Minutes of the meeting of Eurasian Community for Access to Treatment and Macleods

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Representatives of the organization:

- Rohini Karde
- Manish Todi

	Name	Organization
1	Denis Godlevsky	ITPC EECA
2	Tatiana Khan	ITPC EECA
3	Alexey Mikhaylov	ITPC EECA
4	Maria Shibaeva	ITPC EECA
5	Sergey Golovin	ITPC EECA
6	Daria Mikulich	ITPC EECA
7	Yulia Vereshchagina	Patient control
8	Morgan Akhmar	ITPC Global
9	Dietrich Pieler	ITPC Global
10	Aybar Sultangaziev	Partner network association, Kyrgyzstan
6	Ekaterina Novikova	Partner network association, Kyrgyzstan
8	Evgeny Goloshchapov	Positive Initiative, Moldova
9	Elena Rastokina	Answer, Kazakhstan
10	Pavel Savin	Central Asia Association of PLHIV, Kazakhstan
11	Sergey Biryukov	AGEP'C NGO, Kazakhstan
12	Lasha Tvaliashvili	Real people real vision NGO, Georgia
18	Medea Khmelidze	Real people real vision NGO, Georgia
19	Anatoly Leshenok	People plus, Belarus
20	Shorena Nazraidze	TB people, Georgia
21	Marie Chochelia	TB people, Georgia
22	Sergey Dmitriev	Health advocacy coalition, Ukraine
23	Anastasia Gomenyuk	Health advocacy coalition, Ukraine

Beginning of the meeting. Introduction of participants.

Macleods is an Indian pharmaceutical company with a 37-year history. Initially the company's portfolio included anti-tuberculosis drugs, then we began to expand into other therapeutic areas. Initially we had one plant, then we increased their number to fourteen. We produce drugs all over the world. Four of the fourteen plants have been approved by stringent regulatory agencies to supply drugs.

We provide our drugs to various international organizations (including UN organizations). Right now we have 66 drugs that have passed quality control checks and are produced at these facilities. These drugs are intended to treat HIV, tuberculosis, malaria, and viral diseases. In the past year, the company's revenue was $1 billion. Approximately 70% of the revenue come from sales in India. The rest comes from exports and shipments to subsidiaries. This is the basic information on the company. If you have any additional questions, we are ready to answer.

I (Manish Todi) have just returned from Ukraine, where I spent a month, and where we have been developing our business for 17 years. Lately we have been looking at business in the CIS as well, but at the moment we are actively working in Kazakhstan and Ukraine.

Question: Are all 14 plants located in India?

Answer: Yes, all of them.

Question: Do you have plans to open plants in other countries, to increase the number of partners?

Answer: We have a joint venture with a company in Indonesia. It is the only venture outside of India.

Question: Does your company have any representative offices in the EAEU other than Ukraine?

Answer: We work actively in Ukraine and Kazakhstan, and early next year we plan to start working in Uzbekistan. These are the three countries where we have offices.

Question: Who exactly are you working with in Kazakhstan? Do you have any information?

Answer: In Kazakhstan (in Almaty) we have our own representative office.

Question: There was a company in Belarus called Belalek that registered the drug Aluvia. You didn't mention cooperating with them in the past or in the future. Did you exclude them from your partners list?

Answer: I don't have any information on that, but I can find out that for you.

Question: A question on registration of HIV drugs. What are the priority ARV drugs for EECA countries, and what is the registration status of HIV and TB drugs in the region?

Answer: As for the ARVs, we have already registered some drugs and some are in the process of registration. We are ready to send you the list of drugs and their registration status by e-mail.

Question: Please clarify the registration status of TB drugs.

Answer: As for TB, we have been supplying drugs for drug-sensitive TB (i.e. isoniazid, rifampicin, pyrazinamide, and ethambutol) for ten years. The table that we will send you includes all the details of the registration. We have a total of 66 drugs that are prequalified by WHO, of which 34 are anti-TB drugs.

Question: In order to continue the conversation, it is necessary to understand when you plan to register bedaquiline in Kazakhstan?

Answer: We have already registered three drugs: bedaquiline, linezolid, and pretomanid. We have been producing linezolid for quite a long time, and we plan to continue doing so. I can send you information on the registration status for Kazakhstan. We have registration for linezolid in Ukraine, for example. We have not seen the potential for registration in Kazakhstan, but if it is necessary, we can register this drug. We have the dossier ready for that.

Question: Linezolid is already registered in Kazakhstan. I am interested in information on bedaquiline and pretomanid.

Answer: We are preparing the registration documents for pretomanid. We need to look at the patent situation, and then we can register this drug.

Question: You have not mentioned Kyrgyzstan anywhere. Apparently, you were not interested in this market because the Global Fund made most of the procurement. Starting this year, we are significantly increasing state budget expenditures on TB drugs procurement. In addition, there is the issue of registering drugs under the EAEU procedure. At this point, we have the option of registering drugs according to national procedures or allowing a drug that has been prequalified by WHO to enter the market without registration. These things, of course, need to be discussed in more detail. This is the information about the situation on the market in Kyrgyzstan. You are the only licensee who has the right to produce bedaquiline. Will you register the drug in Kyrgyzstan if the government is willing to make the procurement with budget funds? What will be the pricing policy for bedaquiline in this region?

Answer: We are interested in registering the drug wherever it is needed. As for bedaquiline, we are waiting for the patent to expire, which will be sometime in June 2023. Right now we are preparing the documents for registering the drug.

Patient community representative's comment: Under our legislation (in Kyrgyzstan), no patent linkage is required, and the company can start registering the drug before the patent expires.

Company representative's comment: We cannot start producing the drug in India until after June 2023.

Question: You are talking about manufacturing the drug, and we are talking about the registration dossier. Do you mean that you can't use the manufacturing information because it doesn't exist yet?

Answer: As I understand the information obtained from our head office, we can start registering the drug wherever possible, but we can't produce it. So far, we are not active in Kyrgyzstan, our efforts are focused on Kazakhstan. In the EAEU for Kazakhstan everything is clear to me, we can only get registration until December 2025. After that we need to use a centralized procedure, we need a GMP and EAEU certificate for this. We also need bioequivalence studies for five EAEU countries (either in Russia, or in Kazakhstan, or in Belarus).

Patient community representative's comment: Recently, there was a decision in the 'main body of the EAEU' that EAEU member states may not work under the unified registration procedure. This exception works until the end of 2023 due to sanctions and the current situation in the region. 2023 is a temporary window, when there is an opportunity to register drugs via a fast-track procedure. I suggest that we hold individual consultations on this issue to demonstrate these opportunities.

Question: Does this registration procedure apply only to TB drugs?

Answer: This procedure applies to all drugs that are going to be imported into the country.

Company representative's comment: Okay. We need to talk separately on this issue because we need more information.

Question: You said that you are actively working in Kazakhstan. We know that shipments of bedaquiline, your generic drug, are already taking place in Kazakhstan. We are now going through court trials to challenge the patent, and we do not understand the mechanism of supplying the drug to Kazakhstan by your company. We are interested in supplying this drug and it is important for us to know that it will be available in our country.

Answer: It's only been two months since we received approval from a stringent regulatory agency to manufacture the drug, and we simply could not physically make that shipment to Kazakhstan. The information about our company's shipments of bedaquiline to Kazakhstan is very strange, and we would certainly be interested to know whether bedaquiline with the name Macleods on the packaging is available in Kazakhstan.

Patient community representative's comment: I'll contact our TB coordinator now, and we'll try to give you that information right away.

Patient community representative's comment: I would like to add about pretomanid, currently there is no patent, it is at the application stage. In Kazakhstan, Kyrgyzstan, Armenia, and Belarus, there is a mechanism for supplying drugs that are prequalified by WHO and approved by stringent regulatory bodies. Now there are no obstacles for the supply of unregistered drugs.

Company representative's comment: If it is possible to register a drug and supply it without violating the patent, we are ready to do it right away.

The situation with patents is as follows. There is a basic patent that expires in 2023. There are countries that have only the basic patent, meaning that these countries do not yet have a patent for the fumarate salt and for the process of manufacturing bedaquiline. In these countries, Macleods can supply the drug as soon as the patent on the main chemical compound expires. Unfortunately, the countries in our region are not included. The patent on the fumarate salt was issued in our countries, and these are the blocking patents, according to Macleods. That patent expires in 2027.

Question: Can Macleods provide the text of the voluntary licenses, which are not in the public domain? Also, please provide information about the royalties that are included in the voluntary license and the formulas for calculating the royalties.

Answer: We cannot provide information about voluntary licenses because they are confidential. As for the royalties, the information depends on which drug it is and in which country it is sold; there are several websites where you can find this information.

Patient community representative's comment: In addition, it depends on the position of the drug Patent Pool.

Question: Unfortunately, I have not found this information. Can you provide the royalty information on bedaquiline?

Answer: We have not yet made royalty calculations for this product.

Question: Do I understand correctly that there is a separate voluntary license agreement and a separate royalty agreement?

Answer: Royalties are usually part of the agreement; they come in the form of an undisclosed appendix.

Question: Do you have an agreement with Janssen on bedaquiline?

Answer: No comment.

Question: Please, tell us about the possibility of supplying at the issuance of a compulsory license.

Answer: There are 11 countries where there is no patent, to which we can now supply bedaquiline. In your region, it's Uzbekistan. The rest are countries in Africa, Latin America, and Southeast Asia.

Question: Do I understand correctly that you cannot comment on your willingness to supply even if a compulsory license is issued?

Answer: We can supply if a compulsory license is issued.

Question: You say quite confidently that you will manufacture bedaquiline from 2023, so you assume that no patent for fumarate salt will be issued in India.

Answer: We've invested a lot in developing this product, it's actually ready to be released, so we really hope, given our desire to supply to as many countries as possible, that the patent will not be issued, and we can do it.

Patient community representative's comment: Perhaps you will have some developments that bypass the patent. As a plan B.

Question: This question is about joint procurement for several countries, not through international agencies, but specifically through and state agencies. Do you have such experience in the world? If so, how does Macleods make shipments: to one warehouse in one country and then to the other countries, or are shipments made separately to each country? Does it depend on the cost of shipping and drugs, how is the price formed? Is it for each country separately, or is the price the same regardless of where the drugs are shipped to?

Answer: We have such experience of participating in tenders for several countries organized by international organizations Global Fund and other organizations. In these cases, we deliver the product to different countries using different modes. It can be a delivery to the port, then the customer distributes himself, or it can be CIF or CIP delivery, and then the product goes to the warehouse. There are also DDP, DDO when we deliver directly to the door.

Question: The question is not about deliveries by Incoterms. The question is about deliveries organized by public or state organizations. In cases where one country arranges centralized procurement for several other countries. Do you have any experience of such cooperation?

Answer: We don't have that kind of experience.

Question: Which of the 38 EECA countries can get rifapentine at a lower price under the UNITAID and CHAI agreement? Are there any plans to register the drug in the region?

Answer: We have a combination form of rifapentine with isoniazid. Under the UNITAID agreement, all countries are able to supply at reduced prices. Moreover, under the contract with GDF, Macleods has already made deliveries at reduced prices to three countries. They are Tajikistan, Belarus and one more country.

Question: What are your plans for registering this drug in the countries?

Answer: We have submitted dossiers for registration in 35 countries, including some EECA countries, we are registered in Turkmenistan. We are now registering in several more countries. As part of the agreement, we supplied combined rifapentine at a reduced price to Georgia, Moldova, Tajikistan, Uzbekistan. We also expect delivery to Ukraine. We supplied the combination drug to Georgia in March 2022. No delivery has been made to Belarus.

Question: Can you give us the table with the registration status?

Answer: Yes, we can give it to you.

Question: Is rifapentine registered in Russia? Are you planning to register it?

Answer: At present, we are not registering any new drugs in Russia, and we supply only those that were registered earlier. There are no plans to register anything new at the moment either.

Question: Who are your local partners?

Answer: We have partner companies in Dubai and Singapore. These companies purchase and deliver to Russia.

Question: The question of new rules in the EAEU. On the restrictive mechanisms of the EAEU (registration, patent linkage), which may affect the ability to make international procurement for EAEU countries. Have you heard about this and what is your position on this issue?

Answer: We work with Kazakhstan, so we know what's going on there. Until 2025 we can sell if there is registration. After that the single registration is in effect, and we need [to have] a GMP [inspection] under Eurasian rules, and we need to do bioequivalence studies for 5 countries (Russia, Belarus, Kazakhstan, Kyrgyzstan, Uzbekistan). Since EAEU procedure requirements are excessive, so far, we are not very interested in advancing our drugs only in these five countries. But if there is a simplified national procedure and if there is a WHO prequalification, as mentioned above, then we are ready to go forward with this procedure so that we do not have to go through a five-year procedure. We are not ready to conduct additional bioequivalence studies for each country.

Question: Is there no registration in Russia now because of the war or because of the difficulties associated with the requirements of the EAEU?

Answer: It has to do with our business in Ukraine, and we don't want to take any risks.

Question: Are you negotiating with the TB Alliance to develop the combination drug bedaquiline plus pretomanid?

Answer: We have the capacity to produce both bedaquiline and pretomanid. Given the emergence of new drugs within the BPal M regimen, which will be used to treat multi-drug resistant tuberculosis, yes, we are interested in developing such a compound.

Patient community representative's comment: Thank you for the donations you made related to the provision of dolutegravir through WHO to those Ukrainians who left their country. Also, thank you for providing drugs for Ukrainians who stayed in Ukraine.

Answer: Thank you. It was our pleasure, we tried and helped as much as we could. One shipment was directly to Ukraine, the other was via WHO (TLD). We will try to help in the future.

Question: A question about the languages used in the drug instructions. There is information in English, French, Spanish, while there is no information in the language of the country where the drugs are supplied. Does Macleods comply with the language requirements specified in the drug tender?

Answer: When supplying, in accordance with the requirements of the tender we win, we always make the instructions based on the requirements of the relevant legislation. If a national language is required, we put it in the instructions.

We thank you for the meeting, for the interesting information about the registration procedures. We want to supply as many products as we can to as many countries as possible.

End of the meeting