The minutes of the ECAT meeting with Mylan. November 28-29, 2017, Tbilisi, Georgia

List of participants

Beacon Pharmaceuticals Ltd.:

- Prasanna Srinivasan, Lead Commercial ARV – Asia, CIS & Latam

ECAT:

- Abdullaev Timur, Uzbekistan, TBpeople
- Chokheli Mari, Georgia, OSGF
- Biryukov Sergei, Kazakhstan, AGEP'C (ANTIHEPATIT'C)
- Dmitriev Sergii, Ukraine, All Ukranian Network of PLWH
- Galstyan Anna, Armenia, Positive People Armenian Network
- Golovin Sergey, Russia, ITPCru
- Harutyunyan Anahit, Armenia, Positive People Armenian Network
- Khilko Natalia, Russia, ITPCru
- Kondratyuk Sergei, Ukraine, All Ukranian Network of PLWH
- Ladonkin Aleksandr, Russia, Status Plus
- Lapitskaya Galina, Belarus, City Children's Infectious Clinical Hospital
- Leshenok Anatoly, Belarus, Belorussian PLWH community
- Martynyuk Oleg, Ukraine, Sparkle of Hope
- Mazhitov Ravshan, Kyrgyzstan, Plus Center
- Mikhailov Aleksey, Russia, ITPCru
- Molokovskis Aleksandrs, Lietuva, Association HIV.LV
- Mustafaeva Zulfiya, Azerbaijan, Legal Development and Democracy
- Rastokina Elena, Kazakhstan, Kazakh Union of PLWH
- Schneider Alex, Switzerland, PharmActa
- Son Dmitrii, Tajikistan, The young generation of Tajikistan
- Statkevich Irina, Belarus, Positive Movement
- Sultangaziev Aibar, Kyrgyzstan, Partnership Network
- Vergus Gregory, Russia, ITPCru
- Wagner Elena, Switzerland, Ukraine, Independent consultant

Beginning of the meeting.
A minute of silence. Introduction of the participants.

Presentation of the company.

Mylan is a global pharmaceutical company committed to setting new standards in healthcare and providing the world's 7 billion people access to high quality medicine. The company has a large portfolio of HIV medicinal products. The company recently acquired the hormone contraceptives business line and also produces medicinal products to treat virus hepatitis and oncological diseases. Mylan has a broad and diverse portfolio of more than 7,500 marketed products that is available to customers including retail and pharmacy establishments, wholesalers, governments, institutions and physicians across 165 countries and territories.

In 2016, Mylan acquired Swedish company MEDA, which is widely represented in the region of EECA, in order to widen the opportunities of entering the markets of the countries of the region.

The company has high tech manufacturing facilities and it can promptly respond to urgent demands of the countries in contingency circumstances.
Shipments of smaller quantities are possible too, on condition of using uniform standard packaging.

About 40% of the nearly 21 million HIV+ patients being treated today – and a large majority of the world's HIV+ children – depend on one of our products. : More than 50 drug products, about 16 different substances, first and the second line, also pediatric forms. Mylan is the first producer of heat resistant generics and the first producer of generic TDF and its combination.

Mylan follows the highest quality systems across all its manufacturing sites and it's sites have been regularly inspected by regulatory agencies around the world.
Innovation: the company took part in research of efficacy of lowered dosage of efavirenz (400 mg); in research of treatment as prophylactic. Mylan has a large educational company for doctors.

In the nearest future other pediatric medicinal products will be introduced. Mylan recently received the US FDA's tentative approval under PEPFAR program for Lopinavir/ritonavir Oral Granules 40/10 mg.

ARVs PRODUCT LIST

FIRST LINE

	PRODUCT NAME	**APPROVALS**
1	Stavudine Capsules 30 mg	U.S.FDA PEPFAR
2	Stavudine Capsules 40 mg	U.S.FDA PEPFAR
3	Lamivudine Tablets 150 mg	U.S.FDA PEPFAR
4	Lamivudine Tablets 300 mg	U.S.FDA PEPFAR
5	Zidovudine Tablets 100 mg	U.S.FDA PEPFAR*/WHO
6	Zidovudine Tablets 300 mg	U.S.FDA PEPFAR*/WHO
7	Emtricitabine Capsules 200 mg	U.S.FDA PEPFAR*
8	Tenofovir Disoproxil Fumarate Tablets 300 mg	U.S.FDA PEPFAR*/WHO
9	Efavirenz Tablets 600 mg	U.S.FDA PEPFAR*/WHO
10	Nevirapine Tablets 200 mg	U.S.FDA PEPFAR/WHO
11	Nevirapine Extended Release Tablets 400 mg	U.S.FDA PEPFAR*
12	Lamivudine/Stavudine Tablets 150 mg/30 mg	U.S.FDA PEPFAR*
13	Lamivudine/Stavudine Tablets 150 mg/40 mg	U.S.FDA PEPFAR*
14	Lamivudine/Zidovudine Tablets 150 mg/300 mg	U.S.FDA PEPFAR*/WHO
15	Tenofovir/Lamivudine Tablets 300 mg/300mg	U.S.FDA PEPFAR*/WHO
16	Tenofovir/Emtricitabine Tablets 300 mg/200 mg	U.S.FDA PEPFAR*/WHO
17	Zidovudine/Lamivudine/Abacavir Sulfate Tablets 300 mg/150 mg/300 mg	U.S.FDA PEPFAR*
18	Zidovudine/Lamivudine/Nevirapine Tablets 300 mg/150 mg/200 mg	U.S.FDA PEPFAR*/WHO
19	Tenofovir/Lamivudine/Efavirenz Tablets 300 mg/300 mg/600 mg	U.S.FDA PEPFAR*/WHO
20	Tenofovir/Emtricitabine/Efavirenz Tablets 300 mg/200 mg/600 mg	U.S.FDA PEPFAR*/WHO
21	Tenofovir/Lamivudine/Efavirenz Tablets 300 mg/300 mg/400 mg	U.S.FDA PEPFAR*
22	Tenofovir/Lamivudine/Dolutegravir Tablets 300mg/300mg/50mg	U.S.FDA PEPFAR*

SECOND LINE

	PRODUCT NAME	**APPROVALS**
1	Didanosine Capsules 125 mg	U.S.FDA PEPFAR

2	Didanosine Capsules 200 mg	U.S.FDA PEPFAR
3	Didanosine Capsules 250 mg	U.S.FDA PEPFAR
4	Didanosine Capsules 400 mg	U.S.FDA PEPFAR
5	Abacavir Sulfate Tablets 300 mg	U.S.FDA PEPFAR
6	Atazanavir Capsules 150 mg	U.S.FDA PEPFAR
7	Atazanavir Capsules 300 mg	U.S.FDA PEPFAR
8	Ritonavir Tablets 100 mg	U.S.FDA PEPFAR*/WHO
9	Abacavir/Lamivudine Tablets 600 mg/300 mg	U.S.FDA PEPFAR*/WHO
10	Atazanavir/Ritonavir Tablets 300 mg/100 mg	U.S.FDA PEPFAR*/WHO
11	Lopinavir/Ritonavir Tablets 200 mg/50 mg	U.S.FDA PEPFAR*/WHO

PAEDIATRICS		
	PRODUCT NAME	**APPROVALS**
1	Abacavir Tablets 60mg	U.S.FDA PEPFAR*
2	Efavirenz Tablets 50 mg	U.S.FDA PEPFAR*
3	Efavirenz Tablets 100 mg	U.S.FDA PEPFAR*
4	Efavirenz Tablets 200 mg	U.S.FDA PEPFAR*
5	Ritonavir Tablets 25 mg	WHO
6	Zidovudine/Lamivudine Tablets 60 mg/30 mg	U.S.FDA PEPFAR*/WHO
7	Zidovudine/Lamivudine Dispersible Tablets 60 mg/30 mg	U.S.FDA PEPFAR*/WHO
8	Abacavir/Lamivudine Tablets 60 mg/30 mg	U.S.FDA PEPFAR*
9	Abacavir/Lamivudine Dispersible Tablets 60 mg/30 mg	U.S.FDA PEPFAR*
10	Abacavir/Lamivudine Dispersible Tablets 120 mg/60 mg	U.S.FDA PEPFAR*
11	Lopinavir/Ritonavir Tablets 100 mg/25 mg	U.S.FDA PEPFAR*/WHO
12	Zidovudine/Lamivudine/Nevirapine Dispersible Tablets 60 mg/30 mg/50 mg	U.S.FDA PEPFAR*/WHO

Question: Why does the company wait for recommendations of WHO, and does not produce the medicinal products right away?
Answer: WHO sets the treatment guidelines and gives guidance for ARV products (EOI) based on a body of clinical research and/or experience. Hence, all manufacturers prefer to look forward for the appropriate formulation, dosage and other considerations before development of the product.

Question: In Latvia pediatric dolutegravir is already being used. In Russia at the meeting with GSK the dosages were named too.
Answer: GSK is the innovator and has a body of information to support their products. A similar situation is happening with cobicistat, which is approved and used in the USA, but it has not yet been recommended by WHO. Since most of the countries in which Mylan works in the access markets follow the WHO guidelines, so it is preferably to wait for their guidance

Question: Does the company have cobicistat as a monocomponent?
Answer: No.

Question: What countries does Mylan ship lopinavir/ritonavir to, and what is the price?
Answer: Uzbekistan, Tajikistan, where it is shipped with GFATM program and at the prevailing GFATM price

Question: The principle of exhaustion of rights works in Kirgizstan. Can the country buy your products without permission from the rights holder?
Answer: The company has to check how this mechanism works and how it affects Mylan as a supplier.

Question: When are we to expect darunavir at the market of EECA countries?
Answer: No comments at the moment.

Question: EMEA recently approved tenofovir/emtricitabin as PrEP. The price is still quite high, only 30% less than the originator's one. Is there any a possibility to give two prices? One for compensational system and another one for commercial drugstores, much cheaper?
Answer: The decision has to be made by individual country's commercial office.

Question: In 2017, you signed an agreement to produce rilpivirine, combinations of tenofovir/ lamivudine/dolutegravir, tenofovir/lamivudine/efavirenz 400. When will these medicinal products appear on the market?
Answer: The company is already supplying the fixed dose combination of tenofovir DF + lamivudine + efavirenz tablets 300+300+400 mg to the market under the brand name Avonza. As of 2018, we have also received the US FDA tentative approval under PEPFAR program for the fixed dose combination of Tenofovir DF + Lamivudine + Dolutegravir Tablets 300+300+50 mg and is commercialized under the brand name Acriptega.

Question: What countries does the agreement on rilpivirine apply to? This agreement was signed through MPP or directly with the originator?
Answer: The countries will be specified later. Yes, the agreement is two-sided and it applies to a limited number of countries.

Question: Combinations of tenofovir/lamivudine/dolutegravir, tenofovir/lamivudine/efavirenz 400 mg are already included in the nomenclature in Ukraine, and the country is hoping to come out on the market early.
Answer: Pricing will be offered in our competitive bids. Rest assured, we offer very competitive prices to the public health access programs.

Question: Does the agreement on dolutegravir allow to ship it to countries with PL and countries without patents?
Answer: Yes, shipments to licensed countries are possible on condition of ViiV license. Shipments to the countries without patents have to be considered individually in line with the agreement.

Question: In Kazakhstan the prices of local manufacturers are quite high. Does Mylan company plan to come onto Kazakhstan market, since it has the necessary medicinal products in its portfolio that could be competitive? Does the company plan to appeal to antimonopoly service due to the fact that it can offer a more advantageous price?
Answer: We have to take into account local legislature and procurement system. All we can say for sure is that now Mylan offers combination 3 in 1 at accessible price.

Question: Does the company consider producing diagnostic tests?
Answer: Now days there is more talk of a viral load, but so far, we haven't come across a suitable 'point-of-care'. Mylan has launched self-test HIV kits in certain European countries. The company is open to explore new opportunities.

Question: What are the relations with MEDA in Kazakhstan? NGO repeatedly offered to representatives of the company help to promote medicinal products on the market: registration of medicines, entering registers, meetings with ministers, but did not get any result.
Answer: MEDA was recently acquired, and it is a large organization. Companies need time to integrate and align business.

Question: Belarus shows interest in purchasing Mylan's products, but there is an obstacle of active patent on ritonavir. Does the company have an agreement with Abbvie or another possibility to influence the situation?
Answer: We have to understand the IP laws of the country and take suitable steps.

Question: What is the standard price for atazanavir/ritonavir?
Answer: The price information is accessible on the public domain.

Question: There is a program of localization of medicinal products going on in Russia. Does Mylan have plans to localize the production?
Answer: The company is now studying the situation in Russia, where much attention is paid to strategy 2020. Mylan is trying to understand what it means for the manufacturers of the substances, how the situation will develop, and how to continue the work.

Question: A lot of shipments are done with the means of GF, do they have their own purchasing mechanism or they cooperate with other international agencies? For instance, through what agencies lopinavir/ritonavir is bought in Tajikistan?
Answer: The company ships its product through different purchasing systems, it depends on the country. It ships to Tajikistan through UNDP/UNICEF.

Question: What medicinal products will Mylan make in the future?
Answer: The company monitors developments and technologies that are being done in the world now. The portfolio is quite large, but at present stage it is too early to talk about it.

Question: Does the company manufacture only generics or it considers the possibility of development of its own innovation medicines?
Answer: The company manufactures generics and many other complex products.

Question: Is the development of prolonged forms for existing molecules of ARVT being done?
Answer: Extensive analysis needs to be done in order to evaluate the demand and feasibility and to choose the ones that have to be produced in the prolonged form.

Continuation of the presentation of the company.
Hepatitis C - practically 50% of global market of the medicines for HCV is taken by Mylan medicines. More than 200 000 people were treated with the medicinal products of the company by the end of 2017.

Mylan's portfolio of the medicines for hepatitis C treatment:

	PRODUCTS
1	Sofosbuvir Tablets 50 mg
2	Daclatasvir Tablets 60 mg
3	Ledipasvir/Sofosbuvir Tablets 90/400 mg
4	Sofosbuvir/Velpatasvir Tablets 400/100 mg

At present moment SOF is registered in Uzbekistan and Kirgizstan. SOF/LED is registered in Uzbekistan and Kirgizstan. DAC is registered in Uzbekistan.

Question: Why is daclatasvir not registered in Kirgizstan? There are six sofosbuvir medicinal products registered in the country and only one daclatasvir.
Answer: The company is working on it. Daclatasvir has not yet been prequalified by the WHO.

Question: Inside of the company, there is no tight connection between the departments of registration and shipments. When nevirapine was shipped some mistakes were made, that led to the fact that the medicinal product had to be reregistered in Ukraine three times. Do such situations happen because of

faster registration in international purchasing or because of the absence of sufficient connection between the departments? How can it be avoided in the near future?
Answer: This is an exceptional situation. We have taken measures to avoid such situations in the future.

Question: What medicinal products to treat hepatitis B does the company have in its portfolio?
Answer: Entecavir and tenofovir.

Question: In Latvia, only the original of entecavir-containing drug Baraclude is included in compensational system. Does the company plan to register its own generic?
Answer: The company has to study the situation.

Question: Ukraine and Belarus are included in agreement on sofosbuvir. Did the company do any shipments to these countries?
Answer: In Ukraine, the registration dossier was submitted in a week from the moment of inclusion into the voluntary license. The company is working for introducing the products in Belarus.

Question: Does the company work on taking its medicines for hepatitis C treatment into the drugstores of Ukraine and Belarus? What will the price be in the commercial sector, for example for a package of sofosbuvir?
Answer: The company will work both in the framework of state supply and in the private sector.
The pricing will be set by the local commercial offices.

Question: Last year a MEDA company representative announced that medicines for HCV treatment will be registered in Kazakhstan, but so far no action has been made yet in that direction. The country already has a program, with which 8-10 thousand people will be treated per year. Can the company reveal their plans on entering its product onto the Kazakhstan market?
Answer: Kazakhstan isn't part of the voluntary license for sofosbuvir. The company has contract commitments to the originator; but Mylan recognizes its responsibility for affordability of medicines to the patients. The company needs to have more exact information on patent barriers in order to enter its product onto the market.
Comment: At present moment, there are two generic versions of sofosbuvir produced by India and one produced by Egypt that are registered, and daclatasvir is registered too. According to the latest data there are no patents that would prevent our medicines from entering the market. There is an offer to supply it through UN programs for the treatment course of sofosbuvir + daclatasvir for 384$.

Question: Can the company announce its prices on API, so that organizations could understand the cost value and demand of each country of the region?
Answer: The cost of the substance is classified information;

Question: The image of generic medicines is not very high in the countries of EECA, how does the company work on its public image? Can Mylan as a company with good reputation disclose the information where it supplies the substance?
Answer: The image of generics is the question that is raised in many countries. The act of usage and development of a generic medicinal product is a document that is issued by FDA to confirm the high quality of a product. All Mylan products are being tested for bio equivalence.

Question: What is the expected price for sofosbuvir and daclatasvir in the countries of EECA region?
Answer: This is quite a new segment for the company. The company has to understand the demand for the medicinal product, possible volume of deliveries and expected price for a course of treatment.
Comment: The price on sofosbuvir and daclatasvir cannot be the same because it is known that the manufacturing of the latter is cheaper.

The end of the meeting.