Minutes of the meeting of
Eurasian Community for Access to Treatment
And Mylan

October, 2nd 2019 года, Yerevan, Armenia

Representatives of the company:

- Abhishek Datta, Business Development, Mylan Laboratories Limited, Hyderabad, India

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 Asscoiation of PLWH	Kazakhstan
5	Lyubov Vorontsova	Central Asian Asscoiation 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 of the meeting: Sergey Golovin.

Beginning of the meeting. Introduction of participants.

Brief presentation of the Company. The Company was founded in 1961 in the United States. The Company also works with the retail sector, wholesale companies, governments, doctors and patients around the world. The Company employs about 40,000 people and is present in more than 160 countries and territories. In the global market, the Company's portfolio includes over 2,700 individual products. We have applied for regulatory authorities' approval of more than 3,400 new drug products worldwide.

The areas in which we operate are expanding. This includes biologic drug products, drug products for treatment of respiratory and infectious diseases, etc. The HIV initiative began in India, as this issue is very relevant in this country. The company estimates that one in two patients in developing countries receives Mylan products. The company's portfolio includes 16 active pharmaceutical ingredients (APIs) and 50 combination drug products in the first- and second-line regimens, as well as pediatric forms.

The three fundamental principles of the Company are quality, reliability and innovation. Mylan is the first company to introduce a three-part drug for HIV treatment. The Company has nine factories producing APIs and three plants producing combination drug products, which makes the Company one of the largest manufacturers of ARV drugs and allows to reach about 8 million people. All production sites have been audited by WHO and FDA, as well as other strict regulatory authorities. Over the past 18 months, 25 industrial inspections were conducted in India alone.

The Company invests in clinical research and development of innovative combination drugs, from heat-resistant protease inhibitors to dispersible pediatric forms and tablet sets (co-packs) to increase adherence. We do our best to ensure appropriate pricing and availability of our products, and we never do this by means of decreasing the quality of the drugs.

In total, we have about 85 registration dossiers in the EECA region. The main countries in which our products are registered or submitted for registration are Ukraine, Kyrgyzstan, Uzbekistan, Kazakhstan, Armenia and Azerbaijan. To simplify the registration process, we work with partner organizations. Specifically, with Cratia. The Company has a department that deals with registration of ARV drugs, in particular, I am responsible for HIV. For hepatitis C, we have a team based in Kiev. It deals with registration issues and is responsible for Ukraine and the entire region.

Speaking of the registration of drugs: in a separate table (see Appendix 1), ARV drugs, drugs for the treatment of hepatitis C and anti-TB drugs are presented. You can sort by product, country, disease category, and see where each drug is registered.

Question: Mylan is not represented in Kyrgyzstan very widely. A couple of weeks ago, we were negotiating with the Company representatives about registering TLD (dolutegravir/lamivudine/tenofovir) and received an official letter with assurances about the cost of about $7 per package. Does the Company have intentions to expand its presence in Kyrgyzstan? With which specific drugs and in what time frame? We are interested in ARVs and anti-TB drugs. The second question is whether it is possible to obtain a separate list of anti-TB drugs that Mylan produces.

Answer: Indeed, we had negotiations in Kyrgyzstan. As I said, we have a local partner, Cratia, with which we work on registration issues. For HIV, we have compiled a list of priority drugs that we will be registering, including TLD. There is a similar list for TB; it includes pretomanid, Isoniazid and cycloserine. According to the priority list, you can expect the registration to commence from the first quarter of 2020. We will provide you the information on our portfolio of drugs. If a drug is of particular interest in the country, we will be glad if you let us know about it, and then we will include it in the list of priority drugs for registration.

Question: Thanks for the information on anti-TB drugs. Can we get such information on ARV drugs too?

Answer: Yes. There is a combination of dolutegravir/emtricitabine/TAF on this list. We will also register the combination of efavirenz-400/lamivudine/tenofovir.

Question: Our question is about combinations with TAF, dolutegravir, efavirenz 400 mg. Are you planning to enter the market of Kazakhstan with these combinations?

Answer: The combination of efavirenz-400/lamivudine/tenofovir (TLE-400) has already been registered and approved in Kazakhstan. As for the combination of efavirenz-600/emtricitabine/tenofovir, we are also updating the registration dossier of this drug. TAF as a monocomponent is already registered. In Kazakhstan, we plan to register all combinations with TAF. We have already prepared a dossier to register combinations and sent it to our local team that deals with these issues. This dossier is being evaluated at the moment.

Question: Is the price of dolutegravir/emtricitabine/TAF in Kazakhstan available?

Answer: Right now, I can announce the estimated price, which is about $7 per package. But this price is for countries that are included in the voluntary license of the Patent Pool.

Question: Are you planning to register combinations with dolutegravir in Kazakhstan?

Answer: We consider the combination of dolutegravir/emtricitabine/TAF to be one of the main drugs.

Question: Please, tell us what you know about dolutegravir license in Kazakhstan?

Answer: We have already discussed this issue. It will not be possible to enter the market without a compulsory license. We will see if registration of dolutegravir is possible without entering the market, this will be the subject of discussion with our legal team. But it is definite that entering the market without the permission of the patent holder or compulsory license is impossible.

Question: Why are there so many drugs registered in Kazakhstan, but that are only two registered in Kyrgyzstan? Moreover, the combination of sofosbuvir with ledipasvir is already becoming irrelevant, since velpatasvir is already registered in the country.

Answer: When we entered the CIS market, we had only two partners, in Kazakhstan and Ukraine. Initially, we worked with these two countries, and only with time we began to work in other countries.

Question: Have your anti-TB drugs moxifloxacin and protionamide been prequalified by WHO?

Answer: Yes, Moxifloxacin in WHO prequalified, prothionamide is under development

Question: You probably know that for drugs that have WHO prequalification, there is a fast-track 45-day registration in Kyrgyzstan?

Answer: We will send you the information on our portfolio, where it will be indicated which drugs are prequalified by WHO and which are prequalified FDA. You will be able to look and tell us what drugs are your priorities for registration, and we, in turn, will be able to look at them too.

Question: In Ukraine, the combination with TAF was included in the list of drugs for procurement for 2020, and now we are awaiting a decision from the Ministry of Health. The TLE400 combination has been included in the nomenclature since 2018, if I'm not mistaken. Therefore, the question of starting the registration process of combinations with TAF is very relevant. We are interested in whether there are plans or any exact dates available on this issue?

Answer: In Ukraine, the dossiers for TLD, TLE-400 and dolutegravir are being submitted. This month the dossier for combination with TAF will be ready. Between the fourth quarter of 2019 and early 2020, the drug will be submitted for registration.

Question: This file does not contain information on Russia, since you are just entering the Russian market. Have you determined who will be your main partner in registering and promoting drugs for HIV, hepatitis C and TB in Russia? Will it be Pharmstandard or R-Pharm?

Answer: The negotiations are underway, and they are now at their final stage. We have identified a partner, but until the agreement is signed, we, unfortunately, cannot give information about it. For Mylan, Russia is a strategic market that we are interested it.

Question: What drugs are priority for registration in Russia?

Answer: TAF combinations and the TB portfolio.

Let's move on to the list of previously sent questions.

Efavirenz 600 mg and 400 mg

There is new data on comparing efavirenz 600 mg and efavirenz 400 mg. According to the results of the study, there is a publication about the ENCORE study published in The Lancet. We will send you information and slides on these studies. Briefly summarizing the results, these studies give a definite answer: efavirenz 400 mg has no less efficacy but better tolerance than efavirenz 600 mg.

Question: Have you encountered a problem in some countries such as variations to your Marketing Authorization? According to previous studies, an effective daily dose of efavirenz indicated in the instructions was the dose of 600 mg. These studies were conducted by MSD company. New studies have been conducted, and you need to make changes to the prescribing information. Were there any problems with the Ministry of Health or regulatory agencies when registering a new prescribing information?

Answer: This is a very timely question. Indeed, initially there were indications for the use of efavirenz 600 mg. To solve this problem, we started working with regulatory agencies in sub-Saharan Africa (Zambia, Zimbabwe and Kenya). These countries generated our data. We received requests from the Ministry of Health to procure efavirenz 400 mg. We prepared and submitted separate dossiers for registration and variations to the prescribing information for efavirenz 400 mg. In EECA region, we also started this process, the first registration of efavirenz 400 mg combinations is planned in Ukraine. In Kazakhstan, an efavirenz 400 mg combination has already been approved (TLE400).

Question: How do company representatives see the transition from efavirenz 600 mg to efavirenz 400 mg? What challenges do you expect (e.g. clinical guidelines, procurement processes, clinical use, etc.)?

Answer: In terms of volumes of supply, I see no problem. The second question relates to the flexibility of countries in applying the new recommendations. In accordance with the latest WHO recommendations it is clear that efavirenz 400 mg is the preferred alternative. We expect countries to apply this recommendation in their practice. If the Ministry of Health in a country decides in principle to switch from efavirenz 600 mg to efavirenz400 mg, there will be no problems in terms of supply.

Regional expansion plans

We have already partially answered this question, about Russia as well. Generally commenting on the Mylan strategy for EECA region, we can say that we were not the first company to enter your region.

We are now aware of the potential and importance of this region. In the future you will see more and more of our products that will be registered in all countries.

Question: If I am not mistaken, there is not even a representative office of your company in Moldova. Does Mylan have any plans for our country?

Answer: In Moldova there is a distributor that we work with, which is TETIS company. Last year, we participated in a tender and supplied drug products. In particular, the dolutegravir/lamivudine/tenofovir combination is a Mylan product. We also delivered the combination of efavirenz/lamivudine/tenofovir and the anti-tuberculosis drug cycloserine. When a new tender is announced, Mylan will also be able to participate in it. TETIS is also responsible for registration processes.

Localization in the region

In Uzbekistan, localization issues are discussed with ARV Healthcare. This is an international company that has a representative office in Vietnam and Singapore. The Company signed a memorandum of cooperation with the Ministry of Health of Uzbekistan, and negotiations to begin the production process are underway. We have established processes to localize production in sub-Saharan Africa, and when this negotiation process ends, when the company is created, we plan to replicate this process in other CIS countries. When the process is established, we plan to expand this in other countries of the region.

Question: This year in Belarus, after changing the technical specifications, companies that were not registered in the country, but those which had WHO prequalification, were allowed to bid. None of the two Mylan distributors were able to submit documents that were compliant with regulatory requirements. We would like to ask the company to better prepare distributors for their participation in tenders, as we would like to see more generic companies competing in our market.

Answer: Yes, we know about this situation. Indeed, we found out about this tender quite late, and at the last moment we started working with a local distributor. We provided all the necessary information, but, as you rightly pointed out, most likely some mistake was made in the tender documentation. Feedback from you is very important to us in this regard. We will take this into account in our future work.

Bictegravir, cobicistat and TAF in the region

The cobicistat is not available yet. We are conducting a study to determine the demand for this drug. If you could help us with data on the need, information on how many patients may need it, this would greatly help us in planning and allocating resources correctly.

The question of the cost of hepatitis drugs

We received the question that in Kyrgyzstan the drug costs $150-200, and are we planning to decrease the cost of treatment. Please tell if is this the price for a package for one month or for the entire course of treatment for one patient?

Answer: This is the price per a package for one month of treatment.

After the registration, Mylan will reduce the prices of all drugs for the treatment of hepatitis C. We can assure you that the price of a three-month course of treatment with sofosbuvir/daclatasvir or sofosbuvir/velpatasvir will be significantly reduced.

The FDA has approved sofosbuvir and sofosbuvir/ledipasvir for the treatment of children of 3-12 years old. Does the company have plans for the production of pediatric dosages of these drugs?

We are conducting a market research, and we also need your help in providing information on the number of patients who will need these drugs.

Question: No studies on the number of pediatric patients with hepatitis C have been conducted in the region. The estimated percentage of the population with hepatitis C is about 4-7 per cent for the region. If case of Kyrgyzstan, it is over 200,000 people. In recent years, some of them were treated for hepatitis C. In Ukraine and Russia, the number of patients is much higher. If we statistically take the percentage for hepatitis C by analogy with HIV infection, then the percentage of children under 14 is from 5% to 10%. We have up to 90% of children infected with hepatitis C during medical procedures. I dare to suggest that in Kyrgyzstan the number of children under 14 can be up to 20,000. In your calculations, you can safely take at least 5% of the population of patients with hepatitis C. This is a very large number. If there are drugs for treatment of such children, then this may encourage expansion by testing children for hepatitis C.

Comment from a participant: I want to add to the above that you probably heard that recently both in Russia and Kazakhstan there was information about nosocomial infections of children, and there were difficulties with access to pediatric forms. Therefore, the issue of access to pediatric forms for the treatment of hepatitis C is of high relevance.

Compulsory licensing

We recently discussed this issue. The position of the company is as follows: if a compulsory license is issued, the Company is ready to supply drug products. We are ready, if necessary and upon request (preferably from the Ministry of Health) to provide a letter signed by the Company stating that we are ready to supply products if a compulsory license is issued.

Question: In order to make such a request from the Ministry of Health, we, the patient organizations of Belarus, first of all need to receive a letter from Mylan that you are ready to supply the drug product with a compulsory license.

Answer: We talked about it. We have already prepared such a letter for Kazakhstan, and we can make the same letter for Belarus.

Question: Does Mylan have lopinavir/ritonavir ARVs under a voluntary Patent Pool license?

Answer: Yes, we have this drug. The license covers some countries, but not all. We also have darunavir.

Pretomanid (anti-tuberculous drug)

As for pretomanid, it is a drug for the treatment of extensively drug-resistant tuberculosis (XDR-TB). Mylan is an exclusive right for that. Recently we received approval from the FDA. Now the final stage is

underway, and we expect the dossier to be submitted to the countries of the region. By the first quarter of 2020, the drug will appear on the market.

Question: What will be the price of pretomanid?

Answer: The course of treatment will cost around $400, and we are ready to reduce the price when the volumes will increase.

Question: For which countries will this price apply?

Answer: This price will apply for the entire region, excluding Russia. Further price will depend on volumes and economy (affordability) of the country. We expect to price Pretomanid lower and more favorable pricing than delamanid. The volume of supply is the factor that will affect the price.

Question: Have you negotiated with those who work for the funds of the Global Fund (e.g. GDF, UNDP) on centralized procurement of large quantities of pretomanid?

Answer: A discussion with the Global Fund is underway. The CIS is a high priority region, as it is a region with a high prevalence of tuberculosis.

Question: We assume that in bulk procurements through international agencies, the price will decrease even more significantly.

Answer: We are in the process of negotiating with the Global Fund about the price, but we have not yet made deliveries of pretomanid.

Question: Do I understand correctly that you are now distributing pretomanid under a license obtained from the TB Alliance? Are all countries covered by this license?

Answer: Yes.

Question: The price that you announced, is it approximate and will it vary depending on the volume?

Answer: No. We are saying that when we know the volume, then we can set a price. This does not mean that if the volume falls, the price will increase. We will take the total volume, which they will tell us, and we will set the price in accordance with it.

Question: Can you share the information about the licensing agreement between your company and the TB Alliance or disclose any details for other regions and countries?

Answer: I have to discuss this with my team of lawyers. I will disclose the information that can be disclosed.

Question: Did the TB Alliance give a lifetime license only to your company?

Answer: Only Mylan has a license in the region, but it is, of course, not a lifetime license.

Question: Pretomanid has not yet entered the treatment protocols as an analogue of delamanid. Is any work to change these recommendations soon being done?

Answer: Now, according to WHO recommendations, pretomanid is on the list of drugs for the treatment of XDR-TB. But WHO says that it will be gradually used for MDR-TB as well. The work is ongoing now, and we hope that by mid-2020, WHO will include this drug in their recommendations for MDR-TB as well.

Comment: When you receive the entire package of documents from the FDA, etc., then we can try to register the drug in Kyrgyzstan faster.

Question: To continue on the topic of expanding the indications of the use of pretomanid not only for XDR-TB, but also for MDR-TB. To date, there are three very important limitations on the use of pretomanid: it is poorly tolerated in people with co-infection with hepatitis, the use is possible only for a period of 24 weeks, and the drug is used only in regimens with linezolid and bedaquiline. Do you do any research to expand the use of pretomanid? Yes, its price will be much cheaper, but with such restrictions it cannot be an analogue of delamanid. And one more question. Are you conducting resistance studies, and how soon can we expect results?

Answer: You are right, now pretomanid is not a substitute for delamanid. Yes, the price is more favorable, but so far, we can't just tell you: "Stop using delamanide and start buying pretomanid". We will come back to you limitations as I am not sure of it yet. And now we do not have licenses for linezolid and bedaquiline in the region.

Question: Due to the fact that delamanide does not decrease in price, many countries will not be able to procure it through the GDF (Global Drug Facility) mechanism. Countries expect that pretomanid, due to its price and expansion of clinical indications, will eventually become a complete replacement for delamanide. Given the recommendation that bedaquiline will be in basic drugs, and pretomanid is used only with it, we will constantly be facing the choice of how to plan procurements in countries. And if we do not expand the possibilities of using pretomanid, then we will be forced to procure delamanide, since the problem of co-infection with HIV is a problem of the entire EECA region, as well as co-infection with hepatitis.

Answer: Yes, without combined use with bedaquiline and linezolid, pretomanid cannot solve the problem of treatment. Now we do not have a license for the CIS countries. We are working in this direction to be able to supply a combination of drugs.

Question: Registration for bedaquiline is in many countries, it is available. Therefore, the question is not in the license, but in whether you are expanding clinical trials to remove the barriers to the use of pretomanid? If, for example, we know that pretomanid will become available to us, say, after five years, then we will understand that we will work with delamanide during the next period of time.

Answer: Yes, we are now doing this and will be able to give answers to these questions in the near future.

Question: Are you planning to use pretomanid in the treatment of children?

Answer: I will check with my colleagues and I will inform you later.

Question: Do you plan to conduct studies on the drug-drug interaction of pretomanid with ARV therapy, with replacement therapy? If such studies are already available, then what are the results? Can you send us the information?

Answer: I will check with my colleagues and I will send you the information later.

Question: When you say that you will conduct these studies, do you mean that they will be done by Mylan or the TB Alliance? Or will this be carried out in coordination?

Answer: Yes, this is done in partnership with Mylan and the TB Alliance. Even the efavirenz 400 mg study published in The Lancet, Mylan conducted in partnership. I would like to clarify with colleagues what stage these studies are at, and later I will tell you the exact information.

A question from colleagues from ECAB about quality problems of one of the tenofovir/emtricitabine batches in Bulgaria (the tablets were crumbling, the size of the tablets was different in the same package, patients complained of side effects, etc.).

Mylan produces a large number of drug products. In the case of Bulgaria, we assure you that this was a single incident, and in this regard, we are now developing corrective measures, both short-term and long-term. We have made changes and plan to produce an improved shape in the future. As regards this particular situation, we supplied a few more batches afterwards, and they had no such problem.

Question: Have you observed similar situations in our region?

Answer: No. These are very rare situations. We took this very seriously and made corrective measures.

Why is sofosbuvir and daclatasvir still not registered in Kazakhstan?

We prepared and filed a dossier regarding sofosbuvir and daclatasvir in Kazakhstan in April and May 2019, respectively.

Question: A slightly paradoxical situation has developed: we have been using your drug sofosbuvir/daclatasvir for a year now, but there is still no registration. According to the latest data, for the company, which is engaged in registration in Kazakhstan, some observations on the dossier were made. Have these observations been addressed?

Answer: Yes, indeed, we have received these comments. Such issues are resolved in a routine manner. Our team that deals with regulatory issues addressed them and, as far as I know, has already sent this information to local partners. I have to clarify this information, and after that I will inform you what the situation is like.

Question: The first question is on the registration of medicines. From January 1, 2020, the exclusiveness of data on registration of drugs will be introduced. How much do these norms make access to the market more difficult for you? The second question is if the government issues a compulsory license, will you be delivering drugs in the context of having a partnership with the patent holder?

Answer: Regarding the registration, in principle, the process will go as we planned when we worked with our partner. We do not have special clinical studies in Moldova, and if you need to refer to the dossier, then a problem may arise here. We need more information on specific drugs. Do I understand correctly that in Moldova it will be necessary to conduct local clinical trials?

Question: It will not be possible to refer to the research of the originator company.

Answer: In this case, this should not be a problem. The new norm should not affect registration. I thought it was about local clinical trials. Regarding the second question, our partnership with TETIS will not affect this in any way. If there is a compulsory license, we will be able to supply the drug anyway. We will be able to resolve this issue with TETIS legally. We have a formal signed contract, and this should not be a problem.

Question: Question about heat-resistant ritonavir and the combination of atazanavir/ritonavir. Can you supply the drug to countries in the region? For example, ritonavir is already supplied to Armenia, is it your drug or a drug from another manufacturer?

Answer: The position of the company is such that we will not be able to supply heat-resistant ritonavir, since we do not have a license. Unfortunately, I cannot comment on the situation in Armenia and why ritonavir is supplied there. Perhaps the originator company issued a temporary import permit. It all

depends on the patent holder, in this case, Abbvie. If we have a compulsory license or permission from the company, we will be able to supply the drug. Otherwise, the answer is “No”.

Question: My question is about the combination of tenofovir/emtricitabine as a pre-exposure prophylaxis of HIV infection. Do the instructions for the drug product of your company have indications for PrEP?

Answer: Yes, in our instructions there are indications for PrEP.

Question: What questions does your company have for us, the meeting participants?

Answer: For us, as a company, it will be useful to get information from you about specific countries about which drugs you consider to be your priority. Please also provide additional information on the registration process. As, for example, in the case of Kyrgyzstan, where, as we now know, this can be done in 45 days if the WHO prequalification conditions are met, etc. In this case, we can prioritize our actions.

We have a complete portfolio of drugs for which we will share information. We will also give you all the information we talked about earlier. There will be a complete list, including preliminary FDA approval and WHO prequalification.

End of the meeting.

Annex 1. Registration in EECA countries

S. No.	Region	Country	Generic name	Strength	Brand Name	Current status
1	CIS	Armenia	Ledipasvir/Sofosbuvir Tablets	90 mg/ 400 mg	LEDVIR	Dispatched
2	CIS	Armenia	Sofosbuvir/Velpatasvir Tablets	400 mg/100 mg	MyHep ALL	Dispatched
3	CIS	Azerbaijan	Sofosbuvir/Velpatasvir Tablets	400 mg/100 mg	MyHep ALL	Dispatched
4	CIS	Kazakhstan	Abacavir Sulfate and Lamivudine Dispersible Tablets	120mg/60mg		Dispatched
5	CIS	Kazakhstan	Abacavir Sulfate Tablets	300 mg		Approved
6	CIS	Kazakhstan	Abacavir Sulfate/Lamivudine Tablets	600 mg/ 300 mg	Generic	Approved
7	CIS	Kazakhstan	Aciclovir Tablets	200 mg		Approved, MA not to be renewed
8	CIS	Kazakhstan	Aciclovir Tablets	400 mg		Approved, MA not to be renewed
9	CIS	Kazakhstan	Daclatasvir Tablets	60 mg	MyDekla 60	Under Approval
10	CIS	Kazakhstan	Efavirenz Tablets	600 mg		Approved
11	CIS	Kazakhstan	Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate Tablets	600 mg/ 200 mg/ 300 mg		Approved, Renewal dossier dispatched
12	CIS	Kazakhstan	Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	600 mg/300 mg/300 mg		Approved, under renewal
13	CIS	Kazakhstan	Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	400 mg/ 300 mg/ 300 mg	AVONZA	Approved
14	CIS	Kazakhstan	Emtricitabine/Tenfovir Alfenamide Tablets	200 mg/25 mg		Dispatched
15	CIS	Kazakhstan	Emtricitabine/Tenofovir Disoproxil Fumarate Tablets	200 mg/ 300 mg		Approved, Renewal dossier dispatched
16	CIS	Kazakhstan	Lamivudine/Tenofovir Disoproxil Fumarate Tablets	300 mg/ 300 mg		Approved, under renewal
17	CIS	Kazakhstan	Lamivudine/Zidovudine Dispersible Tablets	30 mg/ 60 mg		Approved, MA not to be renewed
18	CIS	Kazakhstan	Lamivudine/Zidovudine Tablets	150 mg/ 300 mg		Approved, Renewal dossier dispatched
19	CIS	Kazakhstan	Ledipasvir/Sofosbuvir Tablets	90 mg/ 400 mg	LEDVIR	Under Approval
20	CIS	Kazakhstan	Moxifloxacin Tablets	400 mg		Dispatched
21	CIS	Kazakhstan	Nevirapine Tablets	200 mg		Approved, under renewal
22	CIS	Kazakhstan	Prothionamide Tablets	250 mg		Approved
23	CIS	Kazakhstan	Sofosbuvir tablets	400 mg	MyHEP	Under Approval
24	CIS	Kazakhstan	Sofosbuvir/Velpatasvir Tablets	400 mg/100 mg	MyHep ALL	Under Approval
25	CIS	Kazakhstan	Tenofovir Alafenamide Tablets	25 mg	HepBest	Dispatched
26	CIS	Kazakhstan	Tenofovir Disoproxil Fumarate Tablets	300 mg		Approved, Renewal dossier dispatched
27	CIS	Kyrgyzstan	Ledipasvir/Sofosbuvir Tablets	90 mg/ 400 mg	LEDVIR	Approved
28	CIS	Kyrgyzstan	Sofosbuvir Tablets	400 mg	MyHep	Approved
29	CIS	Ukraine	Abacavir Sulfate and Lamivudine Dispersible Tablets	120mg/60mg		Dispatched
30	CIS	Ukraine	Abacavir Sulfate Tablets	300 mg		Approved
31	CIS	Ukraine	Cycloserine Capsules	250 mg	Generic	Dispatched
32	CIS	Ukraine	Daclatasvir tablets	60 mg	MyDekla 60	Under Approval
33	CIS	Ukraine	Daclatasvir tablets	60 mg	MyDekla 60	Approved
34	CIS	Ukraine	Dolutegravir Tablets	50 mg		Dispatched
35	CIS	Ukraine	Dolutegravir Tablets	50 mg		Dispatched
36	CIS	Ukraine	Dolutegravir/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	50 mg/ 300 mg/ 300 mg		Dispatched
37	CIS	Ukraine	Dolutegravir/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	50 mg/ 300 mg/ 300 mg		Dispatched
38	CIS	Ukraine	Dolutegravir/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	50 mg/ 300 mg/ 300 mg		Dispatched
39	CIS	Ukraine	Efavirenz Tablets	200 mg	EFAMAT	Approved
40	CIS	Ukraine	Efavirenz Tablets	600 mg	EFAMAT	Approved
41	CIS	Ukraine	Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate Tablets	600 mg/ 200 mg/ 300 mg		Approved
42	CIS	Ukraine	Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	400 mg/ 300 mg/ 300 mg		Dispatched
43	CIS	Ukraine	Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	400 mg/ 300 mg/ 300 mg		Dispatched
44	CIS	Ukraine	Emtricitabine/Tenfovir Alfenamide Tablets	200 mg/25 mg		Dispatched
45	CIS	Ukraine	Lamivudine/Nevirapine/Zidovudine	150 mg/ 200 mg/		Dispatched

S. No.	Region	Country	Generic name	Strength	Brand Name	Current status
			Tablets	300 mg		
46	CIS	Ukraine	Lamivudine/Tenofovir Disoproxil Fumarate Tablets	300 mg/ 300 mg		Dispatched
47	CIS	Ukraine	Lamivudine/Zidovudine Tablets	30 mg/ 60 mg	ZOVILAM	Approved
48	CIS	Ukraine	Lamivudine/Zidovudine Tablets	150 mg/ 300 mg	ZOVILAM	Approved
49	CIS	Ukraine	Ledipasvir/Sofosbuvir Tablets	90 mg/ 400 mg	LEDVIR	Approved
50	CIS	Ukraine	Ledipasvir/Sofosbuvir Tablets	90 mg/ 400 mg	LEDVIR	Under Approval
51	CIS	Ukraine	Moxifloxacin Tablets	400 mg	Generic	Dispatched
52	CIS	Ukraine	Nevirapine Tablets	200 mg		Approved
53	CIS	Ukraine	Nevirapine Tablets	200 mg		Approved
54	CIS	Ukraine	Sofosbuvir Tablets	400 mg	MyHep	Under Approval
55	CIS	Ukraine	Sofosbuvir Tablets	400 mg	MyHep	Approved
56	CIS	Ukraine	Sofosbuvir/Velpatasvir Tablets	400 mg/100 mg	MyHep ALL	Under Approval
57	CIS	Ukraine	Sofosbuvir/Velpatasvir Tablets	400 mg/100 mg	MyHep ALL	Approved
58	CIS	Ukraine	Tenofovir Alafenamide Tablets	25 mg		Dispatched
59	CIS	Ukraine	Tenofovir Disoproxil Fumarate Tablets	300 mg		Dispatched
60	CIS	Uzbekistan	Abacavir Sulfate and Lamivudine Dispersible Tablets	120mg/60mg		Approved
61	CIS	Uzbekistan	Abacavir Sulfate Tablets	300 mg		Approved, under renewal
62	CIS	Uzbekistan	Abacavir Sulfate/Lamivudine Tablets	600 mg/ 300 mg		Approved
63	CIS	Uzbekistan	Atazanavir Sulfate/Ritonavir Tablets	300 mg/100 mg		Under Approval
64	CIS	Uzbekistan	Daclatasvir Tablets	30 mg	MyDekla 30	Approved
65	CIS	Uzbekistan	Daclatasvir Tablets	60 mg	MyDekla 60	Approved
66	CIS	Uzbekistan	Darunavir Ethanolate Tablets	600 mg	DURART 600	Approved
67	CIS	Uzbekistan	Darunavir Ethanolate Tablets	800 mg	DURART 800	Approved
68	CIS	Uzbekistan	Dolutegravir Tablets	50 mg		Approved
69	CIS	Uzbekistan	Dolutegravir/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	50 mg/ 300 mg/ 300 mg	ACRIPTEGA	Approved
70	CIS	Uzbekistan	Efavirenz Tablets	600 mg		Approved
71	CIS	Uzbekistan	Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate Tablets	600 mg/ 200 mg/ 300 mg		Approved
72	CIS	Uzbekistan	Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	600 mg/300 mg/300 mg		Approved
73	CIS	Uzbekistan	Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate Tablets	400 mg/ 300 mg/ 300 mg	AVONZA	Approved
74	CIS	Uzbekistan	Emtricitabine/Tenofovir Disoproxil Fumarate Tablets	200 mg/ 300 mg		Approved
75	CIS	Uzbekistan	Isoniazid Tablets	100mg		Dispatched
76	CIS	Uzbekistan	Isoniazid Tablets	300mg		Dispatched
77	CIS	Uzbekistan	Lamivudine/Tenofovir Disoproxil Fumarate Tablets	300 mg/ 300 mg		Approved
78	CIS	Uzbekistan	Lamivudine/Zidovudine Tablets	150 mg/ 300 mg		Approved, under renewal
79	CIS	Uzbekistan	Ledipasvir/Sofosbuvir Tablets	90 mg/ 400 mg	LEDVIR	Approved
80	CIS	Uzbekistan	Lopinavir/Ritonavir Tablets	200 mg/ 50 mg		Approved
81	CIS	Uzbekistan	Moxifloxacin Tablets	400 mg		Approved
82	CIS	Uzbekistan	Nevirapine Tablets	200 mg		Approved
83	CIS	Uzbekistan	Sofosbuvir Tablets	400 mg	MyHep	Approved
84	CIS	Uzbekistan	Sofosbuvir/Velpatasvir Tablets	400 mg/100 mg	MyHep ALL	Under Approval
85	CIS	Uzbekistan	Tenofovir Alafenamide Tablets	25 mg	HepBest	Approved