

To: Mr. Mark Snyder, Executive Director,  
Public Affairs

Copy: Ms. Rhiannon Bid, Senior Manager

Copy: Mr. Igor Rukavishnikov, Director  
General, Gilead Sciences Russia

Copy: Alexey Brevnov, Government and  
Public Affairs, Gilead Sciences Russia

Open letter from patient organizations concerning non-enforcement of patents for  
tenofovir/emtricitabine in Russia

Dear Mr. Snyder!

Patient organizations working in the field of HIV in Russia are writing this letter to ask Gilead Sciences **to stop enforcing all patents** covering the combination of tenofovir and emtricitabine, TDF/FTC (marketed by Gilead Sciences in Russia under the trade name *Truvada*), including Eurasian patent No 015145.

This key patent in relation to TDF/FTC is now being opposed by Russian civil society organizations in the Chamber for Patent Disputes; the next hearing is scheduled for September 9, 2020. Our analysis shows that the patent does not meet the patentability criteria in accordance with the Russian regulatory framework. The same patent was declared invalid on the territory of Kazakhstan by Astana Specialized Inter-District Economic Court in March, 2019<sup>1</sup>. As Patent 015145 expires in January 2024, at least 3 years of generic access to TDF/FTC at affordable prices can be ensured if the patent is not enforced, which will significantly benefit people living with HIV and their partners in Russia.

It is important to note that Gilead Sciences on several occasions have made it clear that the company has no plans to actively market *Truvada* in Russia, and that the company's strategy would focus on the novel drugs instead (see, for example, the minutes<sup>2,3</sup> of the meetings between the Eurasian Community for Access to Treatment (ECAT) and representatives of Gilead Sciences Inc. which took place April 25 and October 16, 2019). *Truvada* was registered in Russia in 2011, and since then it has not been made available to Russian patients despite numerous requests by the patient community. The drug is not included in the Essential Medicines List (EML), and during one of the meetings with patient organizations the company stated explicitly that it was not planning to re-submit the dossier for inclusion of TDF/FTC into the EML. Due to the absence of TDF/FTC in the EML, the price of TDF/FTC in Russia is not regulated. The current price in the range of USD200 per month places the drug out of reach for most patients either as HIV pre-exposure prophylaxis (PreP) or as treatment. There are very few patients who can access TDF/FTC as part of the highly-active antiretroviral treatment within the government treatment programme in Russia (10 out of 534,990 in 2019 based on the monitoring results). PreP is not yet covered and

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<sup>1</sup> <https://www.eapo.org/ru/patents/reestr/patent.php?id=15145>

<sup>2</sup> <https://eeca-cat.info/en/minutes-of-the-meeting-of-ecat-and-gilead-sciences-janssen-msd-and-viiiv-healthcare/>

<sup>3</sup> <https://eeca-cat.info/protokoly-rossijskoj-vstrechi-ecat-s-kompaniyami-gsk-gilead-farmasintez-i-viriom/>

provided by the government, and patients have to purchase the drug themselves. According to a study about PreP carried out by one of the Russian patient organizations<sup>4</sup>, only 6% of the respondents are willing and able to buy the original version of TDF/FTC at approximately USD200 per month.

To summarize, given that:

- Gilead Sciences have publicly stated that TDF/FTC is no longer an option that is going to be actively promoted in Russia;
- Gilead Sciences have openly stated that the company is not going to re-submit the dossier for including TDF/FTC into the Essential Medicines List;
- The combination of TDF/FTC is still part of the WHO-recommended first-line regimen and the most well-studied and widely used option for PreP, and thus its broad availability is clinically important;
- There are already a number of generic options registered and ready to supply the drug at significantly lower prices if the patent is not enforced or declared invalid;
- The analysis shows patent 015145 does not meet the patentability criteria, and the same patent was successfully opposed in Kazakhstan;

we are asking Gilead Sciences to issue a letter of non-enforcement pertaining to all patents covering TDF/FTC, Eurasia patent 015145 in particular, and send an official notification confirming voluntary disclaimer of these patents. Taking all the factors stated above, we believe it is the best solution for expanding access to this combination in Russia.

Signed by (in alphabetical order):

1. AIDS, Statistics, Health Regional Public Organization, St. Petersburg
2. Azbuka N Charitable Foundation, Moscow
3. EDINSTVO Volgograd Regional Public Organization
4. E.V.A. Association
5. H-Club Initiative Group of People Living with HIV
6. House of Hope Charitable Fund, Ivanovo
7. Humanitarian Action Charitable Foundation, St. Petersburg
8. Humanitarian Project Regional Public Organization, Novosibirsk
9. Life4me.plus to fight AIDS, Hepatitis C and Tuberculosis
10. Nasledie Kaliningrad Regional Public Organization
11. Navigator Irkutsk Regional Public Organization
12. New Life Sverdlovsk Region Public Organization
13. Ostrov Local Community to Help People Living with HIV, Novosibirsk
14. Phoenix Plus Orel City Regional Public Organization
15. Patients in Control Movement
16. Pokolenie Non-Profit Organization, City of Tumen'
17. Positive Environment Regional Public Organization, Republic of Bashkortostan
18. Prevention and Initiative Regional Public Organization, Republic of Tatarstan
19. Status-Plus Kaliningrad Regional Public Organization

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<sup>4</sup> <https://parniplus.com/health/prevention/polovina-rossijskih-geev-hotyat-prinimat-prep-dkp/>

20. Svecha Charitable Foundation, St. Petersburg
21. Svetlana Izambaeva Non-Profit Charitable Fund, Kazan'
22. Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru)
23. UMKA City Public Organization, Sverdlovsk Region
24. Vector of Life Public Foundation, Samara
25. VERA Regional Public Organization to Support Relatives of Drug Users, Kazan'