Minutes of the conference call of Eurasian Community for Access to Treatment and Gilead Sciences

April, 25th 2019, Saint Petersburg, Russia

Representatives of the organization:

Igor Rukavisnikov, General Manager, Gilead Russia
Felipe Rogatto, Sr Director, Medical Affairs, EMEAC
Ben Holgate, Sr Director, Legal, EMEA
Candido Hernandez, Director HCV Medical Affairs, EMEA
Stephen Head, Director, HIV Public Affairs, EMEA
Darcy Bowman, Associate Director, Liver Disease, Public Affairs, EMEA

Participants of the meeting:

#	Name	Country	Organization
1	Nikita Trofymenko	Ukraine	100 Percent of Life Charity Organization
2	Lyudmila Untura	Moldova	PLHIV League of Moldova
3	Sergey Biryukov	Kazakhstan	AGEP'C Non-Governmental Fund
4	Dmitry Lisenkov	Russia	Vector of Life Charity Fund
5	Lubov Vorontsova	Kazakhstan	Answer Public Foundation's Subsidiary in Almaty
6	Anahit Harutyunyan	Armenia	Positive People Armenian Network
7	Anna Galstyan	Armenia	Positive People Armenian Network
8	Elena Rastokina	Kazakhstan	Answer Public Foundation's Subsidiary in Almaty
9	Anatoly Leshenok	Belarus	People PLUS NGO
10	Ekaterina Novikova	Kyrgyzstan	Partnership Network Association
11	Irina Statkevich	Belarus	Positive Movement NGO
12	Oleg Dymaretsky	Ukraine	Wave Charity Organization
13	Diana Imamidin Kyzy	Kyrgyzstan	Partnership Network Association
14	Vladislav Denisenko	Ukraine	100 Percent of Life Charity Organization
15	Alexey Trutnev	Russia	NAVIGATOR Social Support Center
16	Ruslan Poverga	Moldova	Positive Initiative Public Association
17	Denis Godlevsky	Russia	AIDS, Statistics, Health NGO
18	Natalia Egorova	Russia	ITPCru
19	Julia Vereshchagina	Russia	ITPCru
20	Alexey Mikhailov	Russia	ITPCru
21	Maria Shibaeva	Russia	ITPCru
22	Andrey Skvortsov	Russia	AIDS Relief Fund
23	Gregory Vergus	Russia	ITPCru
24	Artem Vereshchagin	Russia	Support Group "Mayak"
25	Tatyana Khan	Russia	ITPCru
26	Vitaly Bespalov	Russia	Parni Plus
27	Sergey Golovin	Russia	ITPCru
28	Anna Garkusha	Ukraine	Consumers of Ukraine Charity Organization
29	Ilya Lapin	Russia	Canadian Legal Network
30	Anatoly Garkusha	Ukraine	Consumers of Ukraine Charity Organization

Meeting Facilitator: Sergey Golovin

Beginning of the conference call. Introduction of participants.

Representatives of Gilead: We will start with the list of questions sent in advance to Gilead, then we will answer additional questions arising from the meeting. Among them, there was a question about our company's plans for the next three years, including plans for long acting forms and plans in the EECA region. Unfortunately, we cannot provide a three-year registration plan for innovative forms, as these products have not been approved by regulatory authorities yet. We can answer specific questions about access by e-mail, and some of them can be answered in the course of today's discussion.

Part 1. Drug products for treatment of hepatitis C

Question 1. Access to drug products for treatment of hepatitis C in Russia.

(Igor Rukavishnikov) First of all, we welcome the decision of the Government of the Russian Federation on the inclusion of Sofosbuvir into the VED list. We believe that this is a giant leap forward towards increasing the availability of therapy for treatment of chronic viral hepatitis C (HCV infection) for patients in Russia. We are open for the dialogue with the Russian Government in order to provide the best possible access to our drug products to a wide group of patients. The prices of Gilead products are determined by several factors: the economic development of the country, the burden of the disease, the readiness of the Government to solve the problem of the many unmet medical needs. We are ready for such a dialogue and are confident that if such a dialogue is established, we will come to a mutually acceptable solution.

> Question: There is a need for sofosbuvir, and we see that after its inclusion in the VED, the price gradually decreases. Is a further price reduction expected with increasing volumes?
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> Answer of the company representative: When we submitted our dossier to be reviewed by the relevant commission for the inclusion of sofosbuvir in the VED list, we made a significant price reduction and reduced it by 25%. Since the drug was included in the VED, and the tariff is regulated by the state, the price has dropped even more significantly. So far, this is the price we keep to. We are open for a dialogue with the state in order to increase the availability of the drug for a wide range of patients.
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> Question: As a civil society, we can assist in the dialogue between Gilead and the Government. Could you provide us with the information, if you submitted any price quotations to the Government of the Russian Federation, proposals for negotiating, including the volumes required to reduce the price? How did your willingness to have a dialogue manifest in your actions?
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> Answer of the company representative: We welcome your willingness to support and facilitate this dialogue. We are ready for the dialogue with the Government, and I keep repeating this at every opportunity, at every interview. Currently we are focused on identifying next steps which company will take in the nearest future to make this dialogue possible.

Question: Can you comment on the situation that was recently reported in the press about the Russian company R-Pharm, which plans to buy Sofosbuvir from the Baltic company SIA Tamro? Do you have any detailed information about the reasons for this situation, why the drug product will be purchased from the Baltic States, and not in Russia?

Answer of the company representative:

R-Pharm and SIA Tamro are independent participants of the medicinal products market. Gilead supplied the products to SIA Tamro. SIA Tamro makes independent decisions to supply our products to the interested distributors. Starting this year, Gilead products for the treatment of hepatitis C and HIV infection are produced and supplied to the Russian market by our partner, which is Pharmstandard.

Question:

Can you provide information on plans or updates about the registration of sofosbuvir/velpatasvir and sofosbuvir/ledipasvir?

Answer of the company representative:

Both drug products are now being registered by the Ministry of Health of the Russian Federation. We hope that both of them will be approved in 2019. I cannot say the exact date, since it is not us who determine this, but it is the Ministry of Health.

Question: Given that this is a combination dosage form, have there been any additional requirements from the Ministry of Health?

Answer of the company representative: I am not at liberty to disclose the details of the registration process as well as any requirements of the Ministry of Health. The dialogue between the manufacturer and the Ministry of Health is confidential. We believe that the registration process is progressing well, and we hope that both drug products will be registered soon. Gilead is doing its best to have both products available in Russia as soon as possible.

Question: Given the complex position of Russia regarding the fixed-dose combinations, will any new strategy be developed to promote the combination drug products, for example, price reduction?

Answer of the company representative: We believe that the fixed-dose combinations (or the full treatment regimens in one tablet, to be precise), provide patients with great clinical benefits. We try to convey our point of view to the medical community and to the Government. We hope for success of a dialogue with the Government about the price issue that you mentioned.

Part 2. Drug products for treating HIV infection

Question 1. Change of indications for Truvada (tenofovir/emtricitabine) and acceptance of indications for its use as pre-exposure prophylaxis (PrEP) in EECA.

As you know, in Russia, indications for the use of Tenofovir/Emtricitabine as a means of PrEP were accepted in 2018. At the moment we have no plans to change and accept these indications in other EECA countries.

Question: Why do you have no plans for other countries in the region? Perhaps you have other drug products that you consider as PrEP? In many EECA countries there is access to generic Truvada, but manufacturers do not make changes to the instructions.

Answer of the company representative: Unfortunately, we cannot comment on the desire or willingness of generic manufacturers to change the indications. It might be worth talking to them directly. As for this particular situation, I will consult with my colleague Graeme Robertson , who is responsible for the access in the region.

Question 2. The study of the use of Genvoya (elvitegravir/cobicistat /emtricitabine/tenofovir alafenamide) for women in the Russian Federation.

Study 961 was presented at the Conference on retroviruses and opportunistic infections (CROI) in 2018, and this data is publicly available. In short, initially there was the WAVES study during which patients received Stribild, then there was a roll over to Genvoya. In the second phase, they were all transferred to a regimen that contained bictegravir/emtricitabine/TAF. The study was conducted in about 500 people, including a large group (about 100 people) from Russia. The average age of patients was 39-40 years. All patients had suppressed viral load, tolerated treatment well, had good adherence and good response to treatment.

When considering the primary outcome endpoint, the FDA recommends to consider the percentage of people with detectable viral load at Week 48. In both groups, the percentage of patients whose viral load was above 50 copies/mL was very low (about 2 percent).

No major safety situations were detected. There were no cases of discontinuation of therapy due to intolerance. Diseases that are not associated with the regimen (e.g. respiratory diseases and infectious diseases of the urogenital system) were recorded. The study is completed. Now we are still following up the patients; and we will monitor them until the access to the studied drug products is obtained, in accordance with local requirements.

Question: What were the main and most often registered side effects with elvitegravir and bictegravir?

Answer of the company representative: There were two groups in the study. Group 1 received bictegravir; Group 2 mainly received Stribild or Genvoya; a small number of patients received boosted atazanavir with Truvada. The main side effects, according to the frequency of occurrence, were side effects of the genitourinary system side, respiratory diseases, headache, vaginal candidiasis, not related to the drug exposure.

Question: So there are no side effects?

Answer of the company representative: We cannot say that there are no side effects at all. I would suggest that some cases of headache were related to the drug. In any case, those side effects that were found in the study will be listed in the slides.

Question: Did I understand correctly that the company will follow up the patients who were in the study until the state settles the issue of access to the drug products? Will you supply Biktarvy (bictegravir/emtricitabine/TAF)?

Answer of the company representative: Yes, we will provide the drug for the patients until it is available on the market.

Question: Does this mean that you will continue to study and collect data? That is, will the study take longer?

Answer of the company representative: Of course, we will continue to collect safety data within our pharmacovigilance system. They may not be included in the presentation, since in this case the sample size becomes too small.

Question 3. Registration of Genvoya and Biktarvi in the Russian Federation.

These drug products have been submitted for registration. The decision is expected in 2019, we cannot say when exactly.

Question: Do you plan to register these drug products in Kazakhstan and Kyrgyzstan?

Answer of the company representative: I have no information on these registration plans at the moment. We will contact you later about this.

Question: What is the expected price for Genvoya and Biktarvi after registration?

Answer of the company representative: Right now it is difficult to comment on this issue. It is too early to talk about prices, because these drug products have not been approved in Russia yet. When this happens, the price will be approved in Gilead and announced.

Question: Are you taking any actions to have bictegravir and elvitegravir included in the WHO recommendations?

Answer of the company representative: We are carrying out an extensive data collection. There have been extensive clinical trials performed. For Genvoya, we have the data for three years' time range, for Biktarvi, it is for two years' time range. There are several cohorts in Europe that we monitor for these two drug products (for Genvoya there are also cohorts in Italy and Germany). This data is already used in real clinical practice. We are constantly generating the data, and we hope that together it will be used to change the recommendations of WHO.

Question: Does the decision to include the drug product in WHO recommendations depend on the size of the cohort? What are the sizes of your cohorts?

Answer of the company representative: WHO have not provided any clear instructions on how many patients should there be in order to meet the requirements of the WHO Commission. For example, for TAF, we recently crossed the 1 million mark, but still it has not been included in the recommendations. Therefore, it is difficult for us to comment on this question. We hope that the information we provide will be sufficient for its inclusion in the recommendations.

Question 4. Plans of your company to market elvitegravir as a mono-component.

In 2014, our company abandoned the idea of introducing elvitegravir as a separate drug product due to insufficient demand. However, we have provided access to the drug in Europe through a program for specific patients. At the moment we have no requests for elvitegravir as a mono drug.

Question 5. Plans of your company to register TAF as a mono-component for treatment of HIV infection.

Our company does not plan to register TAF as a separate drug product. At the same time, TAF is available as a separate drug product for treatment of hepatitis B.

Question 6. Plans of your company to register cobicistat as a mono-component.

Our company does not plan to register the cobicistat as a separate booster. There are two boosted drug products on the market, one of them is supplied by Gilead.

Question 7. The inclusion of bictegravir in the model list of the essential WHO drug products.

We have already discussed this subject. We do not know what the plans of WHO are, and how much data they will need to make such a decision.

Question: Does Gilead work in the area of expanding the commercial market in EECA?

Answer of the company representative: First of all, its distributors not Gilead that supply our products to supply chain participants, e.g. health authorities, pharmacies, hospitals etc. Starting this year, some of Gilead drug products for treatment of hepatitis C and HIV infection have been manufactured and supplied by Pharmstandard, including supplying to pharmacies. Gilead products are already available in private clinics that specialize in these diseases and in general pharmacies. The information about the availability of the drug products can be found online: there are several mobile applications that can provide information in which pharmacy, at what price and in what quantity there is the drug that is required. Drug products that are currently being registered, will also be delivered in the same way to the public procurement sector and to the pharmacy segment.

Question: Is any work being planned for Russia to include Truvada (tenofovir/emtricitabine) in the VED list and localize the production of drugs?

Answer of the company representative: Truvada is scheduled for localization in Russia. Starting from mid-2019, it will be produced at one of Pharmstandard's facilities and will be supplied by them to the Russian market. We intend to continue the production and supply of Truvada to the Russian market in the future.

Our company has no plans to re-submit Truvada for the VED list. As you know, we had made many attempts, including the recent one, when we offered an unprecedentedly low price. We believe that in the future we should focus on complete treatment regimens in a single tablet, because they provide patients with significant clinical benefits. Such is our strategy.

Question: In such case, how do you plan to market Truvada in Russia? What will be the access policy, given that the drug will not be on the VED list?

Answer of the company representative: Truvada will remain available for procurement for the regional budget and in pharmacies.

Question: Are there any plans to revise the pricing policy of Truvada taking into account its localization?

Answer of the company representative: We cannot answer this question yet. This issue is currently being considered by Gilead internally.

Question: Quite often we see that in the regional procurements, instead of the combination drug product Truvada, they procure Tenofovir and Emtricitabine mono-drugs. What is your strategy about this? How do you see the further participation of Truvada in these procurements?

Answer of the company representative:

This is the element of the regional administrations' procurement approach which we are not going to challenge or dispute. To our regret Gilead's submission of Truvada for inclusion of the product in VED was declined.

End of the meeting.

The registration status of ARV drugs in EECA countries (the information had been sent separately)

Tybost, Genvoya, Biktarvi, Deskovy:

- Armenia, Uzbekistan (access to branded drugs)
- Azerbaijan, Belarus, Georgia, Moldova (access to generics)
- Ukraine: there are plans to register Biktarvi

Truvada and Viread are registered in: Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Turkmenistan, Ukraine and Uzbekistan.

Baltic countries:

- Estonia: Stribild and Truvada are registered
- Latvia: Eviplera, Truvada, Viread are registered
- Lithuania: Emtriva, Truvada, Viread are registered