

Legal opportunities for scaling up HIV treatment access using government use and compulsory licensing: recommendations based on legal framework analysis in the countries of the Eurasian Economic Union

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Abstract

BACKGROUND: TRIPS flexibilities, including compulsory and government use licenses, have proven to be effective to improve treatment access. The antiretroviral therapy coverage in the Eurasian Economic Union (EEU) is below 90% of those knowing their status, partly because of high prices for key medicines, (e.g. dolutegravir), due to patent monopolies. The COVID-19 pandemic reiterated the need to assess legal provisions related to compulsory licenses and government use of inventions for medicines. We analyzed national and regional regulatory framework in the EEU to demonstrate opportunities for government use or compulsory licensing to improve access to antiretroviral medicines and beyond.

METHODS: For analysis, we used international regulatory framework (TRIPS Agreement, Paris Convention, and Doha Declaration); official national and regional legal databases (<https://www.garant.ru/>; <https://regulation.gov.ru/>; <https://adilet.zan.kz/kaz/> and <https://online.zakon.kz/>; <http://cbd.minjust.gov.kg/>; <https://pravo.by/>; <https://www.aipa.am/hy/>; <https://eec.eaeunion.org/>). The Russian versions of the following key words and combinations were used: compulsory license/licensing, government use of inventions, use without the consent of the patent holder, anti-competitive practices, limitation of intellectual property rights, actions not considered as patent infringement.

RESULTS: Our analysis identified three categories of legal provisions related to use of patents for medicines without the consent of the owner: government use of inventions, compulsory licenses, and use of patents not considered as patent infringement. We focused on language that can be related to access to medicines, such as "healthcare/health", "epidemics", "national security", "medicines", "insufficient use", "non-use" and "anti-competitive practices".

Country	Government use	Court	Use of patent not considered as patent infringement
Armenia	-	+ national security; health (including lack of access to medical products); unfair use of patent rights by restricting competition; non-use or insufficient use;	+ national security (issuing authority n/a)
Belarus	-	+ non-use or insufficient use	+ epidemics (issuing authority n/a)
Kazakhstan	-	+ national security; health protection; abuse of patent rights; non-use	
Kyrgyzstan	+ national epidemics	+ non-use or insufficient use	+ epidemics (issuing authority n/a)
Russia	+ national	+ non-use or insufficient	-

protection of life and use
health of citizens

CONCLUSIONS: The key finding is that Armenia, Belarus and Kazakhstan lack provisions related to government use of inventions without patent holder consent, which limits opportunities for rapid actions to close treatment access gaps. In Belarus and Kazakhstan, this could have had a negative impact on increasing access to patented dolutegravir. The media reported that the Kazakh government intended to seek compulsory license for dolutegravir through court. Countries are recommended to revise their regulatory framework to include provisions enabling government use of inventions for medicines in a variety of situations to improve access to essential medicines.

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