

# THE MEETING ON THE ISSUES OF INTELLECTUAL PROPERTY AND ACCESS TO TREATMENT IN EASTERN EUROPE AND CENTRAL ASIA

TBILISI, GEORGIA, NOVEMBER 02-04, 2016

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**November 02-04** Tbilisi hosted a meeting dedicated to the issues of access to medicines in terms of the barriers associated with intellectual property. The meeting was attended by representatives from the following pharmaceutical companies: Pharmasynitez (Russia), Biocad (Russia), Cipla (India), Mylan (U.S.), Tatchempharm (Russia), and PharmEvo (Pakistan).

The following issues have been discussed at the meeting:

- **The companies' plans for authorization and the market launch of the second or third-line medicines for HIV infection treatment and antiviral drugs for hepatitis C virus treatment (lopinavir/ritonavir, atazanavir, darunavir, dolutegravir, sofosbuvir and combination therewith, daclatasvir).** The meeting participants have highlighted the need to take urgent measures aimed at authorization of these medicines in the countries where there is no patent protection:
  - a patent has not been issued, there are no barriers (e.g. daklatasvir in Ukraine);
  - the patent is not maintained (e.g. Eurasian patents for daclatasvir in most countries of the Eurasian Patent Organization);
  - there is an official letter from the patent holder on its waiver from pursuing intellectual property rights (e.g., abacavir and abacavir/lamivudine and tenofovir/emtricitabine/efavirenz in Ukraine);
  - the country has been included into the voluntary license (e.g. Kazakhstan has been included into the voluntary license for atazanavir, but at the time of the meeting the medicine has no marketing authorization in this country).
- **The necessity to challenge patents** on such medicines as tenofovir/emtricitabine (Eurasian application No 15145), lopinavir/ritonavir, and sofosbuvir due to the weakness of these patents from the point of view of the experts. Currently, All-Ukrainian Network of People Living with HIV is challenging one of the patents on lopinavir/ritonavir, and it was pronounced that generics producing companies may also be involved in this process. In the Russian Federation the patent on sofosbuvir pro-drug is currently being challenged both by the patient organizations and Pharmasynitez. The need to monitor the prospective of the Eurasian patent applications related to sofosbuvir (primarily EA201490903) was highlighted as should the patents be issued, they can block the access to the market by already authorized sofosbuvir generics in the countries of the Eurasian Patent Organization (e.g., Kazakhstan and Belarus). When granting a patent, it is required to take measures for its abatement according to an administrative procedure<sup>1</sup>.
- Abatement of the **patent on entecavir in the Russian Federation** by Pharmasynitez was announced (Eurasian patent on entecavir No 6181, granted pursuant to application No EA200200812, protecting the entecavir composition until 2021. The Rospatent official decision will be issued after November 20.
- **Decisions on abatement of Eurasian patents in the Russian Federation may and must be used for the abatement of the respective patents in other countries.** In the context of the discussion, it concerned the patents on abacavir, tenofovir/emtricitabine, entecavir, and sofosbuvir.
- As far as access to darunavir is concerned, it has been emphasized that in the market **there are several darunavir generics (amorphous form of darunavir), which do not infringe the existing patent on this medicine** (including produced by Pharmasynitez and Hetero). Tatchempharm also announced that their medicines would not infringe a valid patent on darunavir. Subject to the completion of the WHO

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<sup>1</sup> <http://www.eapo.org/ru/patents/dispute/>

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prequalification or obtaining an approval from FDA/EMA, these medicines can be delivered within the procurement carried out by international agencies.

- Some companies announced their plans to develop and manufacture the **generics of tenofovir/ emtricitabine and lopinavir/ritonavir, which would not infringe the existing patents.**
- **Compulsory licensing.** The meeting participants said that in the current context, the possibility of issuing a compulsory license largely depends on the political climate. However, the companies' production capacities allow to produce sufficient quantities of the medicines to treat HIV and HCV, as well as to launch the medicines on the market within 1-2 years of the date of issuing the license.
- **The data exclusivity** was mentioned in the discussion as one of the potential barriers (e.g. in the case of sofosbuvir in the Russian Federation and Ukraine), but not as a key barrier. The participants mentioned the ways to bypass the data exclusivity by conducting own short clinical studies and submission of the complete application alongside the originator.
- **The process of authorization.** Some companies said that the medicines authorization in a number of countries is considered inexpedient due to a relatively high cost (an average of 15-20 thousand US Dollars), and a bureaucratic procedure. A way out is a mechanism of accelerated authorization and recognition of the marketing authorizations obtained from the FDA or the EMA or other stringent drug regulatory authorities. The meeting participants agreed to provide information about the authorization procedures in the countries of the region. In addition, it was pronounced that one of the barriers is too strict requirements to a product labeling, including in Kyrgyzstan. Authorization clinical studies have also been noted as one of the barriers preventing the generics from entering the market even in the absence of the patent protection (the Russian Federation, Belarus). It was pronounced that this requirement is redundant, and it is required to seek simplification of the authorization procedures.
- **WHO Prequalification.** The patient organizations continue to highlight the importance of the WHO prequalification in the context of the quality control. WHO prequalification is an important criterion for participation in the procurements carried out by international agencies (including UNICEF), and for the state authorization. Several Russian companies announced their plans for prequalification of the generics of the second line ARV medicines, including darunavir. On the other hand, the delegates expressed their concerns about possible increases in the cost of completing the prequalification procedure, which until recently was 25 thousand US Dollars.
- **The problem of preferences for domestic producers in public procurements,** especially in Kazakhstan, Belarus, and the Russian Federation. Companies from other countries have to take measures aimed at localization of production that extends the market entry time and, probably, increases the medicine price. It has been opined that these national regulations contradict the EurAsEC laws.
- Taking into account a great demand for the medicines, first of all in the Russian Federation, the issue of the **ARVs commercial market** was raised at the meeting. The delegates discussed a possibility of entering the market without patent protection of the generics at an affordable price (the benchmark - 150 USD per year for the entire regimen). It was argued that in the case of an urgent need, and as a last interim measure it can partially solve the problem of providing the medicines in the following cases:
  - in the event of irregularities in the medicines supplies;
  - for domestic and foreign migrants;
  - for the patients willing to promptly commence the treatment but not having such an opportunity.

Biocad has voiced its strategy of entering the commercial market of the medicines for the treatment of hepatitis C and B under the "Focus on Recovery" program, and mentioned the possibility to include the medicines for the treatment of HIV infection into the program.

- Several companies have announced their **pricing policy for specific medicines** and commitment to their authorization and delivery to the region countries markets in the absence of patent barriers. PharmEvo
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announced a price of USD55 for a unit with 28 sofosbuvir tablets, as well as the planned price of 100 USD for 28 tablets of combined sofosbuvir/daclatasvir medicine, which is currently undergoing the process of authorization. The USD55 price is for domestic market only; the export price will have a markup of approximately 20-25% depending on the export documentation, freight costs, charges etc. It is planned to apply for the WHO prequalification of sofosbuvir/daclatasvir within three months. Sofosbuvir is currently being tested in terms of comparison with the original medicine<sup>2</sup>. Biocad announced reduction of the price for cepeginterferon alfa-2b to 1,574 Rubles per prefilled syringe when purchasing 48 syringes (75,600 Rubles, or 1,200 USD). The price of tenofovir for the treatment of hepatitis B under the "Focus on Recovery" program amounted to 5,544 Rubles for 30 tablets.

- Mylan announced that upon acquisition of Meda it has now representative offices in the region (Ukraine, the Russian Federation, Kazakhstan, and Belarus). The contacts of the representative offices have been provided.
- Mylan has helped support the ENCORE study of lamivudine/tenofovir/efavirenz 400 mg in one tablet<sup>3</sup>. This medicine, subject to obtaining prequalification or approval from EMA/FDA and licensing/patent restrictions, can be supplied to the region markets.
- Cipla announced that it is developing a new dosage form of tenofovir (100 mg with a pharmacokinetic enhancer), which will be comparable in terms of efficacy with the 300 mg dosage form, but the quantity of the side effects will be much lower. The company also develops new dosage forms, including pediatric and subcutaneous with prolonged release.

Furthermore, one of the key discussion issues was the fact that the absence of patent protection does not automatically mean broad access to the medicine, and that it is required to work towards elimination of other barriers as well (please see above).

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<sup>2</sup> <http://apps.who.int/trialsearch/Trial2.aspx?TrialID=NCT02804386>

<sup>3</sup> [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)62187-X/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62187-X/abstract)

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