Meeting minutes

EECA CAB and Gilead Sciences, Inc.

22 November 2016, Kiev, Ukraine

The Meeting participants:

Gilead Sciences, Inc.:

- Dr. Michael Mertens, Associate Director, Medical Affairs, Hepatitis C (Europe, Asia and Middle East), Gilead Sciences.
- Felipe Rogatto, Associate Director, Medical Affairs, HIV (Europe, Asia and Middle East), Gilead Sciences.
- Arran Attridge, Associate Director, Public Affairs - Europe, Middle East & Australia, Gilead Sciences.
- Stephen Head, Associate Director Public Affairs International, Gilead Sciences.

EECA CAB:

№	Participant	Organization	Country
1	Igor Chilchevskiy	League of people living with HIV in the Republic of Moldova	Moldova
2	Nofel Sharifov	Public Organization Against AIDS	Azerbaijan
3	Aibar Sultangaziev	Harm reduction programs association "Partner Network"	Kyrgyzstan
4	Igor Pchelin	"Shagi" (Steps) Foundation	Russia
5	Kiromiddin Gulov	NGO "RAVNYYE VOZMOZHNOSTI" (Equal Opportunities)	Tajikistan
6	Paata Sabelashvili	Free consultant, expert	Georgia
7	Sergey Birukov	NGO AGEP'C(ANTIHEPATITIS'C)	Kazakhstan
8	Aleksandr Ladonkin	KROO "Status Plus"	Russia
9	Alexei Mikhailov	ITPCru	Russia
10	Kanat Alseitov	Parents Community	Kazakhstan
11	Samarin Vyacheslav	Positive Movement	Belarus
12	Anatoly Leshenok	Community of People Living with HIV	Belarus
13	Vladimir Zhovtiak	East Europe and Central Asia Union of People Living with HIV	Ukraine
14	Vladimir Mayanovskiy	All-Russian Network of People Living with HIV	Russia
15	Konstantin Fegjajev	Estonian Network of PLWH	Estonia
16	Konstantin Lezhentsev	ECUO	Ukraine
17	Anahit Harutyunyan	"Positive People Armenian Network" Soc. NGO	Armenia

Facilitator – ECUO

Start of the meeting. Introducing participants

HIV

Gilead Sciences: We'll try to answer the questions you've sent to us and will follow them through discussion. We don't have a formal presentation on HIV, so if there are specific questions about clinical data, Felipe will help us with them. I just say we can answer to certain issues we know, but some questions could be not answered yet. Also, as you know there are small access program related changes in the countries classification in your region. The latest news is that Ukraine, Moldova, Georgia and Armenia joined our access program and it happened in the last two or three months.

Question: Now the entire market of drugs and mechanisms allowing drugs to all EurAsEC countries is forming. Will Gilead Sciences protest, if the drugs from Kyrgyzstan are used in other EurAsEC countries?

Answer: Well, we certainly want our products which have been registered in the country to continue to be used.

Question: There is a prioritization of the domestic producers in the Republic of Belarus now. What are the plans for the domestic production development in the Republic of Belarus?

Answer: Yes, we know that there is a prioritization of domestic producers now, but unfortunately we don't have any plans on domestic production development in the Republic of Belarus yet. Nevertheless, we believe that our pricing policy makes us competitive in terms of your domestic production.

Question: What pricing policy do you have in the Republic of Belarus?

Answer: In general, our pricing policy is based on tiered pricing and includes a number of factors including the political will of the government to implement treatment programs, as well as on the epidemic level. All these factors together help us actually make our strategy regarding drugs price in certain country. As you can understand, such policy is flexible enough, i.e. it changes over time, and we continuously monitor these factors. The Gross National Income (GNI) per capita is another important factor. For example, I remember I visited EECA CAB a few years ago and Armenia representatives were talking about importance of GNI per capita. And now you can see the result – Armenia is in the list of countries that have joined our access initiative.

Question: Question about Moldova. Please, could you tell us a little more about the access program? As far as I know, in Moldova you have filed an application for a license and thereby blocked all the rest, and now I hear there is some access program…

Answer: The most important thing we do is observing three basic motivating factors in each country - the political will of government, the disease prevalence, and the access to treatment. According to these factors, we estimate the GNI per capita. So, after analyzing all these factors and first assessed government's ability to purchase in comparison with the prices offered by us we adjust our pricing policy. we are constantly reevaluating these factors and adjusting our pricing policy. There are about 134 countries participating our access program and we will talk more about it further.

Question: Question from Republic of Belarus. We have 200 children who need tablet formulations. Will you register a drug? Can you see your participation here?

Answer: If you are talking about pediatric formulations, we have two pediatric medicines licensed and both are not tablet. If we are talking about the TAF, we can see a wider range of formulations, and there will be a tablet formulation.

Question: One more question from the Republic of Belarus. The stumbling block is an assessment of the World Bank's GDP, right? But it is not so clear where this estimate comes from. Our accounting system is inherited from the USSR – we haven't changed and accepted the European accounting system. Our GDP is considered as produced products, i.e. there are many nuances. Can you make your assessment basing on other criteria? The fact is that living in our country; we rate our standard of living as lower than in countries close to us in World Bank ranking.

Answer: Yes, it's always associated with certain challenges and obstacles. Using the classification of the World Bank with the lack of a single universal mechanism acceptable to all countries is the real problem for us. And the same thing with the World Bank classification shortcomings we were discussing with your colleagues from Armenia at the last meeting. I am pleased to inform our organization about the problem that you highlighted in your country, and I am sure that many companies are also using the World Bank classification for pricing policy.

Question: There was information that you open some clinical trials program in Russia. Could you tell us more about this?

Answer: All of our clinical studies are concentrated in Russia and mainly concerned about women. We started the first phase of research related to Stribild HIV medication. And now the first part of the study is over, i.e. it has roled over into another phase – women continue on Genvoya. It's expected that the research participants will move to the new tablet formulation – medication one time per day. Also there will be a new formation of Tenofovir Alafenamide (TAF) called B/F/TAF. It is a non-boosted integrase inhibitor. Boosted means strengthened. Everyone understands? Probably, it's the same study you were told about. We have a fairly open applications system for potential researchers.

Question: We are certainly glad that clinical trials issue ended. I know that there were problems with Epclusa, fermented Proteravir. The question is when these drugs will appear on the market of Russia? If in the future such situations appear in Russian, please, inform us as patient organizations, so we also could take some action.

Answer: Thank you very much for your suggestion; we will certainly make use of them. What about marketing of our products, which were tested in clinical trials, we understand that we want to move to TAF-based regimens. Therefore, we have decided not to submit the dossier for Stribild on Tenofovir registration and go right directly to the TAF, i.e. apply for Tenofovir Alafenamide. And this is what women actually received in the clinical trials we mentioned earlier. Actually, Genvoya registration dossier for Russia is ready. And in 2017 the filing and registration process will be started. There are still a number of countries in the line for registration, and we really want to prioritize the TAF-regimens compared to Tenofovir-regimens, i.e. the regimens used with Tenofovir should move to TAF.

The latest update about Elvitegravir. In November we removed the product from the market because over the past three years we haven't seen any individuals using this drug. As you can understand , Elvitegravir is a part of Stribild and Genvoya tablets. But no one uses it as a single agent. Only in combination. According to the increasing access to new and improved drugs, including single tablet preparations, we have decided to remove an Elvitegravir as a single agent from the market due to lack of demand.

So, let's get back to the women and clinical trials, and I'll quickly provide some updates. So, as a part of the ARV conference in Glasgow we met with ECAB, actually, with a group of women, ECAB females. And we are interested in the initiative, which emerged during the discussion, meaning to bring together a group of female clinicians and female patients. And they will become the special core that will promote the women gender related aspects of clinical trials. Under this programme we are also considering a special section of the STEP-UP training module.

Question: Another question. Should we wait reduced price for original Tenofovir or Tenofovir Truvada, if Tenofovir slowly comes to price reduction?

Answer: Yes.

Question: One more question. Specifically in Russia we buy what is basically cheaper. No matter, what quality a complex medication is, if it's more expensive, it fails. In my opinion, you as businesses will lose the market in Russia. For the next year at least 250-300 thousand will take therapy, it's for sure.

Answer: We have such challenges everywhere, including Western Europe, where the relevant commissioners misunderstand the importance and benefits of single tablet regimens compared to the usual separated standard. And it's our task to correctly represent the value and uniqueness which is a single tablet regimen for patients. And we will continue this process, in Russia as well. In the first quarter of the 2017 Atripla will be purchased in Russia.

Question: Please, provide us quite clear and understandable explanation why this is more expensive. We understand the benefits, but why more expensive? – Is it a matter of research, technology, or patents question? Why more expensive? And this is important. When there was a transition from Kaletra on a stable tablet, the reason was clearly understood. And the benefits were clear, and why it should be more expensive. But here, if you don't have a clear vision, why so?

Answer: There are common things related to the benefits of single tablet regimens in this case. And things that we see and observe each time leads to cost savings. Single tablet regimens have been shown to increase adherence, hence, it's an effective therapy; we have also seen for those on a singlet tabelet regime that hospitalization reducies, In addtioin, the patients are satisfied with such a friendly regime. We have the evidence base, so we can show that savings can be made in the end. I think that this is a common problem. State government, basically, doesn't look ahead on the potential savings; officials can see specific fact - the cost of "here and now" – instead. And this is the challenge of wrong economic approach. Such approach we face in Europe as well. And our task is to provide them with the data to support the additional value of single tablet regimens and related cost savings. .

Question: What is the pricing policy in Kazakhstan on procurement through UNICEF?

Answer: So we're discussing prices with UNICEF now, i.e., these negotiations are taking place. I can't say exactly what price we've met. This is confidential information. But yes, we've had negotiations with UNICEF on purchases for Kazakhstan.

Question: Last year we've met this time, and I personally asked you the Kazakhstan representatives' contacts, unfortunately I couldn't have a dialogue with them, so there were no contacts. As you know, for children and adolescents we purchase original ARVs in Kazakhstan. I have the procurement data for 2017: Abbott - Lopinavir/Ritonavir $1.5 per day, Viive - Combivir $1.5 per day, Gilead Sciences - Truvada for Kazakhstan $2.6 per day. And we can see that auction didn't take place. What's the reason?

Answer: I don't work in the region, so I don't have such good information. About the contacts in Kazakhstan, we are working with distributors, we don't have an office. This is an exclusive distributor. Kazakhstan is under the supervision of our company's Russian office. I am pleased to give you contacts.

Comment: I would like to comment my question: after the direct negotiations with ViiV and Abbott conducted in Kazakhstan, these companies reduced distributors' appetites for 300%. We've got quarter prices. In your case, unfortunately, it didn't work. And we can add that you are thrown from all the countries' markets, for example, Ukraine.

Question: Stephen, well unfortunately you understand that Russian office refuses to work with Kazakhstan?

Answer: We have an obligation to Kazakhstan. Kazakhstan is managed by the Russian office. And I will deal with this situation and let you know.

Comment: Let me comment a little on the Russian office. Often we can't get information even about Russia from the Russian office. In general, they almost don't answer our letters. Information about your clinical trials we learn not from Gilead, but from the officials. Yes, it's a huge request to give them a magic kick so that they will work.

Answer: I understand that this is a problem. We will solve it. Arran and I work directly with the patient groups. And, unfortunately, there are no workers with such classifications in Russia. But in the next year we will recruit a similar position in the EECA region.

Question: In Kazakhstan, for the 2016 the government purchases for Atripla are 100 000 tablets, $8 per pill, and we don't see your products.

Answer: I will highlight these issues on Kazakhstan and on Russia as well. These pricing policy issues will be considered separately for each.

Question: Do you plan an extension of your Patent Pool license for Ukraine?

Answer: We don't work with a Patent Pool in Ukraine, because we've included Ukraine to our access campaign.

Question: It seems that we shouldn't wait TAF. When will we get it?

Answer: Well, the same process we have in Western Europe as well. In 2017 we are planning to introduce TAF into the region. In Italy it will appear at the same time, i.e., TAF is not there yet. But with every new drug we develop and marketwe learn and become more more responsive to the changing needs in the region.

Question: Returning to the Truvada and Atripla in Russia, Atripla will be provided next year. Is the price for it already known? There is an issue that your products are not included to the list of vital drugs, hence, we won't see your products until 2018. And even then, we can get them only if you are in the list.

Answer: We continue to submit the dossier for Truvada inclusion to Essential Medicinies list. And we applied last year but were refused. Could you do something on this issue? We would be grateful if you can help us in this matter.

Comment: Sure, we'll help.

Hepatitis

Arran Attridge:

Hello everyone. For those who don't know me, my name is Arran Attridge. I've met some of you before, but not everyone. Thank you for invitation to this meeting. We've looked through all questions you sent us. And we divided them for two groups: 1) political advocacy issues on access and 2) clinical questions. Of course, access issues more than clinical information will became a basis for our discussion. But we start with clinical information and Michael will answer the questions.

Dr. Michael Mertens:

Thanks for invitation. I will go through your questions. If you want to ask something in the process, please, raise your hand. So, the first question, is what new products we investigate for Hepatitis C treatment. And the next question is on clinical studies for these and other products, and what we can expect in the near future. Let's start with four products we have developed for Hepatitis C treatment. You have heard about Harvoni and Sovaldi, so we have Sovaldi licensed in 72 countries and Harvoni in 55 countries. Epclusa is a brand new drug that just recently FDA approved. And at the AASLD conference that took place in Boston we have presented our new three-drug combination of Voxilaprevir, Velpatasvir, and Sofosbuvir.

Why do we have four clinical development programs? Our goal is simplify treatment that can benefit the majority of patients. And in general, our ultimate goal is HCV elimination, i.e. the complete destruction of Hepatitis C virus.

Let me give you a clinical update of our programs. Let's start with the second wave – it's Harvoni (LDV/SOF). According to our Phase 3 studies, up to 94-99% of the patients were cured.

At AASLD a study was presented that examined Harvoni worked in Russian and Estonian patients with HCV and HIV/HCV. As you can see, the Russians and Estonians, achieved comparable SVR rates as seen in the IION-3 program.

And then there was a series of studies that was presented at AASLD in different patient groups. I will quickly go through a meta-analysis - a comprehensive analysis among previously untreated patients without cirrhosis. It's important to note that here we present data collected among the groups of patients usually not included in the clinical trials program: patients over 65, co-infectied patients, people of different races, and people at different fibrosis stages These patients are very often underrepresented in Phase 3 studies.

But in above mentioned groups patients achieved the same result – 99% were cured. There was no difference in mono-infected and co-infected patients or patients on opiate substitution therapy.

A different analysis has shown the impact of DAA therapy on an American liver transplant list. The overall number of patients listed due to HCV decreased after the introduction of DAA's. There was a sharp reduction of patients listed due to decompensated liver disease and a slight reduction in HCC as reason for transplant listing was observed.

Our data set in cirrhotic patients implies that virological responses (cure) is associated with a decreased likelihood to progress and develop decompensated disease. A substantial amount of patients improved their liver function.

Another study showed that comparable cure rates can be achieved if care is delivered by non-specialist (GPs and Nurse Practitioners).

What about Epclusa, we've been testing it among genotypes 1-6. The results: 98% cure rate, regardless of cirrhotic patients or not cirrhotic, treatment naïve or treatment experienced patients.

Question: And this is one pill during twelve weeks?

Answer: Yes.

GILEAD Sciences Presentation:

Let's move to women regarding the clinical studies with a gender component. We have seriously embraced your question and have separated our patients by gender and genotype. Women are as responsive to treatment as men. Nevertheless, we continue to deal with the specific women issues; and now we have an opened application call for conducting clinical trials directly among women on the virus behavior specifics and treatment.

Question: Where can we see the application call?

Answer: You need to go on our website and choose the HIV direction. It always contains ads on applications submission, starting from individual doctors to research institutes, for conducting clinical trials.

GILEAD Sciences Presentation:

The fourth wave, three-in-one (Voxilaprevir, Velpatasvir, and Sofosbuvir) tries to address the question how to retreat patients that initially failed a DAA. Those 2% who have not responded to DAA's, and were not cured. We have added to Epclusa (Sofosbuvir/Velpatasvir) apangenotypic Protease Inhibitor - Voxilaprevir.

Now we'll compare two groups that were investigated in the clinical program: the group of patient that were failed DAA's but have not been cured and the group of patients who were DAA naive. We wanted to test if we can retreat DAA failures for 12 weeks or can cure DAA naïve patients in 8 weeks. The studies achieved high SVR rates in both treatment groups, but the company will focus on DAA failure patients.

We conducted Sofosbuvir studies among adolescents and children. Data was presented for adolescent age 12-18. 97% achieved a cure.

Question: Are there pediatric forms for children under five years old?

Answer: We have presented the analysis of pharmacokinetics and pharmacodynamics, i.e. drug behavior the in the body of children from 6 to 12 years. We reduced the dosage of both SOF and ledipasvir by 50% to minimize potential toxicity for kids. And according to our preliminary data, this drug is well behaved. Very soon we'll be ready to present efficacy data for this patient population.

Question: Is it ok to break the pill in two and give?

Answer: There will be a dedicated formulation for patients that require half dose SOF and ledipasvir.

GILEAD Sciences Presentation:

You had a number of questions about access and we've prepared answers to them - let's get started. I am ready to answer the political and advocacy questions. So, I divided them into three groups. The first - pricing policy and access & registration updates in EECA, the second - access to generics, the third –national hepatitis C elimination programs. We can go through countries or address issues individually. Well, let's go to the first part, pricing and access to the drug. As I said before, we are expanding our access country by country. Like HIV the basic criteria and factors when reaching access agreemnents are disease prevalence,

the country economic indicators and the government's commitment, the will of the government, to tackle HCV. The third component - this commitment, the announced government will and confirmation – is the key one. It significantly informs our strategy regarding pricing and access for countries.

Question: I really don't understand what you're saying now. That's something I'm really listening to and I have a feeling that I don't communicate with you, but the first time met. When we last met, I told you clearly - let's work together and you agreed. I promised you that supervise the Hervoni registration process in Kazakhstan and I've done it. I promised you that hepatitis C elimination program in Kazakhstan will take place. Right before I arrived here, I've got a message informing that such a program established. I have repeatedly offered, to you as well, to participate in the development of this program that conducts at least some consultation meetings. Unfortunately, it did not happen. I don't understand, the Ministry of Health today is willing to work with you, but you don't come. Mr. Rukavishnikov doesn't want to work with Kazakhstan and Russia as we see now. We need to understand whose this policy – Rukavishnikov's or Gilead's.

Answer: So, we have already understood and accepted that there are problems in work with the regional office. In particular, with such countries as Russia and Kazakhstan. It's clear. As already mentioned, Stephen and I do not work in the region. But regional level interaction is the duty of our office there, and we plan to improve it.

Question: Today Harvoni is registered in Kazakhstan, so there is a question about the price. The thing is that we lost the whole year for the national program creation, because you didn't take part in it. And now we can't see any price offer from you. What I want to say is that today the drug is purchased in frames of the free medical care guaranteed volume, i.e., this is guaranteed state payment for the drug. So now I propose to strengthen this process in Kazakhstan, in so far as the program has already been created, and you can join it.

Answer: As Stephen said – after arrival we'll immediately contact the Russian office and come back to you with suggestions on further actions.

GILEAD Sciences Presentation:

Now we move on to access agreements. But I want to lead all this with common language. I grouped all countries by registration submission, approval and access agreements in place.

In addition we have license agreements with authrorised generic companies to make those available in countries with a high burden of disease and low economic status.

In some countries treatment is only available on an individual patient basis. For individual use – Georgia, Moldova, Armenia. Moldova and Armenia are in our access program. That is, we already have a new team, which is in its portfolio got these two countries, and then there is also Ukraine.

Question: What's the price?

Answer: There is no fixed price.. Now I'll briefly describe how patients access treatment on an individual patient basis. A doctor in the country tells the patient that the drug is needed, there are no other options available and the doctor writes an application directly to Gilead. Each request from a doctor is evaluated on the following criteria: no access to drugs in the country, the patient's vital condition requires immediate attention and there is no other option for the patient.

Question: Can you tell us about what companies are licensed to produce generic sofosbuvir? I remember exactly that it's Mylan and Hetero. What else?

Answer: 11 companies have received the technology transfer from Gilead to produce Sovaldi, Harvoni and Epclusa..

GILEAD Sciences Presentation:

So, briefly on what is an access program and how it works. One of its benefits is a significant brand price reduction. And it's based on all the things Stephen said before, i.e. the burden of disease and the economic status of a country. As part of the access program we also look at existing programs aimed at screening for vulnerable populations and/or the possibility to launch them. We look very broadly at our potential partners in different countries. We use the option of drugs delivery and treatment access in frames of clinical trials in one of the Quick Access features. We have a special team that deals with Hepatitis C related access development. And now 101 countries classified as poor countries have access to generic. As I said, we have partner license agreement with eleven Indian producers.

All of these companies have got from us a complete technology package (technology transfer, how to produce drugs) on three drugs – Sovaldi, Harvoni and Epclusa. Thus Sovaldi: dossiers are processing in the selected developing countries; confirmed and is in the certification register in the following countries: Egypt, India, Mongolia, Pakistan, Brazil, Dominican Republic, Rwanda, Chile, Thailand, the Philippines, Bolivia, El Salvador, Argentina, Mexico and 13 more countries plus Ukraine. Harvoni confirmed in Mongolia, Rwanda, Egypt, Ethiopia, Mexico; more than 200 thousand patients have received treatment with a Gilead HCV based therapy, in the developing countries - 145 thousand plus patients treated in Egypt under the state program, that is, more than one million. 53 thousand in Pakistan and 10 thousand in other developing countries. Well, as I said, Armenia, Georgia, Moldova and Ukraine have recently joined our access program, and they will be able to get products for differentiated price.

Question: What's the price for Moldova?

Answer: The price is not set yet, but Moldova is included in the access list because we acknowledge that Moldova needs the specific lowest price.

Question: This is just a question to clarify the situation. In Tajikistan we don't have these drugs for Hepatitis C treatment. Even if there is, it costs about $1500 for generic and from India we can order the same drug for $ 800. Generic for fifteen hundreds is too expensive. And I thought that Gilead's products registration could be the upper bound. And such bound, in general, is lower than fifteen hundreds. This situation is so strange for me.

Answer: We need to register our products, our branded products in your country, and to set a price ceiling. Yes, our prices through the access program are likely to much less than $1500 but this will be determined on a country basis.

Question: I am from Kyrgyzstan. We have five types of generic Sofosbuvir registered and the average price is $250 per jar. Selling price from India factories is around $150. If you register and put a control price of $150 at the pharmacies, we will be very happy.

Answer: Thanks. We will keep it in mind.

Question: Pata's question was, remember, we talked about a very strict approach to the prevention of drug export with the special price for HCV medicine in Georgia. The main problem that Pata expresses whether

Gilead somehow weaken or even remove these very strict guidance on drugs monitoring program management, i.e. opening the bottle in front of camera, returning bottles etc. All this is and will be a major obstacle for the participation of patients, especially from marginalized groups, drug users. Pata assures that as long as the program exists in general there were no particular attempts of violations.

Answer: Yes, right. And this is extremely important because if we want to achieve the infection elimination we should build the treatment program to treat all patient types. I understand in harm reduction services, where people come confidentially, and above mentioned measures require the box opening and taking of the first tablet in front of camera .

As you rightly said, we pay very much attention to political and social issues. But as we know the stigmatization of people living with the virus occurs even in the presence of medicines, that is, access to drugs doesn't solve the problem. Data shows that treatment of people who inject drugs works not only for the individual patient, but also gives significant benefits on a social level, at the community level - this is a very powerful factor. Clinical data is a very powerful factor in tackling stigmatization at a policy level..

Comment: My comment is on behalf of the CAB. I think that they have the right policies for patients switching to replacement therapy active consumers and obtaining evidence base - is a powerful factor, but I am extremely sorry because not enough attention is paid to the dissemination of this information.

Answer: I requested information on these strict measures of drug anti-diversion measures and now I'll share you this information. No reform is expected at the moment. But your suggestion about treatment decentralization in low-threshold program, harm reduction program - this is a very interesting proposal. We look at opportunities of these programs studying and evaluation in a number of European countries. And, given the fact that Georgian program is a program of elimination, this is necessary for us to be anywhere, anytime, and so on, we'll specifically look at how it can be corrected to make it really accessible and low-threshold, and remove all existing barriers. We recently met with Georgian Minister of Health and I'll let you know what decisions are made. Regarding access to information and promotion of these findings on hepatitis C + drugs use among patients with tests, i.e. consumers, we work with ENPUD, and candidates from ENPUD attend western conferences, so they know this information, but it is necessary to talk with them about the access to these data, and I'll talk personally as well.

Question: I just wanted to clarify what means for Armenia to participate in this access program. When actually will drugs appear? Maybe we somehow find ourselves at what you are doing in Georgia? May we also have such version or still need to wait for this program when you register and when here will be generics?

Answer: You have the transition into a new group now. So, the first approach in Armenia is likely to be in brand at low prices.

Question: The Ministry informed us that they are already preparing a national project, but we hear this during two years. There is no project yet. If you have a project, so we can officially say that Gilead's ready to do the same in our country as in Georgia, we can initiate processes and go to the Ministry to talk. That is, it should come not only from us, but from you as well. I mean, if you will come in 2018 it is needed to initiate processes now. Well, I want to say that in Moldova a national program for the Hepatitis treatment was adopted earlier this year (with new drug – a pegylated interferon that is more expensive than your preparations). And since last year, funds for a thousand people have been laid in the national budget. Of course, Moldova is a small country, but we have fifty thousand of your potential customers. If you could interact a little bit more, then it would be great. You don't have representation, you don't even have people to work as distributors, but we are ready to work with you even free, give you information. We've

told about this many times, so we are in all working groups on hepatitis, tuberculosis and HIV treatment. Thank you.

Answer: Thank you. It's very important information. I will relay that back to the access team.

GILEAD Sciences Presentation:

In our program, originally licensed generics - licensed generics - are Sofosbuvir and Ledipasvir + Sofosbuvir, which should be available in Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan only. Hence, any licensed generic that appears outside of these countries, is unlicensed. We understand that there are a number of firms-distributors in your country that provide these unlicensed generics. From our side, I can say that we still have earned the right to protect our intellectual property. We want patients who get treatment that is available, get the quality of treatment as well, even from generics.

Comment: I would like to mention two points - in our country Egyptian products are registered – not licensed products. In our country we have an international exhaustion regime, so we rightfully can register unlicensed product, because it's registered and can be sold in Egypt. This is one moment. The second one is our neighbors, Kazakhstan and Russia. I haven't heard the whole companies were engaged in the distribution there. Perhaps this is most likely the initiative of people, who worth the matter of life. They transport medicines in their suitcases. They organize communities, and in fact they have already squeezed branded Gilead out of the market. And those few percent, that have lower response rate, as you said before, they are the price to pay for the difference in the price that you offer as a brand, but they also say that something affects the quality. Well, even one or two percent decline. Just if they did not have such an opportunity, they would all have died because they have no money to buy your brand.

Question: Question from Russia. No more than hundred thousand patients can by drugs paying for available brands required price. Some of them have no money at all, and had never had. But the largest number of patients able to buy use what distribution companies can offer. And of course we understand that it's an ethical aspect of people's lives, but from the other side, you as business representatives should understand that maybe it's better to lower the price and sell more?

Answer: We understand the issues that concern unlicensed generics widely appearing in the region. And people import them accumulating for personal use. And our goal is also to convince people they shouldn't do that, so there are options. And we are still confident that our access program is the best way to handle this. Yes, we would like it to be faster, but we're working as fast as we can.

Question: I have a question on Ukraine. I understand the whole situation. The question is whether Gilead plans to register Harvoni, if so, when and what the entering price will be?

Answer: The dossier is submitted, Sofosbuvir is already purchased in retail tenders. We have a project with the Alliance as well. But as Ukraine joined our access program we look at a broader solution for your country. And this is key task for our team.

End of the meeting