



December 8, 2021

Brian Nelson
Under Secretary for Terrorism and Financial Intelligence
Office of Terrorism and Financial Intelligence
Department of the Treasury
1500 Pennsylvania Ave., N.W.
Washington, D.C. 20220

Re: Request for meeting to discuss sanction exceptions for drugs and vaccines.

Dear Under Secretary Nelson,

Knowledge Ecology International (KEI) is a non-profit organization with offices in Washington, DC and Geneva, Switzerland. Among our activities are efforts to make access to medical technologies more equal. Our organization and body of work is described in extensive detail at <https://keionline.org>, <https://keionline.org/about> and <https://www.keionline.org/ourwork>.

KEI is concerned that U.S. trade sanctions have created barriers to the development of COVID-19 vaccines and access to a broader set of vaccines and drugs. This letter provides some context, and concludes with a request for a meeting to discuss efforts to make the U.S. sanctions program humanitarian exceptions for medicines and vaccines work better.

Cuba. On July 1, 2021, we sent a Memorandum to Gayle E. Smith (State), Eric Lander (OSTP), Loyce Pace (HHS) and Samantha Power (USAID) asking the U.S. government to clarify that its sanctions against Cuba do not extend to activities and agreements related to the development, manufacturing, distribution and sale of its COVID-19 vaccines. The Cuban vaccine program, which seems quite important, has faced barriers as a number of businesses and nonprofit organizations have been reluctant to work with the Cuban vaccine program, because of the U.S. sanctions.

Iran. We subsequently were in contact with Vaxine, a company in Australia founded by Nikolai Petrovsky, a professor of medicine at Flinders University. The Australian company has worked with CinnaGen, a company in Iran, to undertake clinical trials of Vaxine's recombinant protein subunit vaccine for COVID-19. The affiliation with the Iranian company may have led to delisting of stock exchange offering and losing funding, among other things. More recently, KEI has been approached by an Iranian student and a U.S. NGO working on U.S.-Iran relations, both describing the broader impact in Iran of the sanctions on access to medicines, including off-patent generics and cancer treatments.

North Korea. More recently, KEI was asked about the challenges in supplying COVID-19 vaccines or drugs to North Korea, leading us to examine the provisions in two Medicines Patent Pool (MPP) licenses to manufacture COVID-19 therapeutics.

MPP Licenses. The MPP is a respected non-profit organization operating from Geneva, Switzerland that negotiates voluntary licenses to use patented inventions and manufacturing know-how and rights in regulatory data for a variety of medical technologies, including drugs and diagnostic tests related to COVID-19, viral hepatitis (HCV and HBV), tuberculosis, cancer, cardiovascular disease and diabetes. Historically the MPP has negotiated licenses that include a licensed territory of roughly 95 to 115 lower and middle income countries, representing more than half of the world's population, as well as a collaboration with the World Health Organization (WHO) for global licenses for COVID-19 technologies. The MPP has recently announced licenses with Merck and Pfizer for COVID-19 therapeutics. Both licenses have a licensed territory consisting of LMICs where sales are authorized, and both authorize global manufacture with some restrictions. Among the restrictions are those relating to any operations involving the countries, persons, businesses or other entities that are the target of U.S. sanctions.

The Pfizer license. A license between the MPP and Pfizer for the COVID-19 combination drug PF-07321332+ritonavir has 45 mentions of sanctions. The sanction target countries are identified as including, without limitation, Cuba, Iran, Crimea, North Korea, Venezuela, and Syria. The license requires the MPP to comply with all applicable economic sanctions and export control laws in the performance of the agreement, including those administered by:

- the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC")
- the Export Administration Regulations ("EAR") administered by the U.S. Department of Commerce's Bureau of Industry and Security ("BIS").

The MPP must receive permission from Pfizer before it can be involved with persons or entities that are the target of sanctions administered or enforced by:

- the U.S. Government, including OFAC,
- the governments of Switzerland,
- the EU,
- the United Kingdom, or
- any country listed on any denied party lists maintained by OFAC, BIS or on the European Union's Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions.

The MPP is also required to obtain prior authorization, in the form of general licenses, specific licenses, and/or other authorizations, from OFAC and/or BIS, before any engagement with sanction targets.

The Merck/MPP license. The license between the MPP and Merck for the therapeutic molnupiravir has similar restrictions, and also makes reference to several OFAC licenses that appear to expire on June 16, 2022, less than one year from now.

- Iran General License N,
- Syria General License No. 21, and
- Venezuela General License No. 39.

It is our impression that the U.S. sanctions program has both a legal impact, that includes importantly, the possible exceptions for drugs, vaccines and other medical supplies, and a practical impact, which is much larger.

The larger impact is related to the uncertainty and costs of compliance with the U.S. sanction program, which are a significant deterrent for many businesses and other entities that would otherwise be working to make, supply or sell needed drugs, vaccines, equipment or inputs to making drugs or vaccines, or other related health products in the sanctioned countries.

We are aware that the January 21, 2021 National Security Memorandum 1, on the International COVID-19 Response has called for an interagency review of sanction policies and practices. KEI requests a meeting with your office to discuss measures that can better clarify and simplify the sanctions program so that the humanitarian exceptions work better. This would include but not be limited to:

- A web page relating to health care products with plain language guidance that clarifies the scope of sanctions that can be understood by persons who are not experts on the legal issues.
- Expanded use of “white lists” for products that are not subject to sanctions.
- A program of working with trusted organizations and businesses to fast track and facilitate the granting of required permissions.
- Comfort letters to reassure third parties such as financial institutions that certain activities are not subject to sanctions.
- Best practices for providing drugs, vaccines, and other related products and services within the humanitarian exceptions.

Sincerely,



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Cc:

Jeff Zients, White House Coronavirus Response Coordinator;
Loyce Pace, Director of the Office of Global Affairs within the United States Department of Health and Human Services;
Erik Woodhouse, Deputy Assistant Secretary For Counter Threat Finance And Sanctions;
Samantha Power, Administrator, United States Agency for International Development;
Jeremy Pelter, Deputy Under Secretary for Industry and Security, Department of Commerce;
Representative Andrew Levin.

ANNEX: NATIONAL SECURITY MEMORANDUM –1

National Security Memorandum on United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness, January 21, 2021

(c) COVID-19 Sanctions Relief. The Secretary of State, the Secretary of the Treasury, and the Secretary of Commerce, in consultation with the Secretary of HHS and the Administrator of USAID, shall promptly review existing United States and multilateral financial and economic sanctions to evaluate whether they are unduly hindering responses to the COVID-19 pandemic, and provide recommendations to the President, through the APNSA and the COVID-19 Response Coordinator, for any changes in approach.

ANNEX: ACTIVE SANCTIONS PROGRAMS:

<https://home.treasury.gov/policy-issues/financial-sanctions/sanctions-programs-and-country-information>

1. Balkans-Related Sanctions
2. Belarus Sanctions
3. Burma-Related Sanctions
4. Central African Republic Sanctions
5. Chinese Military Companies Sanctions
6. Countering America's Adversaries Through Sanctions Act of 2017 (CAATSA)
7. Counter Narcotics Trafficking Sanctions
8. Counter Terrorism Sanctions
9. Cuba Sanctions
10. Cyber-Related Sanctions
11. Democratic Republic of the Congo-Related Sanctions
12. Ethiopia-Related Sanctions
13. Foreign Interference in a United States Election Sanctions
14. Global Magnitsky Sanctions
15. Hong Kong-Related Sanctions
16. Iran Sanctions

17. Iraq-Related Sanctions
18. Lebanon-Related Sanctions
19. Libya Sanctions
20. Magnitsky Sanctions
21. Mali-Related Sanctions
22. Nicaragua-Related Sanctions
23. Non-Proliferation Sanctions
24. North Korea Sanctions
25. Rough Diamond Trade Controls
26. Russian Harmful Foreign Activities Sanctions
27. Somalia Sanctions
28. Sudan and Darfur Sanctions
29. South Sudan-Related Sanctions
30. Syria Sanctions
31. Syria-Related Sanctions
32. Transnational Criminal Organizations
33. Ukraine-/Russia-Related Sanctions
34. Venezuela-Related Sanctions
35. Yemen-Related Sanctions
36. Zimbabwe Sanctions