Minutes of the Meeting of the Eurasian Community for Access to Treatment with Emcure

October 6, 2020, ZOOM conference

Representatives from EMCURE PHARMACEUTICALS Ltd , INDIA:

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Participants of the meeting:

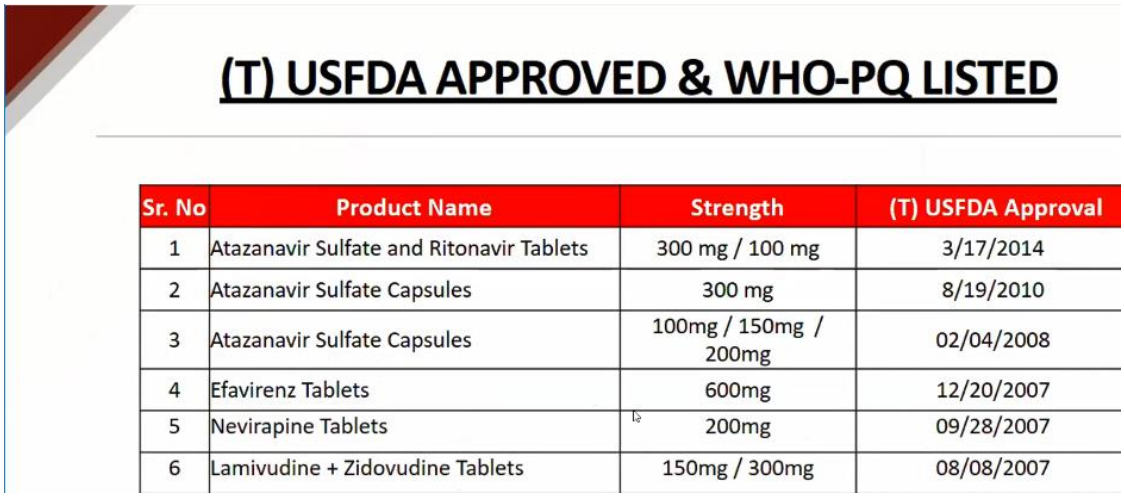
	Name	Organization, country
1	Denis Godlevskiy	ITPCru, Russia
2	Maria Shibaeva	ITPCru, Russia
3	Sergey Golovin	ITPCru, Russia
4	Tatyana Khan	ITPCru, Russia
5	Mykyta Trofymenko	100%Life, Ukraine
6	Taras Savchuk	100%Life, Ukraine
7	Pavel Savin	Public Fund "Answer", Kazakhstan
8	Anna Galstyan	"Positive People Armenian Network", Armenia
9	Anatoliy Leshenok	Public organization "People Plus", Belarus
10	Tatyana Zhuravskaya	Public organization "People Plus", Belarus
11	Nurali Amanzholov	"Central Asian Network of people living with HIV", Kazakhstan
12	Lyubov Vorontsova	"Central Asian Network of people living with HIV", Kazakhstan
13	Irine Petriashvili	National CDC, Georgia
14	Sergey Uchaev	ISHONCH VA HAYET, Uzbekistan
15	Tamar Zurashvili	"Georgian harm reduction network", Georgia

Beginning of the meeting. Presentation of the participants.

Presentation of the company.

We would like to bring to your attention a presentation where we describe drugs and products, production capabilities and geography of the company's activities. The presentation has the following structure: we will talk about the portfolio of EMCURE's ARV drugs tentatively approved by the US Food and Drug Administration (FDA) and products that are Pre-Qualified by World Health Organization (WHO), the sources of our substances, plans for registration of tenofovir, lamivudine, dolutegravir, innovations and new drugs under the development, as well as the company's social responsibility.

FDA-approved ARVs are listed below: a combination of atazanavir/ritonavir tablets, atazanavir capsules in various dosages, efavirenz tablets 600 mg, nevirapine 200 mg, and lamivudine/zidovudine 150 mg and 300 mg, respectively.



(T) USFDA APPROVED & WHO-PQ LISTED

Sr. No	Product Name	Strength	(T) USFDA Approval
1	Atazanavir Sulfate and Ritonavir Tablets	300 mg / 100 mg	3/17/2014
2	Atazanavir Sulfate Capsules	300 mg	8/19/2010
3	Atazanavir Sulfate Capsules	100mg / 150mg / 200mg	02/04/2008
4	Efavirenz Tablets	600mg	12/20/2007
5	Nevirapine Tablets	200mg	09/28/2007
6	Lamivudine + Zidovudine Tablets	150mg / 300mg	08/08/2007

The drugs for which the dossier has been filed for obtaining the WHO pre-qualification certificate and FDA approval are provided below. The tenofovir/emtricitabine FDC tablets has received WHO-PQ and the company expects to receive USFDA approval for this product shortly. Similarly Dolutegravir 50 mg tablets has received WHO-PQ while USFDA tentative approval is expected shortly. The tenofovir/emtricitabine/efavirenz (TEE) combination is also pending the FDA approval. The tenofovir/lamivudine/dolutegravir (TLD) combination is expected to receive the WHO pre-qualification certificate and the FDA approval in the coming months. The documents for abacavir/lamivudine/dolutegravir (ALD) combination have been filed and now the drug is pending the FDA approval. The tenofovir alfanamide (TAF)/emtricitabine/dolutegravir (TAFED) combination is also pending the FDA approval.

PRODUCTS AT USFDA/WHO-PQ APPROVAL

No	Product	USFDA	WHO PQ
01	TDF 300mg + FTC 200 mg FDC Tablets	ANDA # 206213	APPROVED. Ref no.: HA726
02	TDF 300mg + FTC 200mg + EFV600 mg FDC Tablets	ANDA # 206584	--
03	Dolutegravir 50 mg Tablets	ANDA # 210036	APPROVED. Ref no.: HA 701
04	TDF 300 mg + 3TC 300 mg + DTG 50 mg FDC Tablets	ANDA # 211868 FD: June 2018.	APPROVAL AWAITED Ref no.: HA722
05	Abacavir 600 mg + Lamivudine 300 mg + Dolutegravir 50 mg Tablets	ANDA # 212181 FD: Oct 2018	--
06	Tenofovir Alfanamide 25 mg + Emtricitabine 200 mg + Dolutegravir 50 mg Tablets	NDA # 212108 FD: Dec 2018	--

When developing its registration plan, the company endeavors to cover the maximum number of people living with HIV, as specified in the last column of the slide below. We are making every effort to maximize PLHIV coverage rate over 90%.

IN-country Registrations

S.NO.	PRODUCT	LICENSED	APPROVED	PENDING APPROVAL	REGISTERED	FILED	COVERAGE (PLHIV) %
1	TDF/3TC/DTG	143	6	20	35%	45%	80%
2	ATV/r	112	23	12	87%	9%	96%
3	DTG	143	15	16	60%	25%	85%
4	TDF/FTC	158	18	12	65%	4%	69%
5	TDF/FTC/EFV	154	20	09	66%	7%	73%
6	ABC/3TC/DTG	127	2	14	7%	55%	62%
7	TAF/FTC/DTG	131	1	14	7%	32%	39%

The next important information concerns the registration status of ARVs in the Eastern Europe and Central Asia region (hereinafter - EECA). Let's consider some examples.

Russian Federation: The dossiers are available for registration in the Russian Federation of the following combinations: tenofovir/emtricitabine; tenofovir/emtricitabine/efavirenz. No dossier has been filed for tenofovir/lamivudine/dolutegravir, since dolutegravir is protected by a patent in Russia. The atazanavir/ritonavir combination is already registered and supplied to the country. The tenofovir/emtricitabine combination is ready for registration in Russia. Documents for other drugs containing dolutegravir are currently not being filed for registration due to a valid patent.

Ukraine: Registered products in Ukraine are Tenofovir/emtricitabine/efavirenz, tenofovir/lamivudine/dolutegravir, tenofovir/emtricitabine (TE), dolutegravir &

abacavir/lamivudine/dolutegravir. Products pending registration are atazanavir/ritonavir and TAF/emtricitabine/dolutegravir.

Uzbekistan: TLD, ATV/r, TE, DTG, ALD have been registered, documents for TAFED have been filed for registration, and TEE we would like to understand if it is required.

Kazakhstan: TE has been registered; documents for TEE, ATV/r are planned for filing in 2020, drugs with dolutegravir are under patent protection.

Belarus: documents for ATV/r, TE are planned for filing in 2020; TEE and drugs with dolutegravir are under patent protection.

Moldova: documents for TLD, TE, DTG are planned for filing in 2020; documents for ATV/r, ALD, TAFED are scheduled for filing; the decision on TEE will be made later.

Tajikistan: documents for DTG have been filed for registration; documents for TLD, ATV/r, TE are planned for filing in 2020; documents for ALD, TAFED are scheduled for filing; the decision on TEE will be made later.

Georgia: documents for ATV/r, TE, DTG, ALD, TAFED are planned for filing; the decision on TEE will be made later.

Azerbaijan: documents for TEE, ATV/r, TE are planned for filing; drugs with dolutegravir are under patent protection.

Kyrgyzstan: documents for DTG have been filed for registration; documents for TLD, ATV/r, TE are planned for filing in 2020; documents for ALD, TAFED are scheduled for filing; the decision on TEE will be made later.

Armenia: documents for TLD, ATV/r, TE, DTG are planned for filing in 2020; documents for ALD, TAFED are scheduled for filing; documents for TEE are not planned for filing.

In general, the company has a registration plan in each country with the dossier filing dates, except for patented drugs.

CIS country's Regulatory status/plans

Rank	Country	PLHIV in '000	TEE	TLD	ATV/R	TE	DTG	ALD	TAFED
1	Russia	998	Review	DTG-2029	Registered	Review	DTG-2029	DTG-2029	DTG-2029
2	Ukraine	240	Registered	Registered	Filed	Registered	Registered	Registered	Filed
3	Uzbekistan	52	Review	Registered	Registered	Registered	Registered	Registered	Filed
4	Kazakhstan	26	Filing in Oct -20	DTG-2030	Filing in Oct -20	Registered	DTG-2030	ALD-2031	DTG-2030
5	Belarus	19	EFV- 2021	DTG-2030	Filing in Nov-20	Filing in Nov-20	DTG-2030	ALD-2031	DTG-2030
6	Moldova	15	TBD	Filing in Nov-20	Planned	Filing in Oct -20	Filing in Oct -20	Planned	Planned
7	Tajikistan	14	TBD	Filing in Dec-20	Filing in Nov-20	Filing in Dec-20	Filed	Planned	Planned
8	Georgia	12	TBD	TBD	Planned	Planned	Planned	Planned	Planned
9	Azerbaijan	9	Planned	DTG-2026	Planned	Planned	DTG-2026	ALD-2032	DTG-2026
10	Kyrgyzstan	9	TBD	Filing in Dec-20	Filing in Nov-20	Filing in Dec-20	Filed	Planned	Planned
11	Afghanistan	8	TBD	TBD	Planned	Planned	Planned	Planned	Planned
12	Armenia	3	No Plan	Filing in Nov-20	Filing in Oct -20	Filing in Oct -20	Filing in Oct -20	Planned	Planned
13	Mongolia	1	TBD	TBD	TBD	TBD	TBD	TBD	TBD
14	Turkmenistan	-	TBD	TBD	TBD	TBD	TBD	TBD	TBD
	Total	1,406							

Question: Do you have information and plans for such countries as Mongolia and Turkmenistan?

Response: At the moment, the company has no contacts in these countries. It is necessary to study information on the ARV drugs and regimens used, familiarize with the regulatory and procurement authorities. If any of those present have the necessary contacts, we will be pleased if you share this information with us.

Question of the company to the participants: Which regimen is currently used more frequently in Uzbekistan: tenofovir/emtricitabine/efavirenz or tenofovir/lamivudine/dolutegravir?

Response of the representative from Uzbekistan: Initially, the first regimen was used, but now the transition to the dolutegravir regimen takes place, although tenofovir/emtricitabine/efavirenz and tenofovir/lamivudine still prevail. Dolutegravir is in the process of inclusion in national protocols.

Question of the company to the participants: Do we understand correctly that in this case for us it makes little sense to register a regimen including efavirenz in Uzbekistan? A similar situation is in Kazakhstan, where dolutegravir is patented, and we have the opportunity to register tenofovir/emtricitabine/efavirenz. Perhaps, the country representatives could comment on this situation?

Response of the representative from Uzbekistan: Logically, I think this is the case.

Response of the representative from Kazakhstan: The dosage of efavirenz proposed by the company is 600 mg, while the preferred dosage is 400 mg. But registration of efavirenz 600 mg would also be beneficial as it would create healthy competition in the market.

Comment of the Company: We plan to include efavirenz 400 mg in our portfolio.

Question of the company to the participants: The question concerns such countries as Moldova, Tajikistan and Georgia: our company is filing documents for registration of the tenofovir/lamivudine/dolutegravir combination and is considering the possibility of registration of tenofovir/emtricitabine/efavirenz 600mg. Perhaps, the country representatives could comment on this situation?

Response of the representative from Georgia: We still cannot give any comments, but we will provide the information to our ARV procurement specialists and request feedback from them.

Question: In 2020, Belarus purchased some unregistered ARVs that are pre-qualified by WHO. Did the company participate in the procurement? If so, what were the obstacles? According to our information, the company did not become a supplier of these drugs.

Response: Our company was not aware of these tenders and, therefore, did not participate therein. If there is an opportunity to present our company to the relevant authorities in Belarus, in the future we will be able to participate and supply the necessary drugs. The table shows that we can supply atazanavir/ritonavir and tenofovir/emtricitabine to the country.

Comment of the representative from Belarus: We are planning a zoom meeting with companies that have in their portfolio drugs with the WHO pre-qualification certificate, and we invite Emcure to participate therein.

The following table shows the production capabilities of the company, for example, we produce about 800,000 units of atazanavir/ritonavir per month, and in the future we plan to increase the volume up to 1,400,000 units. We also pay attention to the fact that now the tablet size is very small and the shelf life is 36 months. We would like to note that our company supplies ARVs to 75 countries of the world.

ATV /r Tablets

ATV/r Tablets (30's) Capacity Ramping

	Submission Batch	Initial Capacity	Expanded Capacity	Future scale up
Pack Size of 30 Tablets	5,000 Packs	21,333 Packs	32,000 Packs	32,000 Packs
Monthly output	125,000 Packs	500,000 Packs	800,000 Packs	1,440,000 Packs

ATV/r Tablet Comparison

Parameter	Emcure	Other US–FDA approved Product
Weight (mg)	1,691	2,025
Thickness (mm)	8.2	10.0
Shelf Life (months)	36	24

The figure below shows how the tablet size has changed over time.

TLE/TEE/TLD/TAF E D

Product		T L E	T E E	T L D	TAF E D
Tablet dimension	Length (mm)	~23.20 mm	~23.20 mm	~21.90 mm	~17.7 mm
	Width (mm)	~11.15 mm	~11.15 mm	~10.40 mm	~ 7.7 mm
	Thickness (mm)	~7.40 mm	~7.50 mm	~8.40 mm	~6.00 mm
Gross weight		~1596 mg	~1560 mg	~1574 mg	~800 mg
Shape of tab		Modified Capsule	Modified Capsule	Capsule	Capsule
Photograph of tablet					

On the next slide, among others, there is information that combined three-component drugs are produced by our factories with a volume of up to 3 million packages per month.

TEE/TLE/TLD Production

Equipment	Existing Capacity	Expanded Capacity
Batch Size	900,000 Tablets	1,500,000 Tablets
Rapid Mixer Granulator	1,200L x3 Nos , 4,000L x 1 blender	1,200L x 6Nos , 4,000L blender x 2 Nos
Compression Machine	1 x 53 Station Korsch Bilayer	2 x 53 Station Korsch Bilayer
Capacity/Month (30's T)	1.2 Mio packs	3.0 Mio Packs

Information about where the company obtains active pharmaceutical ingredients for the production of drugs is provided below. There are several such sources: Emcure KK, Emcure-F2, Laurus, Mylan and Hetero. An extensive network of suppliers allows the company to minimize possible risks of interruptions.

API SOURCES

S. No	API	Source 1	Source 2	Source 3	Source 4	Source 5
1	Atazanavir Sulfate	Emcure KK	Emcure DMF @ Laurus	--		
2	Ritonavir	Emcure KK	Emcure-F2	Emcure @ Laurus	Mylan	Laurus
3	Efavirenz	Emcure KK	Laurus	--		
4	TAF	Emcure KK	Laurus	--		
5	Dolutegravir	Emcure KK	Laurus	--		
6	Darunavir	Emcure KK	Laurus	--		
7	Maraviroc	Emcure KK	--	--		
8	TDF*	Emcure KK	Laurus	Hetero		
9	Lamivudine*	Laurus		--		
10	Emtricitabine*	Laurus		--		
11	Abacavir	Laurus	--	--		

* Under Development at Emcure.

Emcure

The following figure shows the company's capabilities for the production of active substances.

Drug Substance Capacity

	Product	Monthly API Capacity	Equivalent 30 T Packs
1	Atazanavir	8 MT	0.88 Million
2	Ritonavir	3.5 MT	1.17 Million
3	DTG	5 MT	3.32 Million
4	TAF	2.5 MT	3.32 Million

Drugs that are currently under development are listed below. The company is negotiating with the patent holders of prolonged innovative drugs pending the FDA approval. Thereafter, it is planned to proceed to development.

Products under Development

1. **DTG 50 mg + 3TC 300 mg tabs**
2. **Emtricitabine 200 mg + TAF 25 mg FDC tabs.**
3. **Darunavir 800 mg + Ritonovir 100mg FDC Tabs.**
4. **Darunavir 600 mg+ Ritonovir 100mg FDC Tabs.**
5. **Abacavir 60 mg + Lamivudine 30 mg + Dolutegravir 5 mg dispersible FDC tabs**
6. Long acting Injectable (Nano) Cabotegravir Injections.
7. Long Acting Injectable (Nano) Rilpivarine injections.

I would like to talk a little about our innovations. We have developed the atazanavir/ritonavir combination in a single tablet.

For improving the adherence, we offer atazanavir/ritonavir and tenofovir/emtricitabine in a single blister.

Another example of a package containing the entire regimen is atazanavir/ritonavir and tenofovir/lamivudine.

Also in our portfolio there is a unique drug - maraviroc, it is produced by Pfizer in Germany, and we are the only company in the world that has its generic - a tablet 150 mg. We manufacture both the substance and the entire tablet.

We also have an improved formulation of nevirapine, which is a single-dose extended release tablet containing a full dose of 400 mg.

The company also has the darunavir/ritonavir combination in a single tablet. Two versions are available Darunavir 800 + Ritonavir 100 mg tablets & Darunavir 600 + Ritonavir 100 mg tablets.

As you can see from the rating below, our company occupies over 50% of the Indian market and ranks first. This is an example of Emcure's acceptance by Doctors and Pharmacists.

AIOCD AUGUST 2020- INDIA

RANK	CORPORATE	MAT AUG 19	MAT AUG 20	MAT Value Growth AUG 20
1	EMCURE	19.3	25.6	32
2	CIPLA	11.0	15.2	38
3	MYLAN	3.3	3.3	0
4	HETERO	4.1	2.6	-37
5	MSD	0.0	0.0	-45
6	SUN	0.1	0.0	-96
7	AUROBINDO	0	0	0
TOTAL		**37.8**	**46.7**	**23**

As a part of the company's activities, we support social projects and initiatives, for example, dedicated to World AIDS Day, street events intended to draw attention to the stigma of people living with HIV, as well as various street promotions. In addition, within the framework of cooperation with the Network

of People Living with HIV, our company has opened a specialized pharmacy. We also take part in international meetings and conferences.

Question: How the Covid-19 pandemic affected the drug delivery dates? What is the duration of the cycle from the signing of the contract to the shipment of the drug to the customer?

Response: Initially, there were small delays in supplies, but now, since the pandemic continues for 6 months, we have established processes and are ready to supply drugs within the time frames specified in the contracts.

Question: Does the company have plans to register bictegravir or its combinations?

Response: We have a license to manufacture bictegravir, but the drug is still not featuring in WHO guidelines nor featuring in WHO EOI. In addition, it cannot be used by HIV-infected patients with tuberculosis co-infection who are on rifampicin therapy Safety of administration to pregnant women and children is yet to be concluded. In general, the company is waiting for the inclusion of bictegravir in the WHO recommendations. We would also like to note that the drug development and registration cycle is approximately two years or more. In this regard, another option is to continue working with the Patent Pool to expand the license for dolutegravir. Algeria was recently included in the license. In case of successful negotiations with the patent holder, it will be easier to supply dolutegravir, since there are more suppliers and, therefore, the price will be lower.

Question: Question regarding darunavir 600 mg. Can you confirm that your version of the drug does not infringe the current patent for the amorphous form of ethanolate? Do you plan to supply the drug to EECA countries?

Response: Our drug is a generic of the drug (solvated form) manufactured by Janssen, the patent for which expires in 2023. We see no reason to develop an amorphous form of darunavir, since by the time of its manufacture the patent will have expired. In addition, darunavir/ritonavir is more expensive than atazanavir/ritonavir and lopinavir/ritonavir.

Question: Does the company plan to supply a generic of lopinavir/ritonavir? Do you have any ideas for promoting boosted atazanavir as AbbVie no longer uses its patent for temperature-resistant ritonavir?

Response: Our portfolio includes lopinavir/ritonavir, atazanavir/ritonavir, and darunavir/ritonavir. Strategically, the consumption of lopinavir/ritonavir in the world is decreasing, while the consumption of atazanavir/ritonavir is growing, respectively, it would be more reasonable for us to focus on atazanavir/ritonavir, as well as darunavir/ritonavir, and to introduce the latter into circulation after 2023, when the patent for darunavir expires. AbbVie has informed us about worldwide withdrawal of Ritonavir patents.

Question: Is it planned to launch the dolutegravir/lamivudine combination? In Kazakhstan, this combination is already included in the national recommendations.

Response: The drug is under development, we plan that next year it will be ready for release, and we will file documents for registration.

Question: Let's talk about tuberculosis. As you told us earlier, the company does not manufacture bedaquiline. Perhaps, you have other drugs for the treatment of MDR-TB in your portfolio, are there any negotiations and are there plans to expand the list of drugs?

Response: We understand that bedaquiline is a good drug, we are thinking about its manufacture and are ready to negotiate with innovative companies for a license. Do you have any suggestions for specific drugs for the treatment of MDR-TB?

Response: Bedaquiline, delamanid, linezolid, rifapentine, rifampicin, clofazimine.

Response: We will record these drugs for the further study of opportunities.

Question: What were the difficulties related to Covid-19 that you experienced?

Response: As we mentioned earlier, there were problems with supplies, and some difficulties were associated with the fact that transportation rates increased and, in general, transportation costs increased. The cost of production increased accordingly. The second problem is social distancing, that is the number of employees who enter factories and quality control laboratories was limited, which affected the production output.

Question: What plans does the company have on remdisivir and vaccines against Covid-19?

Response: As for remdisivir, communication with the copyright company has been established, and if Gilead gives us a license we will be ready to manufacture the drug. Our company structure includes Gennova Bio-pharmaceutical, which is developing a messenger RNA-based COVID vaccine.

Question: Is the company working towards registration and/or re-registration of drugs according to the unified rules of EAEU?

Response: Our Regulatory team in charge of EAEU will respond to this question.

Question: What are the company's plans for tocilizumab?

Response: Upon clarifying the information with the biotechnology department, we will be ready to answer your question.

Update as of Nov 2020: Tociluzimab is not in Emcure manufacturing range and there are no plans to produce it yet.

Question: How often does the company supply drugs to countries directly, without the involvement of distributors?

Response: Our company does not have such restrictions, in case of an order directly from, for example, the Ministry of Health, we supply drugs without problems.

In conclusion, we want to thank everyone present and express our readiness to continue working to ensure that drugs for the treatment of HIV, hepatitis and tuberculosis are available to patients. Thank you, everyone. Looking forward to further fruitful cooperation.

End of the meeting.