Minutes of the Meeting of the Eurasian Community for Access to Treatment with ViiV Healthcare

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Representatives of the company:

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- Bryn Jones, Patient Affairs Director, ViiV Healthcare
- Elena Zaytseva, Healthcare Policy and Patient Advocacy Manager, GSK Russia, AO GlaxoSmithKline Trading

	Name	Organization, Country
1	Denis Godlevskiy	ITPCru, Russia
2	Maria Shibaeva	ITPCru, Russia
3	Sergey Golovin	ITPCru, Russia
4	Tatyana Khan	ITPCru, Russia
5	Aleksey Mikhaylov	ITPCru, Russia
6	Nurali Amanzholov	Central Asian Association of PLWH, Kazakhstan
7	Mykyta Trofymenko	100%Life, Ukraine
8	Zoya Zamikhovska	100%Life, Ukraine
9	Sergiy Dmytriev	100%Life, Ukraine
10	Sergey Uchaev	ISHONCH VA HAYET, Uzbekistan
11	Tamar Zurashvili	Georgian Harm Reduction Network, Georgia
12	Mari Chokheli	OSF Georgia, Georgia
13	Pavel Savin	PF "Answer", Kazakhstan
14	Irine Petriashvili	National CDC, Georgia
15	Sergey Biryukov	NGO "AGEP'C", Kazakhstan

Beginning of the meeting. Presentation of the participants.

Presentation of the company.

Thank you very much for giving us the opportunity to participate in your meeting. We will start with presentation of ViiV Healthcare's access policy. ViiV Healthcare has a clear goal of ensuring access to treatment for all people living with HIV (PLHIV). We have three areas in which we are working to achieve this goal, namely: development of a portfolio of medicines that plays a key role in HIV treatment, innovation and research in the field of HIV infection, and expanding of important partnerships.

Access to treatment is a very complex area which is influenced by many different factors: issues related to logistics, availability of resources in the health care, prioritization of prevention issues and their inclusion in national budgets, stigma and discrimination, low level of knowledge in health care etc.

We strive to make our medicines available to the largest possible number of people living with HIV, regardless of their income level or the place where they live. We strive to play our maximum role in addressing health care problems in developing countries, and we do so in an innovative, responsible

and sustainable way. We also consult with the global HIV community to ensure that our strategy is aligned with the global response to the HIV epidemic, UNAIDS goals and sustainable development goals.

Our policy on access to treatment includes:

1) Development and registration of innovative medicines: we collect data on the use of our medicines in real-life practice, adherence, effectiveness, the information that complements the data obtained in clinical studies; we conduct research and development in the treatment and prevention of HIV infection, including the Treatment as Prevention strategy, pre- and post-exposure prophylaxis (PrEP and PEP), and behavioral strategies; development of optimal pediatric forms. We also cooperate with researchers in the context of working with groups that are underrepresented or receive little attention (women, children, people over 50; people with high viral loads, people with drug resistance, etc.). In the area of registration, we have a strategy according to which we register those medicines for which there is a clinical need. When registering, we assess the clinical profile of each medicine, the problems in each country, the burden of the epidemic, and the country's economic status.

2) Patents and Licenses: We believe that intellectual property (IP) drives investment in research and development which in turn drives new and improved medicines. We believe that improving access to ARV drugs and PrEP in developing countries requires a flexible and comprehensive approach to IP protection. In 2016, we changed our approach to how we protect our IP based on the economic status of a country, that is, we will not apply for patents in the least developed countries and low-income countries. For lower middle-income countries, we will protect our patents where necessary and appropriate.

   In cases where voluntary licenses (VLs) contribute to price reduction and improve access in developing countries, the company will provide them. VLs allow supplying generic versions of medicines to countries that otherwise would not be able to access generics. This, in turn, allows for lower prices and has a major impact on the fight against the HIV epidemic. However, there are cases where VL is not a suitable option. This applies to innovative medicines the production of which may require specific equipment and special training of specialists. Secondly, some medicines may not be included in the recommendations of international organizations and may not be a priority for the country since their clinical role is not yet clear.

   The company's main criteria for inclusion in the VL are as follows: all licenses of the company for drugs for the treatment of adults include all the least developed countries, all countries with lower middle income and sub-Saharan Africa (as classified by the World Bank). All pediatric licenses include all of the above countries and some upper middle income countries (as of the time of license signing). If the status of a country changes to a higher one, that country is not excluded from the license. Licensees can supply their medicines to the countries outside the VL territory if there is no patent in such countries.

   Our VLs provide for royalties for adult forms of medicines in some lower middle-income countries, depending on the country. None of the VLs for pediatric forms stipulates for royalty payments.

   VLs for both adult and pediatric forms allow the development of combination drugs which are regimens that are included either in the WHO recommendations, or the US recommendations. Also VLs for medications for pediatric use allow the development of forms with reduced dosages or the development of more suitable forms. In addition, we allow to use our data for registration (that is, we do not apply the clause on the exclusivity of the registration dossier data, that is, we use a waiver).

Currently, countries that together are home to 94% of adults and 99%[1] of children living with HIV in low- and middle-income countries, are covered by ViiV Healthcare's voluntary licenses. In cases where VL fails to meet the goals of expanding access to treatment, we consider alternative mechanisms and different partnerships to ensure access based on clinical need.

3) Flexible pricing and local production: we try to find a balance between access to medicines for PLHIV and the need to invest in research and development of new medicines. ViiV Healthcare does not expect to profit from sales of its marketed products to public HIV programmes and international donor agency programmes in all LICs, LDCs, and SSA countries, that is, the countries with the highest barriers to access to treatment and where medicines should be supplied at the lowest prices. In middle income countries, we are engaged in dialogue with governments in order to determine the optimal approach to pricing and take into account such factors as gross national product, drug demand, epidemic level, etc. We are also actively working on the production localization, for example, in Russia. This approach allows reducing production costs and lower prices, invest in the local economy, and share our expertise.

4) Strengthening capabilities of health care systems and communities: we work in the field of clinical trials, strengthening capabilities in the field of manufacturing, health care systems and strengthening of community capabilities. We work with scientific organizations to develop optimal treatment options for different population groups. In terms of capabilities strengthening in the field of manufacturing, we are in a strategic partnership with generic manufacturers and international agencies such as UNITAID and the Clinton Initiative (CHAI); our partnership, among other things, stipulates for technology transfer and support where needed. We also support such initiatives as Fast-Track cities. An example of work in the field of community capabilities strengthening is our Positive Action initiative.

The last slide deals with the development of pediatric ARV drugs. There are many complexities in this field such as low volumes, complex forms, taste issues, solubility issues, clinical studies, etc.

Question: We look forward to hearing from you on the inclusion of Belarus, Kazakhstan and Azerbaijan in the dolutegravir license which you spoke about at the last ECAT meeting and AIDS 2020 conference, can you share news on this issue?

Answer: We are now very actively working with the Medicines Patent Pool (MPP) on the finalization of the new agreement on dolutegravir, and I hope that shortly we will be able to formally share something with you. As far as I know, you met with the MPP last week and they gave you roughly the same information.

Question: Is there any clarity on the timing of when this agreement will be signed?

Answer: We quite well advanced in the negotiations, and I hope that we will be able to share something by the end of this year.

Question: Which generic companies from Kazakhstan are planned to be included in this license?

Answer: At the moment I cannot say; it will be the standard MPP procedure; it will be carried out upon the agreement signing. These will be expressions of interest. Potential licensees will be limited to the licensees in our existing agreements, but this will be the procedure that the Patent Pool will handle.

Question: What are the additional conditions and characteristics of the new agreement (royalties, antidiversion measures, etc.) compared to the existing agreement?

Answer: As for the price and royalty rate, I cannot say anything specific at the moment, I can say the following - we adhere to the approach that upper middle income countries should pay more than the

least developed countries and low income and lower middle income countries. Upper middle-income countries will be allowed a discount on the price they are currently paying, but it still will be higher than price paid by countries who are currently eligible for voluntary licenses. As far as antidiversion measures are concerned, I don't think this will be an issue in the current license. The purpose of this license is to ensure that countries receive the amount of medicines they need and that these medicines do not end up in other countries.

Question: What will be the price for upper middle-income countries and will it be above USD 50 per package?

Answer: I cannot comment on the price issues, partly because of the competition law, partly because it is the prerogative of generic manufacturers, and I do not know what prices they will establish. These are the questions to the Patent Pool. The license includes a tailored royalty approach. As access to DTG-based medicines increases in each country the royalty will decrease, enabling the generic licensees to further reduce the price to governments.

Question: A clarifying question - if the economic situation in the country worsens, for example, like the current situation in Belarus, and the price level falls, will this country be included in the company's regular license?

Answer: Yes.

Question: Your negotiations have been going on for over two years. Such processes usually go much faster in other companies. It feels like you are deliberately dragging on this process in order to get maximum profit. Could you comment on why the process is taking so long?

Answer: The main reason is that this agreement is innovative, and whenever you are trying something new it takes time to develop a solution. This is the first license specifically designed for Upper Middle-Income Countries. This has not yet been available in the field of tuberculosis, HIV, or vaccines. It is important that we have been designing a license where the company had already been on the market. We strive to balance our business interests with the need to invest in new drug development, and access. Nobody likes that the process is taking so long, but we have been working hard to come up with an innovative solution that meets the needs of all stakeholders.

Comment from Kazakhstan: Kazakhstan expects you to include it in the dolutegravir voluntary license. If the price is higher than USD 50, the community will insist on issuing a compulsory license.

Question: Will the new VL cover pediatric dolutegravir? Is there currently an opportunity for Belarus to purchase generics of pediatric dolutegravir?

Answer: We will add Belarus to our existing voluntary license territory for pediatric formulations of dolutegravir; we will do this immediately upon finalization of this new agreement for adult DTG in specific UMICs. I think it will not take long, as the example of adding Algeria to the existing DTG voluntary license has shown, following its reclassification in July 2020 as a lower middle-income country by the World Bank, it was a matter of several weeks.

Comment of the company: It is worth noting that as of today there are no approved generic forms of pediatric[1] dolutegravir (dispersible tablets in a dosage of 10 mg) on the market, but two dossiers are currently under consideration by the FDA, and we hope that they will be approved soon.

[1] Please note that since the call, Mylan (now part of Viatris Inc.) received tentative FDA approval on 23 Nov 2020 for their 10 mg dispersible tablet formulation of DTG: https://www.prnewswire.com/news-releases/viatris-inc-announces-fda-tentative-approval-of-a-pediatric-formulation-of-dolutegravir-dtg-under-pepfar-301179208.html; Macleods' 10mg DT formulation of DTG is still under review by the FDA.

Question: Dolutegravir in Russia: can you provide specific information on the price/volume ratio? Considering that purchases of dolutegravir in Russia have already significantly increased, what price are you ready to offer?

Answer: GSK takes into account the growing demand for dolutegravir in Russia and takes a proactive position in negotiations with the Russian Ministry of Health, and we hope that this dialogue will continue.

Comment of the representative from GSK Russia: Thank you for this question, it is very important for us. This year GSK Russia has continued its efforts to expand the availability of dolutegravir in Russia, and this year dolutegravir was supplied at a price 27% lower than previous year (2019). With regard to the next year purchases, in July this year we sent a letter to the government, the Ministry of Health and the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) confirming our readiness to further reduce the price for state procurement. We cannot announce specific price/volume details, this is a part of the negotiation process between the company and the RF Ministry of Health.

Question: In negotiations with pharmaceutical companies, we are constantly encountering a vicious circle: pharmaceutical companies are expecting a confirmed purchase volume from the state, the state is always expecting a price reduction to confirm the volume. Can you make the first move and lower the price to give us a tool to negotiate with the government on expanding the number of people on treatment?

Answer: We do not wait for the Ministry of Health to contact us with a request. ViiV Healthcare and GSK Russia were the first to make the first move and sent a quotation at a reduced price for dolutegravir.

Question: Do you know that a new purchasing agency is currently being created in Russia which will deal with the medicines procurement from the next year. Were any negotiations held with you? Are you ready for such innovations?

Answer: Yes, we know about the creation of a special organization, we understand that the Ministry of Health is now preparing regulatory documents that will determine the work of this organization. This has been discussed for a long time, so we are ready for it. As for the potential interruptions, as you know, GSK Russia operates without distributors, and we directly manage in the supply of our ARV drugs. Practice has shown that this is a very effective way to ensure both the timeliness and accuracy of drug supply, promptly respond to requests from the regions, as well as anticipate and avoid the risk of interruptions.

Question: Do you have any data on the timing of registration of the prolonged-release cabotegravir/rilpivirine combination in the EU and EECA region, are you considering a voluntary license and do you have any estimates on the potential cost of this combination?

Answer: We are at a very early stage, and it is worth noting that this combination has not yet been approved in either the EU, or the United States, it is registered in Canada only, so it is too early to talk about anything specific. As for the VL, in this case we cannot yet say whether a VL is a suitable option for expanding access to this medicine, since special conditions are required for the production, and the market size is also not yet clear.

Question: How much does dolutegravir cost in Russia now?

Answer: In 2020, the company supplied dolutegravir at a price of 7,140 rubles per package, including VAT.

Question: Are there any new data on fostemsavir?

Answer: We talked with the MPP for a long time about the VL to expand access to this medicine. We considered the manufacturing capabilities, the place it can take in the WHO recommendations, etc., the potential indications for use. We made a conclusion that, given the specificity of the medicine, a VL would not be the optimal strategy for access expanding. It is a difficult medicine to manufacture which requires a separate line and is needed by a very limited number of patients. We will look for other ways to expand access to this medicine.

Question: Many companies say that they have had problems with the supply of ARV drugs or active pharmaceutical ingredients from India and China due to restrictions related to Covid-19, inter alia to the EECA countries. Could you tell us please whether you had such problems, how challenging they were, and do you anticipate such problems in the future?

Answer: We have not had any supply problems due to Covid-19.

Question: New rules for medicines registration under the procedures of the Eurasian Economic Union will enter into force from 2021. Are you ready for this innovation, are there any difficulties expected?

Answer: Yes, our regulatory group has confirmed that this is a new system and therefore some challenges may occur. Not all requirements are clear, and it seems that we must first submit the dossier, and then we will be able to ask questions. Initially, it is not completely clear what requirements must be met. In addition, there may be delays with the regulatory inspections of our manufacturing sites due to the Covid-19 restrictions. In terms of possible solutions, this should be a two-way process of interaction between the industry and the regulators, some kind of forum where questions can be asked and answered at an early stage, and the possibility of conducting virtual inspections would be very useful in connection with the restrictions imposed by Covid-19.

Question: Are there any updates on the use of cabotegravir for PrEP and a potential agreement on this drug for PrEP?

Answer: We are extremely pleased with the data that we received, we received them much earlier than we had expected, and we are now trying to determine how best to make the drug available. We have not yet discussed with the MPP the possibility of a VL in connection with the use of cabotegravir for PrEP. There are two studies, one involving men who have sex with men and transgender women, but just last week new study results for women were obtained. These are very recent data of clinical trials, and we are analyzing them; we have not yet submitted a dossier for registration either in the EU or in the USA. Access issues will be resolved after we can prepare the registration dossier for the medicine, but we are not even at this stage yet. We hope we can tell more next time.

End of the meeting.