EECA CAB

Community Advisory Board
in Eastern Europe and Central Asia

Notes from the Meeting
with GILEAD SCIENCES

30 May 2013, St. Petersburg, Russian Federation

Participants:

From EECA CAB:

1. Vladimir Zhovtyak, East Europe and Central Asia Unoin of PLWH (ECUO), Ukraine
2. Olga Byelyayeva, ASTAU, Ukraine
3. Dmitriy Sherembey, Ukrainian Community Advisory Board (UCAB), Ukraine
4. Marina Chokheli, OSF, Georgia
5. Paata Sabelashvili, Georgian Harm Reduction Network
6. Anahit Harutyunyan, Positive People Armenian Network, Armenia
7. Sergey Biriukov, AGEP'C, Kazakhstan
8. Denis Maruha,, "CREDINTA", Moldova
9. Liudmila Trukhan, Positive movement, Belarus
10. Ehtiram Pashayev, Public Organization Against AIDS, Azerbaijan
11. Daiva Ausenaite, Informational strategy, Lithuania
12. Aleksandrs Molokovskis, Association HIV.LV, Latvia
13. Pulod Dzhamolov, SPIN plus, Tajikistan
14. Igor Pchelin, Russia, All-Russian Union of PLWH, Russia
15. Timur Abdullaev, Uzbekistan
16. Helina Gluškov, Estonian Network of PLWH, Estonia
17. Nataliia Sidorenko, E.V.A., Russia
18. Nataliia Egorova, E.V.A., Russia
19. Aleksandra Volgina, E.V.A., Russia
20. Grigoriy Vergus, ITPCru, Russia
21. Denis Godlevskiy, ITPCru, Russia
22. Andrey Skvortsov, Patients in control, Russia
23. Aleksandr Ezdakov, ITPCru, Russia
24. Julia Dragunova, ITPCru, Russia
25. Aleksey Mikhailov, ITPCru, Russia
26. Khan Tatyana, ITPCru, Ukraine

From Gilead:

1. Andrey Poliakov, Senior Medical Projects Manager, Gilead Sciences Russia

Facilitator: Sergey Golovin

Introduction of the participants.
Minute of silence in remembrance of those people who died awaiting access to treatment.

Presentation, Andrey Poliakov

We hope that other representatives of European HQ will be able to attend the autumn meeting. We will be able to review drugs and researches in this meeting.

Russian office has been opened recently. Current courses of the company in Russia are HIV and hepatitis.

The structure of the office: GM, Medical Director, Medical Manager, Marketing Manager, Finance Manager. For now not all the positions are occupied.

"DELTA MEDICAL" will provide storage, logistics and regional drug promotion. Russian office is currently working only for the Russian Federation, sometimes it's possible to solve issues from other countries. "DELTA MEDICAL" will provide drug availability in a number of countries presented at the meeting.

Drugs registered in Russian Federation: "TRUVADA" and "VIREAD".

HIV medicines portfolio

"Truvada"
License was obtained in September 2012, but mistakes were revealed there, later some problems occurred with a partner company; "Delta Medical" corrected the mistakes. As a result shipment of 1000 packings is expected at the end of July this year. In Russia request of including of the drug to the standards has been prepared and the file to include "Truvada" into the List of vitally necessary and important medicines has been submitted. In case it is included, the drug will be able to be purchased within the federal program.

"Stribild"
Russia is included into the international study of the phase 3 WAVES. The results of the study will be used for getting a registration certificate for the drug in Russia. The expected date of registration in RF – the second or the third quarter 2015.

In the USA and Europe "Stribild" is registered. In the nearest future it will be available in clinical practice.

The company has decided not to register "Atripla" in RF as it is better to switch to the medications of the next generation, which have a number of advantages in comparison with efavirenz that is a part of "Atripla".

Medicines review

"Eviplera" has been given for the promotion in Russia to Janssen. TAF (tenofovir alafenamide) – a new drug, improved tenofovir.

"Stribild": EVG/COBI/FTC/TDF (STRIBILD; STB)

GS-102, GS-103 researches – "Stribild"
Multicentral, randomized, blind, 192 weeks. Naïve patients, viral load is more than 5000, no restrictions to CD4 cell count.

As tenofovir (TDF) can affect kidneys, patients with kidney function disorder haven't been included.
Regimen comparison:

- EVG/COBI/FTC/TDF QD – EFV/FTC/TDF /QHS – "Atripla"
- EVG/COBI/FTC/TDF QD – ATV + RTV + FTC/TDF QD – boosted atazanavir

The main criterion is viral load reduction below detectable level (less than 50 copies).

"Stribild" and "Atripla" comparison
Efficacy: 48th week – 88% - "Stribild", 84% - "Atripla".
96th week - 84% - "Stribild", 82% - "Atripla".
Failure: 7% "Atripla" and "Stribild" on the 48th week, 6% "Stribild" and 8% "Atripla" on the 96th week.

Slight advantage is revealed to "Stribild", but there was no statistically significant difference in efficacy between the two medications.

Comparison of "Stribild" and boosted atazanavir regimen (ATV + RTV + FTC/TDF QD)

Efficacy:
48th week: 90% "Stribild", 84% boosted atazanavir regimen, 96th week: 83% "Stribild", 82% boosted atazanavir regimen.
Failure: 5% boosted atazanavir regimen and "Stribild" on the 48th week, 7% boosted atazanavir regimen and "Stribild" on the 96th week. Slight advantage has been demonstrated, statistically insignificant difference.

There is no difference in viral load, which means massive suppression of virus replication and high efficacy.

Comparison in CD4 cells - efficacy is the same, good growth of CD4. The average increase of CD4 cells till the 96th week is about 300 cells/mm3 of blood. Approximately if patient started therapy with CD4 count 100 mm3 – on the 96th week the increase is till 400 cells/mm3 of blood.
Adherence. Two groups – adherence below and above 95%. Decrease of regimen efficacy against the background of low adherence: efficacy 72% "Stribild", 63% "Atripla", 76% boosted atazanavir regimen. All the regimens have a quite good genetic barrier.

Q: You mean that with "Atripla" there is statistical difference and between "Stribild" regimen and boosted atazanavir regimen there is not?
A: No. In absolute figures we can see it, but we can't define it as statistically significant. Additional researches must be conducted. We can say that there is a tendency of boosted EVG regimens having higher genetic barrier than EFV ones.

Regimen safety
There was data on regimens containing EFV (regimen with efavirenz) and ATV (regimen with atazanavir), so EVG ("Stribilg") seemed the most interesting. Tolerability of all the regimens was good. As it was expected, side effects from CNS (sleep disorder, drop of concentration, etc.) were observed more often in the group getting efavirenz and hyperbilirubinemia was surely more frequently observed with patients getting boosted atazanavir regimen.

Serious adverse events on the 48th week: 10% in "Stribild" group, 7% "Atripla", 9% boosted atazanavir regimen. 96th week increase: +3% "Stribild", +3% "Atripla", +5% boosted atazanavir regimen. Several patients died during the study, but that wasn't connected to the investigational medication.

Q: What was it connected with?
A: A patient getting "Stribild" died due to suicide, 2 patients in efavirentz group died to a suicide and a metastatic malignant tumor. 3 patients in atazanavir group died of sepsis, pneumocystosis, heart failure. The following information can be provided.

Most common side effects of "Stribild", efavirenz, atazanavir: rush, diarrhea, nausea, upper airways infections, depression, headache. Percentage is low and almost equal. Side effects reduced to the 96th week.

Side effects leading to study drug discontinuation

Kidney function – discontinuation with 1% on the 48th week in "Stribild" group and 0,4% on the 96th week. With all other side effects the frequency is less than 1%.
Laboratory abnormalities of the 2-4th degree, which results in drug discontinuation as well. "Stribild" – frequency is less than 10%, efavirenz – 11%, atazanavir – 7%. Atazanavir – bilirubin increase.
All three regimens may be prescribed to the patients with lipid metabolism disorders and cardiovascular diseases. However higher increase of cholesterol level within efavirenz regimen and significant increase of triglycerides level within efavirenz regimen and especially within boosted atazanavir are noted statistically reliable.

Serum creatinine (kidney disorder): no serious disorders. In "Stribild" group increase is higher comparing to other regimens, but without clinical significance.
Bone mineral density: there is decrease in "Stribild" and atazanavir groups. Those are poor indexes, but if at the beginning of treatment the state was good, there is no risk of osteoporosis development. To reduce the risk patients may be treated by vitamin D and calcium-containing drug prescription.

Conclusions:
GS-102, GS-103. Consistent virological effect. For virological response baseline CD4 cells count of and viral load are not important. Even in case of suboptimal adherence the results were good. Low risk of resistance mutations development. Good tolerability profile. No kidney damage or increase of serum creatinine were observed.

GS-123
Switching from RAL-containing regimens to "Stribild" was studied. The point is that RAL goes two times a day and is prescribed together with "Truvada", which means more pills and higher possibility of mutations development.

At first RAL + FTC/TDF ("Truvada"), 12 weeks of dose, 8 weeks viral load below limit of detection – switching to "Stribild".
The key points of study: non-detectable viral load till the 12th, 24th and 48th week and tolerance and safety of "Stribild" regimen. Conclusions upon study: a good option for switching in order to simplify treatment.

STaR study
International randomized open study.
Two regimens were compared: RPV/FTC/TDF STR ("Eviplera") and EFV/FTC/TDF STR ("Atripla").
Criteria of inclusion: naïve patients with viral load less than 2500 c/ml. Susceptibility to EFV, FTC, RPV, TDF.

Efficacy: "Eviplera" – 86%, "Atripla" – 82%.
Virological failure "Eviplera" - 8%, "Atripla" - 6%. There is a slight advantage, statistically insignificant difference.
"Eviplera" regimen revealed higher efficacy with patients with low viral load (statistically significant), while a tendency to efavirenz regiment preference is noticed through patients with originally high viral load, though statistically the difference is not reliable.
"Eviplera" and rilpivirine won't be positioned as a preferable regimen for patients with high viral load (including in Russia).

GS 264-111 study
Switching from efavirenz (EFV) to rilpivirine (RPV).
EFV/FTC/TDF STR – RPV/FTC/TDF STR
Criteria of inclusion: viral load stability less than 50 copies 8 weeks. Switching connected with intolerance of EFV efavirenz. Lack of resistance to drugs within the study. (N=50)

Efficacy: to the 24th week 93% in the 1st group, 90% - in the 2nd, virological failure in the 1st group was 0,9%, 5% - in the 2nd group.
To the 48th week virus suppression was 89,3%, virological failure – 2,5%.

There is no difference in viral load among the patients, but those were patients switch against the background of suppressed viral load. Frequency of development of resistant virus strains was utterly low. Switching to RPV rilpivirine doesn't make for resistance mutations development.
According to pharmacoeconomical data: about 4000 USD economy while switching of patients.
Conclusions: high efficacy, low level of virological failure, good tolerability, lipid profile improvements.

Desirable dosage is with meals – good influence on pharmacokinetics while having even light meals has been observed.

Q: Is this regimen recommended as the 2nd-3rd line?
A: No. The 2nd – 3rd lines are in case of failure of the 1st regimen or intolerance, if a patient is switched not against the background of virological failure, than switching is important as an improvement of adherence – less drugs and side effects precautions. The key point is prevention, precautions and keeping the efficacy of treatment.

TAF (Tenofovir Alafenamide)

This medication can be regarded as a prodrug of Tenofovir, it has a better antiviral activity and distribution in the cells of lymphatic system, than TDF, which means the dosage may be reduced.
TAF concentration in the cell 20 times more than with TDF, if take into account the dosage 40 mg TAF.
In 10 days of taking TAF suppresses the virus several times more than the standard TDF dosage.

TAF study 2nd phase: GS-292-102:

EVG/COBI/FTC/TAF (E/C/F/TAF) – EVG/COBI/FTC/TDF (Stribild®; STB)
Criteria: naïve patients, viral load ≥ 5000, c/mL CD4 > 50.
Efficiency: E/C/F/TAF 86.6%, STB 89.7%. Virological failure E/C/F/TAF/ 13.4%, STB – 10.3%.

Creatinine: the picture is much better for patients having got TAF, but there was no statistically significant difference in the groups.
Mineral thickness of bones: much better indexes to TAF.
Statistically significant. Good tolerance of both regimens.
Renal safety: TAF – no deviations. TDF – a bit more deviations, but insignificantly.
The company may go further in development of new combined drugs with TAF.
New third agents: PI, NNRTI, etc. – it's important that 3 agent dosage is no more than 500 mg – then dosage of a single pill is possible.

New 3rd agents:
-PIs – the most progressive
-Several drugs which can intensify the work of PIs
-Non-NUC – new
-Integrase Inhibitors of new generation for overcoming steadiness to regular InstI.

Three new regimens: Atripla, Eviplera, Stribild – all in one pill.

Possible appearance DRV-STR (DRV/COBI/FTC/TAF)
Possible appearance E/C/F/TAF (EVG/COBI/FTC/TAF). Stribild with TAF, not TDF, lesser size of a pill.

Q: Have any researches in STR and "Eviplera" safety during pregnancy (especially 1 term) been conducted?
A: Researches on pregnant women are not conducted due to ethical reasons. Affection on fetus has been studied on animals, which allowed to refer these combinations to the drugs not having mutagenic and teratogenic effects.

Q: Are child forms of TDF going to appear?
A: The work is conducted on dosage and form. There will be pills of low dosage and powder for dissolution.

Q: Is there any data on interaction with TB drugs?
A: Rilpivirine shouldn't be prescribed together with Rifampicine and Rifabutin. There are no interaction with ethambutol and isoniazid. On Stribild, as it has booster within, it is unlikely to be chosen with TB.

Q: Which of the medications are better to use with ST?
A: Rilpivirine. "Stribild" with methadone or buprenorfine are also possible.

Q: Are there any prolonged forms, for instance, once a week, etc.?
A: There are researches on rilpivirine, injection form once a month, but it should be taken with other drugs with much shorter half-life period, there are a lot of questions on adherence.

Q: Are there any plans on registration of cobicistat as a mono component? Have any researches been conducted separately?
A: In RF cobicistat will not be registered as a separate component.

COMMENT: You should have it registered as it is important for patients.

Q: FDA rejected request for elvitegravir as a separate drug. Why?
A: It is connected not with its efficacy, but with a study design. Promotion of elvitegravir as a separate drug is unlikely.

Other studies

Phase 3b GS-115 study

Multicentral, international, randomized, open, phase 3, 96 weeks.
Comparison of Stribild to NNRTI (Stribild – NNRTI + FTC/TDF).

WAVES study

Study on safety and efficacy in women.
Phase 3B, multicenter, international, randomized, double blind, 48 weeks EVG/COBI/FTC/TDF ("Stribild") – ATV + RTV + FTC/TDF (regimen with atazanavir).
Criteria of inclusion: naïve patients, viral load more than 5000, no restrictions in CD4.
40 patients.
Moscow, Saint-Petersburg, Nizhny Novgorod, centers of Central Region, Siberia. Exact data on the centers where the study will be conducted may be provided.

Part 2 Hepatitis C

The main problems for now are the duration of treatment, side effects, patients with decompensated cirrhosis, and patients not responding to standard treatment Interferon+Ribavirine. Increase of efficiency, drop in number of side effects, reduction of treatment time are necessary. Sofosbuvir was developed to solve the issues. Genotypes 1 and 3 typical for our region response perfectly to sofosbuvir treatment.

Sofosbuvir

400 mg per day. A wide coverage of virus genotypes. For our region genotypes 1 and 3 are characteristic. Sofosbuvir is effective against both types.

A very high resistance barrier, not a single mutation. On this stage of study there are no observed side effects (on the current 3rd phase).

For 1,4,5,6 genotypes in combination with peg-interferon and ribavirine the duration of treatment is 12 weeks. More than 90% efficiency – SVR.

2,3 genotypes: sofosbuvir + ribavirin – efficiency is 75-100% (three different studyes). 75% are basically to genotype 3, genotype 2 respond to treatment very well.

To treat genotype 1 – sofosbuvir + ledipsavir (NS5A inhibitor, NS5A – component of HCV) + ribavirine 100% efficiency (monoinfected, genotype 1, with no regard to patient's genome CC, TT, CT), there is data for the 12th week. Ledipsavir is a direct competitor for daclatasvir, but it works

only against genotype 1. Daclatasvir is effective against other genotypes. For now data after 4 weeks upon the end of treatment is available.

Q: What are the main side effects?
A: There is good tolerability with no marked side effects. No flu-like syndrome, depression, sleep disorder, GI disorders. There are some slightly marked effects which exist amid placebo.

Q: Is ribavirine used?
A: Treatment may be with or without ribavirine. Dosage is calculated as standard. Those who got ribavirine, the effects were standard for this drug.

There will be a group of patients who previously haven't responded to peg-interferon and ribavirine treatment.

Q: Where will the study be conducted? Will Ukraine and RF be included in it? Is there any procedure of inclusion?
A: I would like Ukraine and Russia to be included in this study, but there is a number of hurdles.

Q: Could you name them? Is there any special procedure? A high-capacity study base has been created in Ukraine. Our countries are not usually included into studies.
A: Decisions upon conducting studies in different countries are made in the HQ. Sometimes the inclusion of countries with no rep office is possible, but countries with working rep office and a fixed system of control and monitoring are included more frequently. When a company enters new markets, it wants to conduct studies, and our (RF) opportunities are sometimes even better, but the approval and logistics systems are very difficult, and in Russia as well. In Ukraine the approval system is simpler comparing to the Russian one. Gilead has a positive experience of working in Ukraine concerning studies dedicated treatment of cardio-vascular diseases.
Suggestion: to submit official letters to Gilead with a request upon the course of actions in order to have such kind of researches conducted in our countries.
Comment: an example from Georgia. There is a French organization which collects a cohort in Georgia.
A: It probably concerns study which initiated by researchers, not the company itself.

Q: Are patients with compensated liver cirrhosis included in the design of study?
A: Yes, about 20% of the whole population. In the international study Fusion took part patients with HCV of genotype 2, cirrhosis, sofosbuvir + ribavirine regimen. The results disclosed good efficiency of the regimen – about 80% at 16 weeks treatment.
Sofosbuvir profile has been submitted to FDA this spring. The number of regimens is limited. For 1, 4 and 5 genotypes the duration of treatment is 12 weeks, combination therapy with interferon and ribavirine is 12 weeks as well. For genotypes 2 and 3 peginterferon is not necessary.

Q: What is the duration of treatment for genotype 3?
A: For genotype 3 efficacy of 16 and 24 weeks is studied, because at 12 weeks the sustained virological response is 67%, which can be compared to the efficacy of standard regimen PEG-IFN + ribavirine, but lower than efficacy of new regimens at other genotypes.

The following studies will be conducted:
-Candidates for transplantation,
-Patients after transplantation with relapse,
-Co-infection HIV and Hepatitis C,
-Acute HCV,

-Patients with compensated liver cirrhosis,
-Patients with decompensated liver cirrhosis,
-Patients of different races.

Our countries (Russia and Ukraine) at the moment are not included in these studies. There is hope that our countries will be included in studies of new regimens.
Perhaps, there will be programs of an early access to the drug in the countries where it is registered.

Study in RF GS-US-334-0119

Sofosbuvir + Ribavirine

24 weeks – genotype 3, genotype 1 – 12 weeks, naïve patients. 18 centers are approved, the study will be likely conducted in 16 of them with 10-8 patients/center. Only for RF. The study will be added to the drug profile. There will be no groups of comparison. Due to budget restrictions the number of patients will be limited as well, though, according to researches, the number of patients treated in Russia is immense. The data of substantial international researches of phase 3 and the results of a local one, which, as we hope, will be comparable to currently existing data of more extensive studies, will be added to the Russian dossier for a drug registration.

Q: What will happen to patients who won't response to the treatment?
A: Upon the end of the study a long observation of those who won't respond to the treatment is not planned within the following report. Probably we will try to agree further observation with the researchers.

Q: What will be the price for a course of Sofosbuvir?
A: It will be decided only in a few months upon the registration.

Q: Have any researches on combination with ST been conducted?
A: As we know, Sofosbuvir has almost no interactions with ST drugs.

Q: What were the expenses for Sofosbuvir development?
A: Unfortunately, I have no information.

Q: We know that in terms of successful treatment with peginterferons there are lots of factors determining treatment success (predictors) – height, weigh, etc. Are there the same factors for Sofosbuvir?
A: For Sofosbuvir, on condition that the regimen doesn't include PEG-IFN, it is a genotype (genotype 3 responds worse). As for the rest, height, weigh and interleukin are no factors. As the drug is antiviral, it affects directly virus polymerase. At the moment doctors recommend some patients to wait for new drugs and, as for me, this is not so good for some of them.

Q: Gilead is not the only company working on antiviral drugs. Who is your most dangerous competitor?
A: I will share my personal subjective opinion. Abbot has an all oral regimen without interferons and highly effective. They also have a regimen without ribavirine, including ritonavir, which is 100% effective. 1 pill one time a day is very unlikely. BMS also possesses a new drug – in combination with Sofosbuvir 100% efficiency is in 12 weeks, but as Gilead has its own drug, it was decided not to keep on common researches with BMS. There is no difference between ledipasvir and daclatasvir in terms of efficiency for genotype 1. BMS used to have its own polymerase inhibitor, but researches have been ceased because of side effects. Janssen submitted semiprevir for registration, 90%, a good

profile of safety and resistance. But in advanced phases of researches Janssen had only 1 pill, that's why they are less competitive.

Q: Is it a turning point for prices for peginterferons? Merck and Roche have kept very high rates for 10 years, with quite modest efficacy. New chemical molecules are easy for reproduction. More and more international organizations start admitting the importance of the epidemic. Can these factors possibly lead to rate changes for peginterferons?
Comment: as soon as the chemistry appears, it will be forged at once.
A: The question is rhetoric. The market is competitive, and companies will have to adapt prices if they want to have their market share. To create Sofosbuvir generic is not difficult, but countries that respect intellectual property will protect it till patents are valid.

Q: As peginterferons are used in regimens with new medications, does your company plan any work with peginterferons producers?
A: No, because the period during which peginterferons will be used is not long any more. It's 2 or 3 years. There is a new peginterferon in Russia. It can be also used, if its price will be competitive and its quality is approved in accordance with evidence based medicine rules.
Companies are open for price discussion, if countries are ready to enlarge treatment and in case there are state programs. Ex.: "Truvada" in Ukraine. If there are programs on HCV, the company will probably regard these approaches.

Q: Do you plan any programs of an early access?
A: I have no information yet. But I will do my best for these programs to appear in the region. This question is to be discussed.

Q: Does the company practice programs of an early access within the Baltic states.
A: I can contact my colleagues and discuss this question. You can address a letter to me and I will forward it to corresponding people and undertake monitoring.
Comment from the company: I hope that Gilead will regard opportunities of enlargement of access to new medications in countries with lower level of economical development. Unfortunately, in Russia the state is not ready for any kind of discussion as there is no state program of viral hepatitis prevention and treatment, and patients pay for the treatment themselves.

Q: What are the relations between Gilead and Medications patent pool?
A: Unfortunately, I have no such information. There is patent advocacy for almost all Gilead medications, but not in all countries. Regrettably, there is no patent for TDF in Russia. The company gives voluntary licenses to generic producers for Gilead medications production in some least developed countries.

Q: Where there is a patent for Sofosbuvir?
A: Apparently, there is such a patent in the USA and Europe. As for Russia, there is no information. I will try to get it from my colleagues who are involved in intellectual property protection in the company.

Q: As we can see, there is patent for "Atripla", but the company is not going to promote it in the region. Do you regard the possibility of giving voluntary licenses?
A: I cannot give the exact answer, but I think the discussion of licensing is possible.

Q: Is it right that patent for "Atripla" and "Truvada" protects composition of TDF with other substances?
A: Yes, the composition is protected by the patent.

Q: There are plans from other companies concerning “Truvada” and “Atripla”. Are you going to sue Russian producers of these drugs?
A: As I know, there was a case of such a lawsuit with “Biocad”. From official sources (Healthcare Ministry website) it is known that 2 companies are conducting bioequivalence studies of a fixed combination of tenofovir + emitricitabine. In spite of this the company plans to ship “Truvada” in the near future, there are small preorders from different regions including Saint-Petersburg.

Q/comment: Sometimes we think that our region is ignored by Gilead both in Russia and Ukraine. Perhaps Gilead will pay no attention to generics producing in the region. The attitude from Healthcare Ministry is tough; the company is blamed for lack of access. Do you feel the same attitude to the region from western colleagues?
A: Thank you for your feedback. The company wants to change the situation with access. But it used to have apprehension concerning corruption aspects in Russia. As for me, I am ready to put all the effort to make regular access in Russia, Ukraine, Asian countries and Baltic as soon as possible.

Q: There is fear at the moment that Global Fund elapses, some countries will have no medications due to lack of registration. What will the situation be within the region?
A: We do our best for the drugs to be available in this region as well, but our physical resources are limited. My duty is to show that for our region access to the company's new drugs is very important. I am sure the company will gradually improve the work concerning access to its new drugs in the region.

Q: Taking into account the company’s decision to consolidate in the region, is it possible to get a promise, maybe not now, but in a couple of months, concerning registration profiles?
A: I provide information on “Stribild”. We have to conduct registration study in Russia. As for TAF, further researches should be planned. We have started study on Sofosbuvir. I have provided information on child’s forms of TDF.
Specification: we would like to get information on registration and patent status in the countries.
A: We commit ourselves to provide the information in a month.

Q: We hope that Chinese and Indian companies will soon forge drugs. Pharmaceutical companies know this and at the moment they are creating protection schemes. Basic consumers of Indian production are our countries as well, only in terms of price. Why don’t you originally plan the strategy of low prices for our countries in order generic companies don’t experiment with forgery?
A: The companies certainly must have the money invested into drugs development back. Russia is a member of WTO and we hope that our country will follow its rules. In other countries generics might appear. The company is building a new price policy according to economical development of the country. There are supplies in Ukraine at low price. Pharmaceutical companies don’t regard Russia as a country with budget problems. Moreover, Russia is a consultant for many countries in the region. I think that new policy concerning new drugs will be regarded in the company from the point of view of access.

Q: Is there any influence on price by working through “Delta medical”, not directly?
A: Yes, and in a good way as “Delta Medical” pays for logistics and collects low distributing margin.

Q: The price for “Stribild” in the USA raised protests even in Congress. Are there any offers for price in Europe and Russia?
A: No, there is no information.

Q: As we know, "Delta medical" had problems with TDF registration. Why haven't you changed the partner?
A: Those were not only the problems of DM, but in regulatory dept. as well. It was decided to work with a small company which is easier to control on unethical behavior prevention.

Q: Taking into account that TDF will be registered for Hepatitis B, will it be available at free sale? What will be the prices?
A: Yes, we'll do our best to make it available in specialized pharmaceutical networks. As for price, you'd better submit an official request. The price for Russia has already been approved, it is considerably lower than the European one, but I am not ready to announce it right now. It is approved for DM.

Q: Most countries of the region are of low income. They can evade patent security. Perhaps, it's simpler to give out voluntary licenses to get something and not to be involved in lawsuits and to save face in the region. Take into account that voluntary licensing is a controlled process.
A: Company already provides HIV-treatment drugs on non-benefit cost in some countries including Ukraine. That's why there is no necessity in voluntary licensing. As for HCV, it's to early to speak. There must be mutual understanding between the company and the state. If, for instance, Georgia says they have the program and infrastructure, and a small budget as well, we are ready to discuss t and make a concession. But if we address to an official in X country, and they are not able to discuss HCV problem at all, we cannot do anything.
Comment: if there is real discount, we are ready to lobby treatment programs. But no one wants to make concessions first.
A: The company is ready to regard an opportunity to supply its drugs on special rate, but I suggest that we returned to this question when the drug is in the market.

Q: When do you expect FDA approval?
A: In December 2013. Each region is to be further discussed.

Q: Will it be any patent for Hepatitis B treatment with the help of tenofovir?
A: As I know there is no TDF patent for Hepatitis B treatment and it is not planned. In Russia there is no tenofovir patent at all.

EECA CAB suggestion: Can we submit an official request to Gilead and ask to regard a possibility of other policy concerning our region because of difficult epidemiological situation?
A: I cannot give any definite answer for now. There is certainly a point in addressing the company if there is some information on the program, the number of patients and budget. I will do my best so that Gilead made a favorable decision.

Meeting closure: we are grateful to Andrey Poliakov for coming and deeply regret that colleagues form Europe and the USA were not able to attend the meeting. The course will be taken upon the results of the meeting.

Andrey Poliakov: From my part I'm grateful for all the questions and comments and I'm ready to do my best for access improvement.

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The end of the meeting.