

Overview of Export Restrictions on COVID-19 Vaccines and their Components

Introduction

Trade policy instruments, mainly tariff and non-tariff measures either facilitating or restricting trade, have been used by various governments since the emergence of COVID-19.¹ To avoid suffering the same fate as HIV medicines, which in the past reached developing countries at a later stage than developed countries, the international community established the COVAX task force, led by the World Health Organization (WHO) and involving various other actors, to ensure equitable access to COVID-19 vaccines and ingredients. Nonetheless, this initiative is facing various obstacles because of vaccine nationalism, vaccine diplomacy, and shortages in supplies.² In particular, vaccine nationalism, in the form of export restrictions on COVID-19 vaccines and ingredients that were imposed and in some cases are still in force, has affected the process of vaccinating populations in developing and least developing countries.³ Countries or blocs imposing export restrictions include the United States (US), India, and the European Union (EU).⁴ Such restrictions are problematic, as only a very few (mainly developed) countries (Ireland, Belgium, France, Great Britain, the US, the Netherlands, Italy, India, Germany, and Canada) are exporting vaccines. Vaccine production and exportation require an extremely sophisticated supply chain consisting of: 1) the drug discovery and development process; 2) mass production; 3) distribution and administration; and 4) reverse logistics.⁵ This *Insight* will summarize current export restrictions and analyze the legality of these restrictions in the general framework of World Trade Organization (WTO) law.

Regulations Imposing Export Restrictions on COVID-19 Vaccines and Ingredients

The EU adopted Regulation 2021/111 on January 29, 2021, which made the export of certain products subject to an export authorization. The Regulation requires an export authorization to export “vaccines against SARS-related coronaviruses (SARS-CoV species) falling under CN code 3002 20 10” as well as “active substances including master and working cell banks used for the manufacture of such vaccines.”⁶ An export authorization can be delivered only when “the volume of exports is not such that it poses a threat to the execution of the Union Advanced Purchased Agreements concluded with vaccines manufacturers.”⁷ Exceptions to the requirement for such authorization include, among others, exports to specific countries mentioned within the Regulation.⁸ Despite the exceptions included in the Regulation, the EU was criticized for imposing such export restrictions, but stated in its defense that the restrictions represented a temporary scheme.⁹

In the same vein, India, after previously exporting COVID-19 vaccines and ingredients globally, has recently restricted these exports due to the deep COVID-19 crisis that has been rampaging across the state in recent weeks. Given the desperate need for the vaccine, the government is curbing COVID-19 vaccine exports, despite previous commitments made and contracts signed with foreign customers.¹⁰ This decision will affect mostly poor countries, and mainly those on the continent of Africa,¹¹ while countries which received the first doses of COVID-19 vaccines from India are struggling to manage these doses given the uncertainty resulting from the Indian export ban.¹²

Finally, the US has imposed restrictions on the export of key raw materials for the manufacture of COVID-19 vaccines, on the basis of the Defense Production Act (DPA), prioritizing domestic production and use of COVID-19 vaccinations and personal protective equipment.¹³ The DPA expressly mentions that the security of the US depends on the ability of the domestic industrial base to “supply materials and services for the national defense and to prepare for and respond to military conflicts, natural or man-caused disasters, or acts of terrorism within the United States.”¹⁴

WTO Law Applicable to Export Restrictions

The multilateral trade system is comprised of several treaties, including the General Agreement on Tariffs and Trade (GATT), the General Agreement on Trade in Services (GATS), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS

Agreement) and the Agreement on Technical Barriers to Trade (the TBT Agreement),¹⁵ which all have a bearing on vaccine global supply chains.¹⁶

Article XI(1) GATT states that “no prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licenses or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party *or on the exportation or sale for export of any product destined for the territory of any other contracting party*” (emphasis added). Article XIII adds a further condition, stating that a prohibition or restriction is not applicable “unless ... the exportation of the like product to all third countries is similarly prohibited or restricted.” These are the main provisions applicable in the case of export restrictions on COVID-19 vaccines and ingredients; the rest of the agreements (the GATS, TRIPS, SPS and TBT agreements) apply generally, given their focus on facilitating trade.

WTO Exceptions Applicable to Export Restrictions

The above-mentioned treaties contain provisions allowing member states to take certain measures for the protection of the health and safety of their populations. Article XI(2)(a) GATT allows “export prohibitions or restrictions temporarily applied to prevent or relieve critical shortages of foodstuffs or other products essential to the exporting contracting party.” Article XX(b) GATT provides another important exception, stating that “nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures ... necessary to protect human, animal or plant life or health.” Another exception is in Article XX(j) GATT, which allows essential measures to be taken for the “acquisition or distribution of products in general or local short supply.” It is worth mentioning in this context that, according to the Chapeau of Article XX, any export restriction measures shall not constitute a “means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.”

The rest of the agreements also provide exceptions. For instance, the TRIPS treaty includes several flexibilities, covering compulsory licensing, including public non-commercial use (TRIPS Art. 31),¹⁷ patent exceptions (TRIPS Art. 30), the Least Developed Country transition provisions (Paragraph 7 of the Doha Declaration on TRIPS and Public Health), and parallel imports (Paragraph 5(d) Doha Declaration).¹⁸ The SPS Agreement enables members to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, even if they restrict trade.¹⁹ Similarly, the TBT agreement allows trade restriction measures, stating that “no country should be

prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health.”²⁰

The exceptions provided under Article XI(2)(a) GATT provide members with legal means to adopt export restrictions on COVID-19 vaccines and ingredients under specific conditions: they must be temporarily applied, only to foodstuffs and essential products, and be made in the context of preventing and relieving crucial shortages. So far, it seems that the Indian, EU, and US measures meet these conditions, given that there is a shortage in all of these countries where restrictions are temporary, and they are imposed to address the current shortage.

Articles XX(b) and (j) GATT provide further legal support in this regard. Among the three examples provided, the US seems to be the one where the measures can be challenged, given the great progress made in vaccinating the population in contrast to the EU, which needs a longer duration, and India, where the situation is critical. Once the population of these countries is sufficiently vaccinated and there is an adequate supply locally, any ongoing export restrictions might be successfully challenged cases before WTO panels.

Ultimately, it would be up to other member states to challenge export restriction measures before the WTO panels. In the context of COVID-19 vaccines and ingredients, it is most likely that the measures taken in the general framework of these provisions are lawful if they satisfy all the conditions mentioned within the provisions. Numerous cases have been filed in previous years concerning trade restrictive measures adopted by member states on the basis of the exception provisions within trade treaties including some export restriction cases.²¹ The WTO panels found some of the measures to be completely justified, but in contrast others were found to be unlawful.²² Still, one has to keep in mind that WTO cases take years to obtain a final ruling from WTO panels, which is likely going to render any case concerning vaccine production and distribution moot.

Conclusion

Despite the criticisms made by international organizations and experts, WTO law provides states with leeway in a time of pandemic. This reality may pave the road in the post-coronavirus period for a discussion of whether the objectives of international trade should remain the facilitation of international trade for producers, or whether new Non-Trade Concerns (NTCs), such as preventing and mitigating pandemics, should be given priority.²³ NTC matters have already been examined in recent decades by the WTO panels, and the current situation may reopen and intensify this debate.²⁴

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¹ UNCTAD, *Covid-19 and NTMs*, <https://unctad.org/topic/trade-analysis/non-tariff-measures/covid-19-and-ntms>.

² World Health Organization, *COVID-19 and Vaccine Equity Panel: What Can the World Trade Organization Contribute?*, <https://www.who.int/director-general/speeches/detail/covid-19-and-vaccine-equity-panel-what-can-the-world-trade-organization-contribute>.

³ Health World, African, Caribbean Nations Support India at WTO on Covid Vaccine Supplies, THE ECONOMIC TIMES (Mar. 4, 2021), <https://health.economictimes.indiatimes.com/news/policy/african-caribbean-nations-support-india-at-wto-on-covid-vaccine-supplies/81329886>.

⁴ Sara Jerving, *Export Restrictions in India Could Stunt Africa's 2021 Vaccination Goals*, DEVEX (Apr. 1, 2021), <https://www.devex.com/news/export-restrictions-in-india-could-stunt-africa-s-2021-vaccination-goals-99567>; The Peninsula, *French President Urges US to lift Covid-19 Vaccines Exporting Restrictions* (May. 8, 2021), <https://www.thepeninsulaqatar.com/article/08/05/2021/French-President-urges-US-to-lift-Covid-19-vaccines-exporting-restrictions>.

⁵ Organisation for Economic Co-Operation and Development, *Using Trade to Fight Covid-19: Manufacturing and Distributing Vaccines*, OECD Policy Responses to Coronavirus (Feb. 11, 2021).

⁶ Commission Implementing Regulation (EU) 2021/111 (Jan. 29, 2021) making the exportation of certain products subject to the production of an export authorization, art. 1(1), <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0111&from=EN>.

⁷ *Id.* art. 1(4).

⁸ *Id.* art. 1(5).

⁹ *Coronavirus: WHO criticises EU Over Vaccine Export Controls*, BBC NEWS (Jan. 30, 2021), <https://www.bbc.com/news/world-europe-55860540>; Simon Evenett, *Export Controls on COVID-19 Vaccines: Has the EU Opened Pandora's Box?*, VOX EU (Feb. 11, 2021), <https://voxeu.org/content/export-controls-covid-19-vaccines-has-eu-opened-pandora-s-box>.

¹⁰ Jeffrey Gettleman, Emily Schmall & Mujib Mashal, *India Cuts Back on Vaccine Exports as Infections Surge at Home*, THE NEW YORK TIMES (Mar. 25, 2021), <https://www.nytimes.com/2021/03/25/world/asia/india-covid-vaccine-astrazeneca.html>.

¹¹ Jerving, *supra* note 4.

¹² Sara Jerving, *Countries May Stall COVID-19 Vaccinations due to Indian Export Limits*, DEVEX (Mar. 31, 2021), <https://www.devex.com/news/countries-may-stall-covid-19-vaccinations-due-to-indian-export-limits-99548>.

¹³ PTI, *U.S. Defends Restrictions on Export of COVID-19 Vaccine Raw Materials Amid India's Request to Lift Ban*, THE HINDU (Apr. 23, 2021), <https://www.thehindu.com/news/international/us-defends-restrictions-on-export-of-covid-19-vaccine-raw-materials-amid-indias-request-to-lift-ban/article34391251.ece>.

¹⁴ The Defense Production Act of 1950, as amended [50 U.S.C. § 4501 et seq.] Current through P.L. 115-232, enacted Aug. 13, 2018; Anshu Siripurapu, *What Is the Defense Production Act?*, COUNCIL ON FOREIGN RELATIONS (Jan. 26, 2021), <https://www.cfr.org/in-brief/what-defense-production-act>.

¹⁵ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 1867 U.N.T.S. 14, 33 I.L.M. 1143 (1994).

¹⁶ Farouq Ahmad Faleh Alazzam, Ali Jabbar Saleh, & Khaled Khalaf Abed Rabbo Aldrou, *Impact of Pandemic COVID-19 on the Legal Regulation of World Trade Activity Using the Example of the Medical Supplies*, LXXIII(7) WIADOMOŚCI LEKARSKIE 1521-1527 (2020).

¹⁷ Mark Eccleston-Turner and Michelle Rourke, *The TRIPS Waiver is Necessary, but it Alone is not Enough to Solve Equitable Access to COVID-19 Vaccines*, 25 ASIL INSIGHTS 9 (2021), <https://www.asil.org/insights/volume/25/issue/9>.

¹⁸ Medicines Law & Policy, *The TRIPS Flexibilities Database*, <http://tripsflexibilities.medicineslawandpolicy.org/>.

¹⁹ Agreement on the Application of Sanitary and Phytosanitary Measures (1995), arts. 2, 3, 5.

²⁰ Agreement on Technical Barriers to Trade (1995), Preamble; arts. 2, 5.

²¹ These include DS135: European Communities — Measures Affecting Asbestos and Products Containing Asbestos; DS332: Brazil — Measures Affecting Imports of Retreaded Tyres; DS161: Korea — Measures Affecting Imports of Fresh, Chilled and Frozen Beef; DS2: United States — Standards for Reformulated and Conventional Gasoline; DS58: United States — Import Prohibition of Certain Shrimp and Shrimp Products; DS394: China — Measures Related to the Exportation of Various Raw Materials dealing with export restrictions); DS366: Colombia — Indicative Prices and Restrictions on Ports of Entry.

²² Stuart MacLennan, *COVID Vaccines: Is it Legal for the EU to Restrict Exports?*, THE CONVERSATION (Feb. 4, 2021), <https://theconversation.com/covid-vaccines-is-it-legal-for-the-eu-to-restrict-exports-154527>.

²³ Joost Pauwelyn, *Export Restrictions in Times of Pandemic: Options and Limits Under International Trade Agreements* 54 J. WORLD TRADE 727 (2020).

²⁴ See, e.g., PAOLO DAVIDE FARAH & ELENA CIMA EDS., *CHINA'S INFLUENCE ON NON-TRADE CONCERNS IN INTERNATIONAL ECONOMIC LAW* (2016).