of the meeting of
Eurasian Community for Access to Treatment and Hetero

October, 2nd 2019, Yerevan, Armenia

Representative of the company:

- Vinay Dixit, General Manager, CIS Countries, Hetero Labs Limited
- Kranthi Kiran Reddy. N, Sr. Manager, Brand management in Virology & Spectra divisions, Hetero Labs Limited

Participants:

	Participant	Organisation	Country
1	Igor Chilcevschi	League of PLWH of Moldova	Moldova
2	Andrei Lungu	OA "Initiativa Pozitiva"	Moldova
3	Alex Schneider	Life4me.plus	Switzerland, Russia
4	Nurali Amanzholov	Central Asian Association of PLWH	Kazakhstan
5	Lyubov Vorontsova	Central Asian Association of PLWH	Kazakhstan
6	Yelena Rastokina	PF «Answer»	Kazakhstan
7	Sergey Biryukov	PF «AGEP'C»	Kazakhstan
8	Tetyana Khan	ITPCru	Russia
9	Denis Godlevskiy	ITPCru	Russia
10	Natalia Egorova	ITPCru	Russia
11	Maria Shibaeva	ITPCru	Russia
12	Meruert Bektemisova	“Partnership network” Association	Kyrgyzstan
13	Aibar Sultangaziev	“Partnership network” Association	Kyrgyzstan
14	Sergey Uchaev	ISHONCH VA HAYET	Uzbekistan
15	Anatoli Leshanok	RPA“People PLUS”	Belarus
16	Irina Statkevich	BPA "Positive Movement"	Belarus
17	Marina Chokheli	TB People/OSF Georgia	Georgia
18	Zoya Zamihovska	100% LIFE	Ukraine
19	Evgenia Kononchyk	100% LIFE	Ukraine
20	Nadiia Savchenko	100% LIFE	Ukraine
21	Olha Klymenko	TB people UA	Ukraine
22	Mykyta Trofymenko	100% LIFE	Ukraine
23	Anastasiia Homeniuk	100% LIFE	Ukraine
24	Anastasiia Rupcheva	100% LIFE	Ukraine
25	Maryna Kopylenko	100% LIFE	Kyiv
26	Anahit Harutyunyan	“Positive People Armenian Network” Social NGO	Armenia
27	Oleksandra Kolotyha	100% LIFE	Ukraine
28	Morgane Ahmar	ITPC Global	Morocco

Facilitator: Sergey Golovin

Beginning of the meeting. Introduction of participants.

Kranthi Kiran Reddy: I represent Hetero company working in the sphere of drugs for viral diseases treatment, such as HIV, hepatitis B and C, drugs that have the license, and those that are not covered by a license. My region is the countries of Asia, the CIS and Latin America.

Vinay Dixit: My name is Vinay, I am the General Manager for the CIS, I am engaged in sales of the company's drugs.

Our presentation consists of two parts. The first part is information about the company, in the second part I want to talk about marketing and licensed drugs in different countries.

Hetero was founded in 1993 by Dr. Reddy. The main goal was offering an affordable price for drugs, so that every patient with cancer or HIV/AIDS could have access to quality and effective treatment. The company has been operating for over 27 years. At the moment, we have 36 production sites and there are more than 300 drugs in our portfolio. The company is present in 126 countries and employs more than 21,000 employees. One of the features of the company is no shareholders, that is, the company has only one owner.

Hetero is the largest pharmaceutical company in India and one of the largest manufacturers of ARVs, active pharmaceutical ingredients (APIs) and fixed-dose combination. We have a developed production infrastructure, which covers an area of more than 500 hectares of land where our substances are produced. One of the largest complexes is located in Visakhapatnam, India.

The company operates in Central and South America, Africa, the CIS, Europe, India and Asia. Our plants are in the USA, Mexico, Russia, Egypt, China, Indonesia and India. We acquired Stada company (Makiz-Pharma LLC) in Russia. At the site, which is located in Moscow, we carry out a full production cycle. In Asia there are 2 plants (in China and Indonesia), and in India there are 23 plants. Our company produces both substances and finished forms. 5-7 years ago, we began to open representative offices of our company.

We have approvals from such following stringent regulatory authorities as FDA (USA), GMP (European Union), TGA (Australia), PMDA (Japan), MHRA (UK), MCC (South Africa), ANVISA (Brazil); IDA, PIC/S (Ukraine), INVIMA (Colombia), COFEPRIS (Mexico), MFDS (South Korea), Ministry of Health (Russia), DIGEMID (Peru). That is, almost all state inspections are represented. I would like to note that in Belarus three factories are about to be approved by inspections.

Hetero is a major supplier of APIs for production of antiretroviral drugs and one of the leading manufacturers of HIV drug products. We have more than 30 ARVs and their combinations. We cover about 4.3 million HIV/AIDS patients worldwide. We have many partners, e.g. SCMS, UNICEF, PAHO, CHAI, IDA Foundation and others. The company also has a distribution network in over 126 countries.

Previously, the company was not very active in the CIS countries. Now we are working in the CIS, and we have representative offices in countries and medical representatives. In Kazakhstan, we have a manager for Central Asia, there is an office in Ukraine. You will be able to contact me with any questions related to the CIS, and you will receive a prompt response. In Russia, we also have a separate representative office.

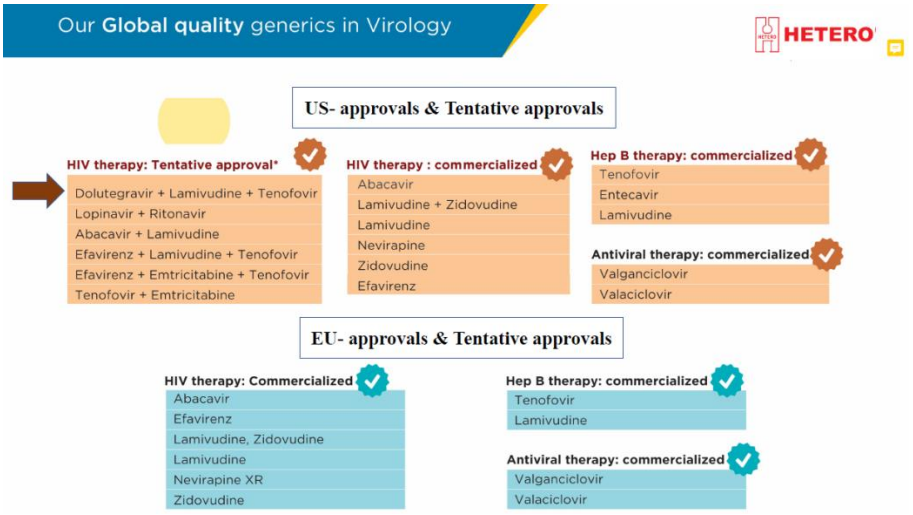
We supply antiretroviral drugs almost worldwide. We have very good cooperation with companies such as MSD (raltegravir), BMS (daclatasvir), GSK/ViiV (dolutegravir and its combinations), Gilead (sofosbuvir, TAF combinations), and we have recently received license approval for bictegravir combination.

Next, we will provide information on the registration status of drugs in the region, as well as on the quality of generics.

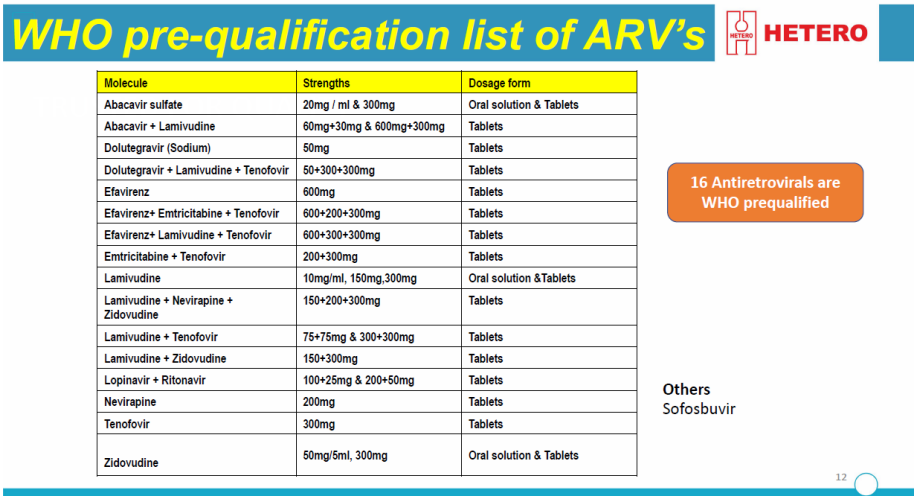
I present to you the list of ARVs that have been approved or pre-approved by the US FDA. It is highlighted with orange color. The first list of drugs that have received FDA preliminary approval is dolutegravir/lamivudine/tenofovir, lopinavir/ritonavir, efavirenz 600 mg/lamivudine/tenofovir, tenofovir/emtricitabine, etc.

The second list includes drugs that are already on the market in the United States. Also, in the US market there are such drugs for the treatment of hepatitis B as tenofovir, entecavir, lamivudine 100 mg, and drugs for the treatment of cytomegalovirus.

The blue color indicates the list of drugs that have an approval or preliminary approval in Europe.



Below are 16 ARVs that have received WHO prequalification. We put sofosbuvir separately, which also received WHO prequalification. We are a reliable partner with proven products that have received WHO prequalification.



Molecule	Strengths	Dosage form
Abacavir sulfate	20mg / ml & 300mg	Oral solution & Tablets
Abacavir + Lamivudine	60mg+30mg & 600mg+300mg	Tablets
Dolutegravir (Sodium)	50mg	Tablets
Dolutegravir + Lamivudine + Tenofovir	50+300+300mg	Tablets
Efavirenz	600mg	Tablets
Efavirenz+ Emtricitabine + Tenofovir	600+200+300mg	Tablets
Efavirenz+ Lamivudine + Tenofovir	600+300+300mg	Tablets
Emtricitabine + Tenofovir	200+300mg	Tablets
Lamivudine	10mg/ml, 150mg,300mg	Oral solution &Tablets
Lamivudine + Nevirapine + Zidovudine	150+200+300mg	Tablets
Lamivudine + Tenofovir	75+75mg & 300+300mg	Tablets
Lamivudine + Zidovudine	150+300mg	Tablets
Lopinavir + Ritonavir	100+25mg & 200+50mg	Tablets
Nevirapine	200mg	Tablets
Tenofovir	300mg	Tablets
Zidovudine	50mg/5ml, 300mg	Oral solution & Tablets

Let's talk about representation in the CIS countries.

In Russia, we are represented by Makiz-Pharma company, where we produce drug products.

In Kazakhstan, we have a branch that is engaged in commercial activities and can also participate in tenders, including in UNDP tenders.

In Uzbekistan, we have a representative office that deals with commercial issues and also participates in UNDP tenders. Recently in Uzbekistan we won a tender for more than 28,000 packages of sofosbuvir/daclatasvir. We began to work in this country in January, and have already made deliveries there.

In Kyrgyzstan, we also have a representative office, which can as well conduct commercial operations, take part in tenders, including UNDP tenders.

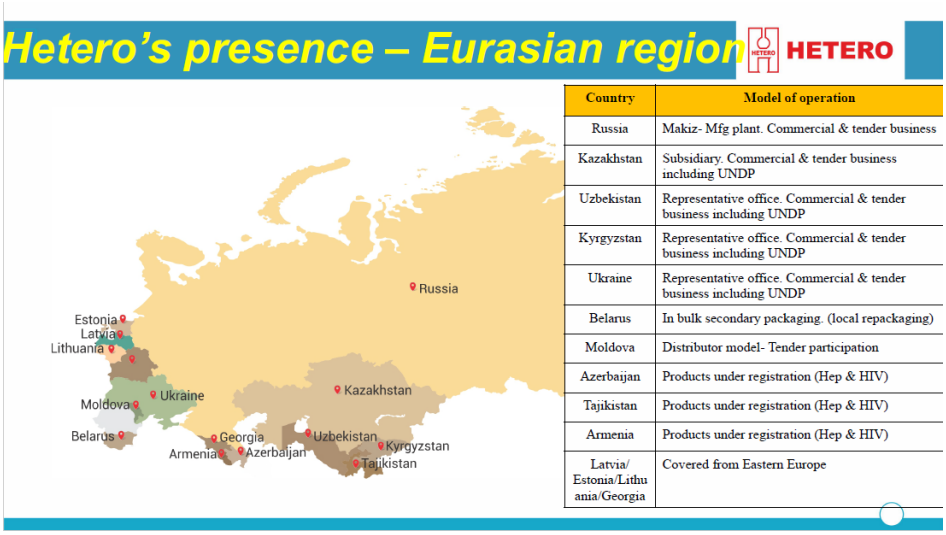
The representative office in Ukraine works in the same principle.

In Belarus, we have secondary packaging, in fact, it is a local re-packing.

In Moldova, we participate in tenders through our distributor.

In Azerbaijan, Tajikistan and Armenia, we are just starting the work. Now we have several drug products undergoing the registration process, and we hope that we will be there soon.

Soon we will be fully present and conduct business in all countries of this region.



Country	Model of operation
Russia	Makiz- Mfg plant. Commercial & tender business
Kazakhstan	Subsidiary. Commercial & tender business including UNDP
Uzbekistan	Representative office. Commercial & tender business including UNDP
Kyrgyzstan	Representative office. Commercial & tender business including UNDP
Ukraine	Representative office. Commercial & tender business including UNDP
Belarus	In bulk secondary packaging. (local repackaging)
Moldova	Distributor model- Tender participation
Azerbaijan	Products under registration (Hep & HIV)
Tajikistan	Products under registration (Hep & HIV)
Armenia	Products under registration (Hep & HIV)
Latvia/ Estonia/Lithuania/Georgia	Covered from Eastern Europe

In our countries, it is very important whether there is a license for a particular drug. In the table below you can see the drugs and countries. The letter P means 'pediatric form', the letter A means 'adult'. Accordingly, there may be differences in the instructions.

In Azerbaijan, as you can see, we have a license for pediatric forms of ARV drugs, but not for adult forms. The same is for Moldova.

License status

P : Paediatric
A : Adults

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Country	Sofosbuvir	Daclatasvir	Sofosbuvir+ Ledipasvir	Sofosbuvir+ Velpatasvir	Dolutegravir & Combi	Raltegravir	TAF & Combi & Bictegravir	Atazanavir	Lopinavir/ Ritonavir
Azerbaijan	✓	✓	✓	✓	✓P ✗A	✗ P & A	✓	✓	✓P ✗A
Armenia	✓	✓	✓	✓	✓ P & A	✓P ✗A	✓	✓	✓P ✗A
Belarus	✓	✓	✓	✓	✗ P & A	✗P & A	✓	✓	✗ P & A
Georgia	✗	✓	✗	✗	✓ P & A	✗ P & A	✓	✓	✓P ✗A
Kazakhstan	✓	✓	✓	✓	✗ P & A	✗P & A	✓	✓	✗ P & A
Kyrgyzstan	✓	✓	✓	✓	✓ P & A	✓P ✗A	✓	✓	✓P ✗A
Latvia	✗	✗	✗	✗	✗ P & A	✗ P & A	✗	✗	✗ P & A
Lithuania	✗	✗	✗	✗	✗ P & A	✗ P & A	✗	✗	✗ P & A
Moldova	✗	✗	✗	✗	✓P ✗A	✗ P & A	✓	✓	✓P ✗A
Russia	✗	✗	✗	✗	✗ P & A	✗ P & A	✗	✗	✗ P & A
Tajikistan	✓	✗	✓	✓	✓ P & A	✓ P & A	✓	✓	✓P ✗A
Ukraine	✓	✓	✓	✓	✓ P & A	✗ P & A	✓	✗	✗P & A
Uzbekistan	✓	✓	✓	✓	✓ P & A	✓P ✗A	✓	✓	✓P ✗A
Estonia	✗	✗	✗	✗	✗ P & A	✗ P & A	✗	✗	✗P & A

Question: (Kazakhstan) Are you doing anything to get this license, including raltegravir? Did you contact the Patent Pool on this issue?

Answer: Gilead did not permit us to sell drugs till August (daclatasvir/sofosbuvir), now we already have such permission. In Ukraine we have permission to sell dolutegravir. If there is demand, we begin to work on obtaining the license. We are working on raltegravir to get this permission, but MSD does not give us any answer, they are closed for dialogue, and we need assistance in this matter.

Comment: (Russia) We had a meeting on raltegravir with MSD, and they said that they have an exclusive license, apparently with Hetero. Civil society has repeatedly appealed to both the Patent Pool and MSD with a request to extend the license that is in the Patent Pool, for adult forms as well. However, the last time we heard from the company is that generics producers are not particularly interested in the production of raltegravir.

Question: (Kazakhstan) Even the original drug cannot enter our market, because there are some kind of difficulties all the time. In the beginning, they were able to register, but did not have time to include the drug to restrictive lists; then they were included in the lists, but the registration stopped. It seems that that the company either does not have an understanding of how to do this, or there is no particular desire to enter the market. We will be glad to see raltegravir in any form, and we will be glad if you work in this direction.

Answer: We are ready to produce this drug; we have no problems with this. But we do not have approval (voluntary license) for this from MSD.

Question: (Kyrgyzstan) Since raltegravir was patent protected, it was not included in many treatment protocols. Until 2018, it was not included in the WHO recommendations, as it was an expensive drug. This year, WHO slightly changed position and included raltegravir as a second-line drug. Probably, now the practice of using the drug will expand. For example, we have included raltegravir in new clinical protocols. I think that it is necessary to maintain interest in it, and not just focus on dolutegravir. Specifically in Kyrgyzstan, in the table that you showed there are two 'crosses' (adult forms of ARVs raltegravir and lopinavir/ritonavir). We are now initiating questions on a voluntary or compulsory license for lopinavir/ritonavir, and raltegravir, obviously, is next in line. If our government is ready to issue a compulsory license, and if we send you an appropriate letter, will you be ready to supply these drugs to our country at the price you provide to countries in South Africa?

Answer: Yes, we are ready. I always say that the issue of price, including this particular one, must be discussed individually. For example, in Ukraine, such a letter was written by several people, there was support from the Ministry of Health. Eight months ago, everything was successfully resolved, and we have already delivered the drug.

Question: (Russia) I have a question about the pediatric form of raltegravir. If I'm not mistaken, now, according to WHO recommendations, raltegravir is the preferred option for use by children, but this form of raltegravir is not available. In view of this, do you plan to talk again with MSD, either directly or through the Patent Pool, to start at least with a pediatric form, so that the countries of the region have the opportunity to purchase at least raltegravir in a pediatric form?

Answer: Indeed, we have an agreement with MSD on the adult form of raltegravir, but it mainly covers Africa. In our region and in the Asian region, there are countries that are not included in the license. If countries collectively write a letter or recommendation, this will help us. We will be able to use the letter as an argument in our negotiations with MSD.

Question: (Kyrgyzstan) As far as I know, Kyrgyzstan is licensed for pediatric raltegravir. Do you plan to register other pediatric forms of drugs? Can you start registering pediatric raltegravir in Kyrgyzstan? The drug is included in the new protocol, but is not yet on the market.

Answer: Yes, 18 dossiers were submitted to the Ministry of Health of Kyrgyzstan, including 9 ARVs.

Question: A question about Moldova. Isn't the adult form of dolutegravir licensed?

Answer: No, we were not given a license. They do not grant it to all manufacturers.

Follow-up update: The Company has recently got approval with effect from November'19.

Question: (Ukraine) A month ago, darunavir 400 mg and 600 mg from Hetero were registered in Ukraine. Can you clarify what your plans for this drug are in our country?

Answer: We produce very large volumes of darunavir. Send us your request and we will deliver it to you. In Ukraine, the substance of darunavir is patent-protected. Hetero's legal team is currently checking this information, including whether the drug can be sold being under patent protection.

Question: As I understand it, in Russia you are present in the market with darunavir in the amorphous form and do not violate the patent for the solvate form?

Answer: Yes, this problem applies to Ukraine only.

Question: (Ukraine) According to our information, the patent was only for the production and synthesis methods.

Answer: We will clarify this.

Question: (Kazakhstan) Please tell us, do you have darunavir with a booster or just darunavir?

Answer: We have darunavir without a booster.

Question: (Kazakhstan) The fact is that in Kazakhstan now a significant part of the budget is allocated for the darunavir/ritonavir combination. We are forced to buy brands, because none of the generics with an amorphous form, which is not patent-protected, come to us.

Answer: The main problem is the ritonavir patent.

Question: Do you have darunavir/cobicistat?

Answer: No, we don't have a cobicistat. Now we are negotiating with our research and development about whether cobicistat is worth developing. As of today, this is all in the pipeline and is very dependent on demand.

Question: (Kazakhstan) It is boosted darunavir that now has a large market share. You can see the report or we will send you information that will show the prospect. We have problems with dolutegravir in our country, and that's why patients use darunavir.

Answer: We will be waiting for your letter.

Question: Are you ready to enter the market with just darunavir, and decide on ritonavir separately? And what will be the price of darunavir then?

Answer: We can answer you individually about the price.

Question: Do you have a production of ritonavir only (not a combination of it)?

Answer: No, there is no such production.

Follow-up correction: The Company has ritonavir plain.

Registration status of drugs

Hepatitis C

The abbreviation PR means that registration is planned; Exp means that the registration is expected; UR means that it is in the process of registration. 'Registered' means registered; 'No license' means that there is no license. I will give an example of how to read this: Azerbaijan plans to register for sofosbuvir and this is expected in March 2020.

Registration status- Licensed products

PR : Planned registration
Exp :Expected registration
PPR : Paediatric only
UR : Under registration

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Country	Sofosbuvir	Daclatasvir	Sofosbuvir+ Ledipasvir	Sofosbuvir+ Velpatasvir
Azerbaijan	PR(Exp:Mar-2020)	PR(Exp: Mar-2020)	PR(Exp: Mar-2020)	PR(Exp: Mar-2020)
Armenia	PR(Exp:Mar-2020)	PR(Exp: Mar-2020)	PR(Exp: Mar-2020)	PR(Exp: Mar-2020)
Belarus	PR(Exp: Oct-2020)	PR(Exp: Oct-2020)	PR(Exp: Oct-2020)	PR(Exp: Oct-2020)
Georgia	No license	PR(Exp: Oct-2020)	No license	No license
Kazakhstan	**Registered**	**Registered**	UR (Exp:Sep-2020)	UR
Kyrgyzstan	**Registered**	**Registered**	**Registered**	**Registered**
Moldova	No license	No license	No license	No license
Russia	No license	No license	No license	No license
Tajikistan	PR(Exp:Oct-2020)	PR(Exp:Oct-2020)	PR(Exp:Oct-2020)	PR(Exp:Oct-2020)
Ukraine	**Registered**	**Registered**	**Registered**	UR
Uzbekistan	**Registered**	**Registered**	**Registered**	**Registered**

Question: (Kyrgyzstan) Now as I look at the website of our department, I can see that sofosbuvir/velpatasvir is not registered in our country yet.

Answer: The work is almost complete, now we are expecting to receive the Kyrgyz translation. It will take two weeks at the most.

Question: (Kazakhstan) When is sofosbuvir/velpatasvir expected to be in Kazakhstan?

Answer: In 6-7 months. The latest is July 2020.

Question: Why does Moldova not have a license?

Answer: Hetero does not have license from Gilead in Moldova.

ARV drugs

Here, dolutegravir is a monocomponent, DLT is dolutegravir/lamivudine/tenofovir, DET is dolutegravir/emtricitabine/tenofovir, TAF is a monocomponent for the treatment of hepatitis B, the combination of atazanavir/ritonavir and lopinavir/ritonavir. In addition to dolutegravir/emtricitabine/tenofovir, we have all forms available.

Registration status- Licensed products

PR : Planned registration
Exp :Expected registration
PPR : Paediatric only
UR : Under registration

HETERO

Country	Dolutegravir	DLT	DET	TAF	Atazanavir + Ritonavir	Lopinavir + Ritonavir
Azerbaijan	PPR(Exp: July-2020)	PPR(Exp: July-2020)	Under plan	PR(Exp: Mar-2020)	Planned	Planned
Armenia	PR(Exp: Mar-2020)	PR(Exp: Mar-2020)	Under plan	PR(Exp: Mar-2020)	Planned	Planned
Belarus	No license	No license	No license	PR(Exp: Oct-2020)	Planned	Planned
Georgia	PR(Exp:Oct-2020)	PR(Exp:Oct-2020)	Under plan	PR(Exp:Oct-2020)	Planned	Planned
Kazakhstan	No license	No license	No license	PR(Exp: Oct-2020)	**Registered**	Planned
Kyrgyzstan	PR(Exp:Oct-2020)	PR(Exp:Oct-2020)	Under plan	PR(Exp: Oct-2020)	Planned	Planned
Moldova	Open for tenders (Paediatric only)		Under plan	Open for tenders	Open for tenders	Open for tenders
Russia	No license	No license	No license	No license	No license	No license
Tajikistan	PR(Exp:Oct-2020)	PR(Exp:Oct-2020)	Under plan	PR(Exp:Oct-2020)	Planned	Planned
Ukraine	**Registered**	UR	Under plan	PR(Exp:Oct-2020)	Planned	Planned
Uzbekistan	**Registered**	PR(Exp:Oct-2020)	Under plan	PR(Exp:Oct-2020)	Planned	Planned

Question: (Kyrgyzstan). You write that you plan to register in October 2020. Why so late? In our country, if the drugs have WHO prequalification, registration takes a maximum of two months.

Answer: We applied for registration this month. The table shows the longest period.

Question: (Kyrgyzstan) How do you plan to register atazanavir/ritonavir and lopinavir/ritonavir if ritonavir is still under the patent?

Answer: The company is now working on the form of ritonavir, which will be heat-resistant, but will not violate the current patent. For now, we cannot speak about exact dates.

Question: How did you register atazanavir/ritonavir in Kazakhstan?

Answer: In Kazakhstan, we have now registered atazanavir/ritonavir in the old form (according to Bolar provision). And since it infringes the patent, we do not bring it to the market. If a compulsory license for ritonavir is issued, then it may be introduced into the commercial market. All of these forms under the terms of the license may be available in countries. For example, Lopirito (lopinavir/ritonavir) is registered in Moldova and Russia. All drugs listed in the table are manufactured under the license and may be available in countries.

Question: (Kyrgyzstan) It is important for us to know the prices in order to understand how many people will be able to receive treatment.

Answer: We will have affordable prices. We can promise you this.

Let's move on to drugs that are produced without a license.

I will explain the abbreviations. EET is efavirenz 600 mg/emtricitabine/tenofovir, ELT is efavirenz 600 mg/lamivudine/tenofovir, ET is emtricitabine/tenofovir.

Registration status- unlicensed product

Country	EET	ELT (600 efav)	ET	Darunavir	Tenofovir DF	Abacavir	Abacavir+ Lamivudine	Lamivudine +Zidovudine	Efavirenz	Lamivudine	Tenofovir+ Lamivudine	Nevirapine
Azerbaijan	-	-	-	-	-	-	-	-	-	-	-	-
Armenia	-	-	-	-	-	-	-	-	-	-	-	-
Belarus	Registered (600/200/300mg)	-	-	Registered	Registered & Under plan	Registered	Registered	Under Plan	Under Plan	Registered & Under Plan	-	Registered & Under Plan
Georgia	-	-	-	-	-	-	-	-	-	-	-	-
Kazakhstan	Registered	Registered	Registered	Registered	Registered	-	-	Registered	Registered	-	-	Registered
Kyrgyzstan	-	-	Registered	Process at MOH	Registered	-	-	-	Process at MOH	-	-	-
Moldova	-	-	-	-	-	-	-	-	-	-	-	-
Russia	-	-	-	-	-	-	-	-	-	-	-	-
Tajikistan	-	-	-	-	Under Plan	-	-	-	-	-	-	-
Ukraine	Registered		Registered		Registered	Registered	Registered	Registered	Registered	Registered	-	Registered
Uzbekistan	Registered	Registered	Registered	Process at MOH	Registered			Process at MOH	Registered		Registered	Process at MOH

The dossiers for drugs are ready, and upon request we can register them in the respective countries. It all depends on the interest of the country. We are constantly discussing issues of supplies to the territory outside the license with patent holders, but these negotiations are difficult. I want to say that Belarus is putting great pressure on us to provide them with drugs. We are ready, but cannot do this, since we do not have a license. For your part, you can influence the patent holder to give you at least a temporary permit.

Question: (Kazakhstan) Kazakhstan is now moving away from the old schemes (regimens), which is the reason why one of the drugs that will be removed soon is abacavir/lamivudine. This year we plan to dispute the patent for this drug, since its prices are very high. It would be great, if you started registering this drug while we dispute the patent.

Answer: Yes, we will register it. But until the patent situation is resolved, we will not bring the drug to the market.

EFV 400: The development of the combination drug efavirenz 400 mg/lamivudine/tenofovir in one tablet is now in its final stages. We are finishing the bioequivalence study, and expect everything to be ready by December 2019.

Bictegravir/emtricitabine/TAF: this drug is ready. The bioequivalence study is already underway. We see that there is already a demand for this drug, and we will accelerate this process after we return.

TAF: Both combinations of dolutegravir/emtricitabine/TAF and dolutegravir/lamivudine/TAF are finished. It will take us about three months to finalize the dossier.

Question: All approvals have already been received, but the drugs have not yet been prequalified by WHO?

Answer: Yes, the approval has been obtained, prequalification has not yet been completed, it's in progress.

Pediatric forms of drugs for the treatment of hepatitis C

In September 2019, the FDA approved sofosbuvir and ledipasvir/sofosbuvir for the treatment of children 3-12 years old. Under the current Gilead license, we do not have a pediatric form. Now, together with our legal department, we plan to negotiate with Gilead to review the terms of the

contract. As soon as the agreement is revised and approved, we will immediately begin the development of pediatric forms.

Question: Does Gilead have a patent for pediatric forms? They only have a patent for the substance, don't they?

Answer: This is all at a very early stage so far. Right now, we need to get a conclusion from our legal department in order to understand what the situation is there. And the dialogue with Gilead is not an easy one.

Question: I would like to raise a question that was not on the agenda: HIV prevention. We are working with both governmental and non-governmental organizations in Southeast Asia and Latin America regarding pre-exposure prophylaxis (PrEP) and the use of tenofovir/emtricitabine. Are there any plans in the region to expand the PrEP program with tenofovir/emtricitabine?

Answer: Kazakhstan plans to include PrEP in the new treatment protocols next year, but has not yet procured drugs for the next year's PrEP. In Almaty, there will be a joint pilot project with the Ministry of Health. As a result of this project, PrEP will be implemented throughout the country. It is not yet clear which direction the Ministry of Health will choose. Inclusion in the protocols does not mean much by itself; in addition, several regulatory acts will need to be developed.

Comment: (Kyrgyzstan) The paradigm of 'treat those who are not sick yet' requires a lot of work in the post-Soviet space. We included PrEP in protocols, but everything that concerns the budgeting, becomes more difficult. It is hard to explain to our fiscal authorities that we are giving pills for a disease that does not exist yet. Due to limited budgets, this will take at least 3-4 years. And only after that it will be possible to think about this issue.

Comment: Georgia has a slightly different situation. We have already launched pilot projects for other drug products. A pilot project on PrEP is now in the pipeline. We actively began advocating for decentralized treatment, because the same PrEP is more effective if work in vulnerable groups is through community organizations, and not through the AIDS Center. More recently, statistics have shown an increase in HIV cases, and the Government is interested in this topic.

Comment: PrEP protocol was approved in Moldova in 2018.

Comment: In Russia, there is a movement along PrEP, but it goes along tenofovir and lamivudine to a great extent. They are prescribed by the doctor, and the patients buys drugs on their own expense at the pharmacies. The fact is that emtricitabine/tenofovir costs about $200. At the same time, a monthly course of tenofovir and lamivudine will cost about $15-20, and even students can afford it.

Comment: Regarding the mentioned model, when ARV drugs are sold in pharmacies. If we launch it in Kazakhstan, then we will be allowed to implement this option in the fastest manner. The problem is that in Kazakhstan there is no ARV drug other than tenofovir for the treatment of hepatitis B, which you could buy on your own in pharmacies. All ARVs are available for free only at the AIDS Center. Even during interruptions, patients have nowhere to buy ARVs. Perhaps this is one of the issues that you should work on.

Comment: I want to propose to think about the need for ARV drugs to come to the pharmacy network, even in a small amount. There can be the demand for them, e.g. from migrants living in another country.

Comment: In Georgia, the issue of chemsex is very urgent, and the spread of HIV infection through chemsex. People very often do not reach the AIDS Center. How interested are you and how much will

it be possible to bring these drugs to pharmacies to small markets of such countries as Georgia or Moldova? At the moment, we do not have patents for ARV drugs.

Answer: In Georgia and Moldova, we want to start working directly with distributors so that they can deliver drugs to pharmacies.

Question: What prevents the ARVs to be sold in the retail network? Is it because you are not interested very much in this, or are there any other barriers?

Answer: We are very interested in this matter. We talked with specialists from the AIDS Centers, and they said that they were interested, but ARV drugs could only be given out to patients. Perhaps the state does not need to take responsibility for PrEP. For a start, doctors can prescribe drugs, and we will provide people with information so that they can reach doctors for prescription of prophylaxis.

Comment: This question concerns not only PrEP, but any ARV drugs. There are people who cannot get HIV medication for free, for example, migrants. Therefore, it is important that they have the opportunity to come to the pharmacy and buy the drugs they need.

Comment: I work with several groups (transgender people, drug users, commercial sex workers). A tenth of these people do not reach the AIDS Center. There are doctors who do not work at the AIDS Center, but they are friendly towards these patients, and the patients come to them because they do not face stigmatized approach. You need to talk with different people, not just AIDS Centers.

Question: (Russia) What are three things that you think could change so that Hetero is widely represented in the Russian market with all of its impressive portfolio of products. Given the fact that Makiz-Pharma was once a great active player who had a good market share.

Comment: (Russia) I want to add a comment about Makiz-Pharma. We have been trying to contact them for many years. We recently invited them to a Russian meeting on access to treatment, and they did not even respond to our invitation.

Answer: Thank you for the information. Please, send me a copy whenever you write to Makiz-Pharma. I communicate with them, and they tell me that in Russia there are only public procurements. If there are retail opportunities, then we are always open for this dialogue.

Question: Are public procurements not your priority?

Answer: No, this is a very serious priority for us.

Question: Makiz-Pharma is involved in centralized public procurement. Please tell us whether you have registered saquinavir. Will Makiz-Pharma also go to these public procurements with a reduction in prices? In Russia there is an odd-one-out rule, but it does not apply to Makiz-Pharma, given that it is a Russian company. But, despite this, the share of Makiz-Pharma products is very small. Tell us what is the reason? Is it in the price or in the fact that there are other players already in the market, between whom everything is already divided, and it is difficult to get into these procurements?

Answer: Yes, what you said is right. Difficulties arise due to the fact that there are players on the market who want to find agreement between them. As for the invitation to the meeting, a very unpleasant situation turned out. Today we will report about it.

Answer: Back to question of three things that must change. There will be a lot of serious work in Russia.

Question: In Uzbekistan, you said you won the tender. Was it government procurement? Only two drugs?

Answer: Yes, these were public procurements of daclatasvir and sofosbuvir. We delivered twice 14250 packages for each procurement.

Question: (Russia) Abacavir/lamivudine combination is also registered in Russia. The Ministry of Health announces the procurement for this drug, but every year it is procured as monocomponents. Is Makiz-Pharma already producing this drug, or has it only been registered? Why do not they go to the tender of the Ministry of Health of the Russian Federation with a combination drug?

Answer: I can't say for sure why Makiz-Pharma is not participating in tenders. I will answer this question later.

Question: (Ukraine) I have a question about the pediatric form of lopinavir/ritonavir. As far as I know, we have very low competition in this area. In my opinion, we still buy the drug from AbbVie. We will be glad if you come in with this product. The demand is quite small, about 2500 packages per year. The second question, I hope it will be of interest to you, is about nilotinib (an antitumor drug). We spend a huge part of the budget on its procurement. I heard that it is under development at Hetero. Perhaps there is some information about it, is there?

Answer: This will take approximately 2 years.

Question: There is a great need for anti-tuberculosis and cancer drugs in the region. Do you have any future plans for this area?

Answer: For today's meeting, we have prepared information specifically on ARV drugs and drugs for the treatment of hepatitis C. Our team has a specialist who focuses on oncology only. We have a very wide range of oncology drugs. Regarding anti-TB drugs, we have linezolid, moxifloxacin, PASK. We are trying to get the rights for bedaquiline, but there is a problem with Janssen.

Question: If possible, please pay attention to bedaquiline, delamanide, pretomanid and the entire existing line for tuberculosis. If you have any plans for negotiations and licensing this in our region, we would be glad to learn about it.

Answer: As of now we can only speak specifically about the drugs that we already have.

Question: (Belarus) It seems that in 2017 rather pompous information announced that a Hetero plant was being built near Minsk. Recently, we met with representatives of Belalek, and they said that the plant would not be finished. Tell us about the reasons.

Answer: Yes. We had rather serious problems with Pharmatech, our partner. They practically went bankrupt, and they have no financial opportunity to invest in construction.

Question: A question about linezolid in Russia. In theory, it should be procured on the centralized basis. This does not happen, because the instructions for use for it do not specify that it is an anti-TB drug. And this is a barrier to the Ministry of Health of the Russian Federation, despite the fact that the drug is in the standards for the treatment of tuberculosis. As a result, the drug is not in the federal procurement program, and it is present only in regional procurement programs. And this is a big problem for patients with a drug-resistant form of tuberculosis. Is there anything you can do about this situation with the instructions? How difficult is it to change it?

Answer: I will answer this question later.

Comment: (Ukraine) I would like to share some information. We made recommendations for changing the nomenclature for 2020, and introduced the combination of dolutegravir/emtricitabine/TAF there. We are very pleased that your product is in the market. We hope that you will participate in the

tender, and we will have a good price. Currently, approximately 24,000 patients are on the tenofovir regimen.

Question: (Russia) I want to say about the pharmacy networks and the drug tenofovir/emtricitabine. The manufacturer of the original drug does not plan to include Truvada in the List of Vital and Essential Drugs and they are positioning that in Russia they will sell the drug only in pharmacy networks as PrEP. They do not plan to participate in public procurement. Therefore, for pharmacy chains it is very important that there is a competitor in the form of a generic with an affordable price. In this case, you should have a clear position, since there will probably be no first step from our pharmacies.

Answer: For you to have an understanding of the situation in Russia, I want to let you know that we published a packaging project once, and immediately received a warning letter from Gilead. They aggressively protect patent rights.

Comment: There is a plan in Russia to dispute the patent, and it would be good for your company to work on including the drug in the List of Vital and Essential Drugs.

Answer: In many countries, we offer PrEP at a price of $1 per day, or $30 per pack. We would like to pursue a more active policy in this direction. In Ukraine, there was a problem with the indication for the use of PrEP. The Ministry of Health of Ukraine does not allow us to include the drug as PrEP, and we need assistance in resolving this issue. Changes to instructions are required to actively promote this regimen.

End of the meeting.