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

November 10, 2020, ZOOM conference

Representatives of the company:

- Abhishek Datta, Business Development, Mylan Laboratories Limited

	Name	Organization, Country
1	Denis Godlevskiy	ITPCru, Russia
2	Grigoriy Vergus	ITPCru, Russia
3	Maria Shibaeva	ITPCru, Russia
4	Sergey Golovin	ITPCru, Russia
5	Tatyana Khan	ITPCru, Russia
6	Aleksey Mikhaylov	ITPCru, Russia
7	Sergiy Kondratyuk	ITPC Global
8	Yulia Stoke	CO Positive Movement, Belarus
9	Ekaterina Novikova	Partner Network Association, Kyrgyzstan
10	Nurali Amanzholov	Central Asian Association of PLWH, Kazakhstan
11	Mykyta Trofymenko	100%Life, Ukraine
12	Zoya Zamikhovska	100%Life, Ukraine
13	Sergiy Dmytriev	100%Life, Ukraine
14	Sergey Uchaev	ISHONCH VA HAYET, Uzbekistan
15	Tamar Zurashvili	Georgian Harm Reduction Network, Georgia
16	Maka Gogia	Georgian Harm Reduction Network, Georgia
17	Pavel Savin	PF "Answer", Kazakhstan
18	Lyubov Vorontsova	Central Asian Association of PLWH, Kazakhstan
19	Elena Rastokina	ICAP, Kazakhstan
20	Sergey Biryukov	NGO "AGEP'C", Kazakhstan

<u>Beginning of the meeting. Presentation of the participants.</u>

Mylan is headquartered in the United States and has the motto “Set new standards in healthcare and provide access to medicines for the entire population of the world”. The company was founded in 1961 and has grown enormously over the past fifty years. In 2007, the company went global, acquired a business in India, and currently all ARV drugs are manufactured there. The company employs over 30,000 people worldwide. The company operates in over 145 countries. Our product portfolio consists of 1,400 items, with other 3,400 being under development or registration worldwide. For example, in the United States, one in thirteen patients takes Mylan’s products, in Canada, Mylan’s products are available in 8 out of 10 pharmacies.

We have a very wide network of plants, 14 of which produce tablet dosage forms, 13 - injectable dosage forms, 3 plants produce complex products, and 9 plants develop active pharmaceutical ingredients (API). We would like to emphasize that we have high capacities to

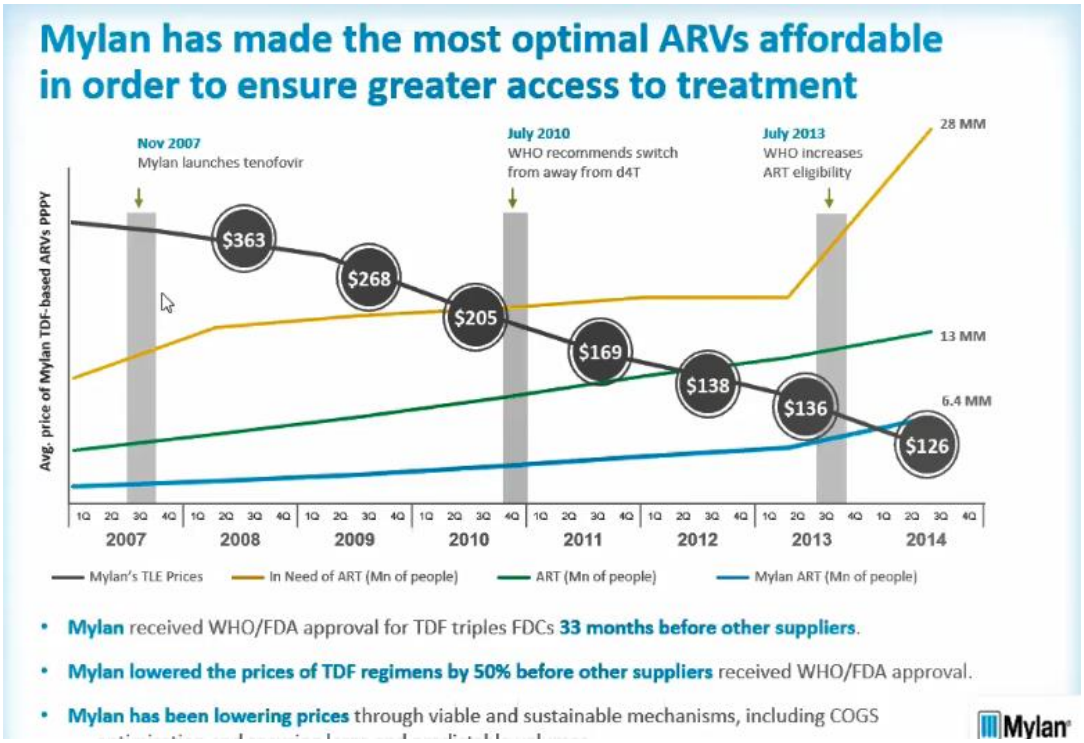
produce API, 80% of which we use in our products which allows us to be competitive in terms of cost.

Our R&D departments are also represented worldwide. They are in the USA, Ireland, India and Japan. The company invests quite a lot in research and development and, specifically, between 2010 and 2014, investments grew by 20%, and have continued to grow since then.

We manufacture products for various fields and diseases, including treatment of infectious diseases. We also produce injectable dosage forms, biological products, medicines for the treatment of respiratory diseases, allergies, and the range is constantly expanding.

As far as ARV drugs are concerned, they constitute an extensive portfolio of 14 substances, 50 first-line and second-line finished dosage forms, and pediatric forms. We are proud of the fact that 50% of HIV patients - one in two worldwide - are taking our drugs.

The production of ARV drugs is our strength and our main priority. The advantage of Mylan in the field of drugs for the HIV infection treatment is that, firstly, we have a large number of ARV drugs and other products for optimal administration in our portfolio, and secondly, we are reducing their prices quite significantly. Thus, the price of tenofovir has been declining since 2007 when our drug was first launched on the market, and as a result, it has more than halved during this time. This happened, among other things, since our API was used in the production of the drug which allowed us to save money without resort to spending on third-party research and development.



Our values also include reliability, quality, and innovation. Examples which we are proud of are the development of heat-stable lopinavir/ritonavir in 2009 and the heat-stable atazanavir/ritonavir released in November 2011.

Question: The question concerns the supply of sofosbuvir/daclatasvir and tenofovir to Kazakhstan. Has the problem with registration and delivery of daclatasvir to the country been resolved? What can be done to prevent such a situation from happening again in the future?

Answer: Indeed, we had difficulties with the supplies, but currently supplies are going smoothly. In the future, we do not expect any supply problems.

Clarification from the representative from Kazakhstan: The question deals more with tenofovir which was supplied through UNICEF. The fact is that deliveries were made in the third quarter of 2020 instead of the first one, but as of today there are no problems anymore.

Answer: We apologize for the delays in the supply of tenofovir. They were inter alia due to the Covid-19 epidemic, but now everything has returned to normal and the medicine is being delivered on time.

Question: Do you have any plans to promote pretomanid? Where the "operational research" of pretomanid is carried out in Kyrgyzstan? How can this research help to register the product? In fact, there is no such a concept in the country's regulatory policy, and the product must undergo full-fledged clinical studies in order to be registered?

Answer: Pretomanid is one of Mylan's core products. We are currently consulting with phthisiatricians from the CIS countries, inter alia from Kyrgyzstan, as well as those from TB Alliance on the issue of pretomanid launch. Apart from Kyrgyzstan, we are negotiating with Kazakhstan, Uzbekistan, Turkmenistan, and Ukraine. In Kyrgyzstan, the negotiations are at the final stage, and in the nearest future, we will be ready to carry out supplies. In Uzbekistan, the protocol is almost finalized, and as soon as we complete it, we will proceed to the deliveries. Ukraine will be the first country where we will supply pretomanid; we are now dealing with this issue. As part of the operational research and on demand, we provide pretomanid for 50 patients free of charge. We understand the seriousness of this process and registration, and we have already submitted a dossier for pretomanid registration in Ukraine.

Clarification of the question: Are difficulties associated with the registration of pretomanid in Kyrgyzstan expected due to the difference in the terms "operational research" and "clinical studies"?

Answer: Pretomanid research is at the end of the third phase. Our company has concluded an agreement with the National Center of Phthisiology of Kyrgyzstan whereunder pretomanid will be supplied for 50 patients, and the registration procedure will be carried out in the future. As far as we understand, difficulties should not arise.

Clarification of the question: Since pretomanid is not patented, will other companies also be able to supply it?

Answer: Mylan is currently the only company licensed and working with TB Alliance on pretomanid. This may change in the future, and other companies will join the agreement. However, this issue is not within our competence.

Question: Do you have any plans to supply pretomanid to Georgia?

Answer: We are planning to bring pretomanid to the market in all countries of the EECA region, including Georgia, Armenia, Moldova.

Question: What are the updates on the approval of bictegravir and its combination BIC/3TC/TAF in the EECA countries? This integrase inhibitor will be important for such countries as Kazakhstan, Belarus and Azerbaijan which are not parties to the dolutegravir

license agreement. In Kazakhstan, bictegravir is already included in the national recommendations for the HIV infection treatment.

Answer: Currently bictegravir is at an early stage of production, that is, we are engaged in research and development work. In the future, we would like to see in our portfolio both a separate product and its combination with fixed doses.

Question: How long do you think the production process can take?

Answer: We believe that between 9 and 12 months, but we need to clarify this information. We will be able to answer this question later.

Question: WHO recommends efavirenz 400 mg as a substitute for efavirenz 600 mg, but as far as we know the coverage with efavirenz 400 mg is very low in the EECA region. Does your company plan to expand access to efavirenz 400 mg in the EECA region? This refers to such actions as registration, work with purchasing agencies, adding a medicine to the VED list, etc.

Answer: We are trying to promote efavirenz 400 mg in all markets of the region in order to replace efavirenz 600 mg. Currently, we are applying for registration in Ukraine, Kazakhstan, Uzbekistan, and we hope that we will be able to increase the coverage.

Question: What are your plans in respect of efavirenz 400 mg for Russia?

Answer: In Russia, we have a group of specialists working on a dossier on efavirenz 400 mg, and we think that we will also apply for its registration there.

Comment of the representative from Russia: This is especially important for us, since it was your company that conducted the research on the medicine.

Answer: Indeed, this is an important product for us, and Russia is one of the key markets for us.

Question: Are you planning to open a representative office in Kazakhstan? This would help to facilitate communication greatly.

Answer: We have concluded an agreement with distributors, inter alia on ARV drugs, and we work through them. As the market expands, we will think about opening more offices in Kazakhstan in the future. We have an office in Kyiv, and we also have representatives in Kazakhstan. It works in the area of biological products and injectable products.

Clarification of the question: Could you tell us exactly which of your distributors is involved in the sale of medicines for the HIV infection treatment in Kazakhstan?

Answer: You may contact us and get their contact details.

Question from a representative from Kazakhstan: What are the terms for submitting the dossier for efavirenz 400 mg in Kazakhstan?

Answer: We are finalizing the dossier and plan to submit it for registration in early 2021.

Question: There are many requests from countries of the region regarding the authorization status of the products. Perhaps you can provide us with a table showing such information?

Answer: Yes, of course.

Question: Currently, the specificity of Russia consists in the promotion of the policy of import substitution and giving priority to domestic producers. Are you negotiating the localization of your production in Russia? Your efavirenz 400 mg is a combination product. At the same time, when procuring, the combination is broken down into monocomponents, since they are cheaper, and the combination product can be competitive if it is priced comparable to the stand-alone drug.

Answer: Our team in Russia is already working on an agreement for the localization of production with local companies. We would also like to note that Mylan offers competitive prices for products, and they are among the lowest. The price for efavirenz 400 mg will be competitive and fairly low.

Question: Do you have any plans to register lopinavir/ritonavir in the EECA countries after AbbVie revoked its patent due to Covid-19? If so, how much will the product cost?

Answer: We are currently able to supply lopinavir/ritonavir upon request due to the AbbVie's revoked patent. We have already had supplies to Moldova and Kyrgyzstan. The price of the product will depend on the volume, but it will be significantly lower than that of the originator.

Question: As far as we understand, the heat-resistant atazanavir/ritonavir is also no longer patented, so can you supply this product to any country of the region?

Answer: According to our data, atazanavir/ritonavir is a patented medicine. In the case of an existing patent, our company cannot supply the medicine, but if it does not exist, we can.

Question: In 2020, the UCHIMP of Moldova (the division for the coordination and implementation of Covid-19 in public health) organized public procurement of ritonavir 100 mg. According to the data received from this organization, requests for quotations have been sent to manufacturers. According to our civil society colleagues, only AbbVie submitted a quotation (USD 1.28 per tablet). However, in 2018 and 2019, the product was procured from Mylan at a price of USD 0.51 per tablet. Has your company received a request for procurement of ritonavir 100 mg for Moldova? If so, what did the company not like?

Answer: Upon request, as part of the Global Fund procurement, our company has already supplied ritonavir to Moldova and is ready to do so further. In this case, we did not receive such a request.

Question: What are your intentions regarding the development, promotion, and registration of generic versions of DTG/3TC in the EECA countries? In Kazakhstan, the combination is already included in the relevant national recommendations.

Answer: This product is still under development. Upon its completion, we plan to launch it on the market of the EECA region countries.

Question: Can you indicate an approximate timeframe?

Answer: We think that by the middle of next year it will be clear when the company will submit the dossier for registration. Presumably, DTG/3TC will be available for supply by the end of 2021.

Question: Has Mylan considered the production and promotion of generic bedaquiline? If so, how long will it take to develop and launch it?

Answer: Currently, we are already developing bedaquiline which will take about two years. If we obtain a license for it, we will be able to carry out the supplies.

Question: Can Mylan provide a letter of guarantee for the supply of bedaquiline by 2022 for Ukraine if it is licensed? Currently, there are negotiations on conclusion of a license with Janssen, the Patent Pool and other stakeholders.

Answer: Our company is already negotiating with Janssen regarding the conclusion of a license for bedaquiline, and as soon as they are completed, we will be able to supply the product to Ukraine.

Question: Does Mylan have plans to manufacture remdesivir under a license agreement? What are the barriers to production and access to the product outside India and how can they be overcome?

Answer: We have a license from Gilead for the production and sale of remdesivir in the EECA countries. We have already supplied the product to Uzbekistan and Moldova and are currently negotiating on its supply to Georgia and Ukraine. The company also bade for tenders in Kazakhstan, Ukraine, and Azerbaijan, but, unfortunately, failed to win contracts. Those tenders were also bidden by the companies that did not have a license from Gilead (which does not guarantee the product quality), but they were able to offer a lower price. In Belarus, the situation was similar, and the tender was won by a company that did not have a license from Gilead. Mylan is well positioned to supply remdesivir (over 100,000 doses) and can supply it upon request.

Question: We have come across the information that the production of remdesivir takes about six months. How long does it take Mylan to produce the product?

Answer: Indeed, at the initial phase the production of remdesivir took some time, but currently the process is so fine-tuned that the production time is 3-4 weeks. Our two plants, including one for production of injectable dosage forms in Bangalore, are ready to manufacture it and meet the needs upon request.

Question: Does the company plan to register and tender for purchase of clofazimine and delamanid in Ukraine? If so, what is the expected price for them? In Ukraine, the need for clofazimine is about 1-1.5 million tablets, the competition for the product is low since it is produced by Novartis only.

Answer: Capacity constraints related to the red colour of the tablet prevent Mylan from manufacturing clofazimine. We have a license for delamanid; it covers some markets in the Middle East and South Asia, but in Ukraine the exclusive license for the product belongs to the R-Pharm company, so we cannot supply it there.

Question: Does the colour of the tablet affect the pharmacokinetics and pharmacodynamics?

Answer: We need to clarify this information. We will be ready to answer the question later.

Question: Are negotiations with the manufacturer of delamanid, Otsuka Pharmaceutical, possible with respect to the transfer of Ukraine under another license, since R-Pharm may have difficulties with supplies?

Answer: Yes, this is an important issue which requires discussion.

Question: Has the company considered the possibility of producing the biosimilar tocilizumab? If so, how long will it take to produce and launch it?

Answer: Mylan currently has no plans to develop tocilizumab.

Question: Have you encountered any problems with the supply of ARV drugs, active ingredients in connection with the spread of Covid-19? If so, to what extent, and how did you manage to overcome them?

Answer: Yes, indeed, the situation with the spread of coronavirus infection affected the deliveries, including flight delays, production difficulties due to the lockdown, and we are still experiencing some difficulties. Nevertheless, thanks to our stocks, we were able to make deliveries without interruption to some extent, but then we still had problems. The strategy for the company's risks minimizing includes forecasting, and we make efforts to ensure that we always have a stock of products for at least 3-4 months, including substances, in order to ensure uninterrupted supply.

Question: Has the company considered its inclusion in the Covid-19 vaccine license? Have negotiations started in this regard, and do you have the capacity to produce vaccines?

Answer: Mylan's management is currently negotiating with the companies that are developing vaccines. Generally, we have the production capabilities to develop and launch a vaccine. But it is too early to speak of it, everything will depend on the type of vaccine and the volume of production capacities.

Question: What barriers are expected in connection with the entry into force of the new uniform registration rules under the EEU procedure?

Answer: We are currently analyzing this new procedure; according to preliminary estimates, the registration process according to the unified rules of EEU will be quite complicated, and we will be able to better understand it when we submit the dossier.

End of the meeting.