Export Controls on COVID-19 Vaccines:

Has the EU Opened Pandora's Box?

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31 January 2021

Last Friday (29 January 2021), the European Commission announced the implementation of a new export regime for COVID-19 vaccines. This regime came into effect on 30 January 2021 and is deemed temporary as it is scheduled to lapse on 31 March 2021. The accompanying Commission Implementing Regulation (2021/111) contains provisions mandating information disclosure by COVID-19 vaccine producers that have Advanced Purchased Agreements (APAs) with the European Commission as well as establishing an export authorisation scheme.[3]

To the best of my knowledge, in taking this step the European Union has become the first major trading power to impose export controls on COVID-19 vaccines.[4] For sure, recently there was a scare that India had banned export of such vaccines, following a statement by the Chief Executive Officer of the Serum Institute of India. However, the government in New Delhi strenuously denied a ban existed and sought to reassure a number of foreign governments that approached it.[5] Moreover, other governments appear to have tied the receipt of state largesse to vaccine producers to export limits.[6] Going forward the critical question is whether other

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[3] The text of the regulation is available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0111&from=EN. This text includes the amendments relating to exports to Northern Ireland, which caused considerable consternation at the end of last week.
[4] Even if these export controls are not the first imposed by a major trading power, they are of significant public policy import both within the European Union and for the world trading system. The argument that the EU's new regime is acceptable because another government imposed a similar regime before it is inane.
[5] See, for example, Indian denials in https://www.hindustantimes.com/india-news/misinformation-health-ministry-says-no-ban-on-export-of-covid-19-vaccine/story-ojAzo9BFLd1ZecdqQM51yN.html.
[6] See, for example, a German measure announced on 10 December 2020, in particular article 6(1): https://www.bmwi.de/Redaktion/DE/Downloads/B/bekanntmachung-foerderrichtlinie-produktionsanlagen-von-point-of-care-antigentests.pdf?__blob=publicationFile&v=4. Legal counsel have noted that the U.S. Defense Production Act can be invoked such that "priority contracts" be fulfilled by local manufacturers, which may have the effect of curtailing delivers to foreign buyers (see https://www.law360.com/articles/1346836/how-defense-production-act-may-affect-vaccine-supply-chain). To the extent that such provisions are invoked in the case of COVID-19 vaccines they could disrupt exports too. To summarise, there are both covert and overt ways to curb the export of COVID-19 vaccines.

governments will impose export control regimes on COVID-19 vaccines, related or essential goods, or take other trade restrictive or punitive measures in response.

While domestic imperatives will surely shape the reaction of the EU's trading partners, deliberations in foreign capitals are likely to be influenced by their assessment of the effects of EU's move. This note focuses, therefore, on two matters. First, whether the Commission Implementing Regulation as announced and associated communication strategy is likely to allay the fears of trading partners. Second, on the options available to foreign governments, bearing in mind that not all of them have COVID-19 vaccine manufacturing sites within their jurisdictions and are consequently dependent on imported vaccines for their national inoculation strategies.

Seven grounds for legitimate concern on the part of the European Union's trading partners

Notwithstanding the declaration made in the Implementing Regulation that "It is not the intention of the Union to restrict exports any more than absolutely necessary, and the Union remains fully committed to international solidarity and strongly supports the principle that any measures deemed necessary to prevent or relieve critical shortages are implemented in a manner that is targeted, transparent, proportionate, temporary and consistent with WTO obligations,"[7] from what is known at this time of writing the European Union's trading partners should be concerned about the following features of the proposed export control regime.

The standard for authorising exports of COVID-19 vaccine is unclear

The standard of authorising exports of COVID-19 vaccine is laid out in Article 1(4) of the Commission Implementing Regulation: "The competent authority shall deliver an export authorisation only where the volume of exports is not such that it poses a threat to the execution of Union APAs concluded with vaccines manufacturers."

This statement begs the following questions and observations. What constitutes a threat in this context? Do volumes of exports above a given threshold constitute a threat? If so, what is that threshold, if indeed there is a single threshold? More generally, in what manner and with what evidence will such a threat be assessed?

Given the Shorter Oxford English Dictionary defines a threat as "a declaration of an intention to take some hostile action; esp. a declaration of an intention to inflict pain, injury, damage, or other punishment for something done or not done…" will evidence of intention be required? Or was the Commission's intent to allow for the prohibition of exports when there is too high a probability that a vaccine manufacturer cannot meet its contractual obligations to the European Union in the future?

In this respect it is revealing that the preamble to the Implementing Regulation contains the following statement: "Export authorisation should be granted by the Member States where products covered by this regulation are manufactured to the extent that the volume of exports is not such that it poses a threat to the continuous supply of the vaccines necessary for the execution of the APAs between the Union and vaccines manufacturers" (paragraph 7).

[7] Paragraph 9 of the preamble.

If the latter statement affects the implementation of the standard, the use of the word "continuous" could imply that an export authorisation decision taken on a given date may be influenced by the relevant official's assessment of the future delivery of COVID-19 vaccines by the manufacturer in question. What factors, beyond speculation, will influence such a forward-looking assessment? In light of these significant deficiencies in design, what assurance is there that the EU's new export control regime will generate targeted and proportionate outcomes?

Authorisation of exports may be arbitrary

Notwithstanding the Commission's attempt to outline a standard for export authorisation, in light of recent statements by senior European Commission officials, trading partners may have legitimate concerns that the authorisation of exports will be arbitrary.

On 27 January 2021, Prime Minister Trudeau of Canada spoke with European Commission President von der Leyen. According to the Canadian read-out of that call "President von der Leyen provided assurances that the proposed European Union vaccine export transparency mechanism is not intended to disrupt exports of vaccines to Canada."[8] Subsequently, Canadian Trade Minister Ng spoke with European Trade Commissioner Dombrovskis. According to the Canadian read-out of the latter conversation: "Executive Vice-President Dombrovskis reiterated assurances to Minister Ng that the mechanism will not affect vaccine shipments to Canada."[9] Later news reports suggest that President von der Leyen has made similar assurances to UK Prime Minister Johnson.[10]

If the implementation of the new EU export control regime on COVID-19 vaccine is supposed to be implemented on objective, transparent, and proportionate grounds, how can senior European Commission officials give assurances in advance to a trading partner concerning the export of vaccines? Is the authorisation process rule-based or influenced by diplomatic considerations and therefore arbitrary?

The export control regime may not lapse on 31 March 2021

The European Commission has made much of the new export control regime being temporary, this being one of the criteria agreed at the G20 to guide trade policy interventions during the COVID-19 pandemic.

However, such statements are belied by the reasoning presented in the Commission Implementing Regulation. Paragraph 17 of the preamble states: "It is considered that measures should remain in force until 31 March 2021, when full production capacity for COVID-19 vaccines in the EU has been installed and the risk of shortages and diversion of supplies will be reduced."

This statement does not state for sure that the regime will lapse on 31 March 2021. More importantly, the date is linked to the establishment of full production capacity of COVID-19 vaccines. Trading partners may worry that the scheme won't be removed if such capacity has

[8] https://pm.gc.ca/en/news/readouts/2021/01/27/prime-minister-justin-trudeau-speaks-president-european-commission-ursula

[9] https://www.canada.ca/en/global-affairs/news/2021/01/minister-ng-speaks-with-european-commissioner-for-trade-about-vaccine-exports.html

[10] See https://www.ft.com/content/93555276-fc30-41cc-8f94-ca968e3622aa.

not been established. Given recent press reports concerning delays in expanding production capacity of COVID-19 vaccines in the European Union this is far from a hypothetical concern.

Furthermore, given how far behind many EU Member States are in inoculating their populations, and with limited prospects of this changing by 31 March 2021, political pressure to extend the export control regime cannot be ruled out. Only time will tell if the EU's export control regime will be as short-lived as presently advertised.

The strict timetables in the Implementing Regulation may not deliver fast authorisation decisions

On the face of it, the Commission Implementing Regulation lays out tight deadlines for the respective implementing agencies in the Member States and for the European Commission. Should these deadlines be respected, then a vaccine manufacturer and implicated buyers abroad (including foreign governments) would learn in a matter of days where matters stand with respect to an export authorisation request.

However, there are two practical reasons why delays may occur. First, the Commission Implementing Regulation only requires a EU Member State to make a decision two days after receiving "all required information" (presumably from the manufacturer seeking to export, although that is unclear). A Member State seeking to exercise leverage over a vaccine manufacturer may escalate information demands.

Second, the Implementing Regulation makes provision for circumstances where the Member State and the European Commission are at odds over an application for an export authorisation. On paper, the European Commission's decision trumps that of a Member State. In the case where the Commission decides to allow export but the Member State opposes, since it is the latter which operates the customs houses in their territory, what prevents the Member State from delaying and frustrating export of a vaccine shipment? The Member State may be in breach of EU rules but, while any dispute with the European Commission continues and exports are frustrated, the interests of the destination trading partner are adversely affected.

In sum, the provisions in the Commission Implementing Regulation to prevent delays are not watertight.

Trans-shipments through the European Union may be implicated

What of COVID-19 vaccines or their ingredients shipped from outside the European Union to another country outside the European Union via a port or airport inside the EU? Suppose a vaccine manufacturer X which has an Advanced Purchased Agreement with the European Commission transhipps COVID-19 vaccines through the EU as it seeks to fulfil a contract with a non-EU government. If the European Commission is of the view that company X is not meeting its obligations under the Advanced Purchased Agreement with the European Union, then what stops the transhipment from being impounded?

Given the centrality of European ports and airports in global transportation networks, this is not merely a theoretical consideration. Plus, there were cases in 2020 where medical goods being transhipped through the European Union were delayed or frustrated outright by the implementation of the export control regime on personal protective equipment. The EU may have designed the new control regime to influence the allocation of vaccines produced within

its borders, but would it forgo the leverage over a vaccine manufacturer that tranships through the EU?

Export authorisation decisions may be conditional on commitments to import vaccines into the European Union

Nothing in the Commission Implementing Regulation prevents the European Commission or a Member State conditioning approval of an export authorisation request on a manufacturer diverting COVID-19 shipments to the European Union. For example, a vaccine manufacturer that had production facilities in Germany and the United Kingdom may find that its export authorisation requests from its facilities in the former are made conditional on increased vaccine shipments to the European Union from the latter. This could divert vaccine contracted exports from the United Kingdom to another non-EU member, such as South Africa. The implication being that bilateral vaccine trade outside of the European Union can be curtailed or disrupted by the new EU export control regime.

Exports to trading partners exempted from the control regime may still be affected

In its communication strategy European Commission officials have highlighted that vaccine exports to many trading partners (in the European neighbourhood as well as to lower- and middle-income developing nations) will fall outside the new export control regime. Formally, this appears to be the case (see article 1(5) of the Commission Implementing Regulation) but, in reality, matters may turn out differently.

The European Commission and the Member States will almost certainly be concerned that the integrity of the new export control regime is not undermined by shipments to exempted trading partners being sold on to non-exempted nations. A vaccine manufacturer seeking export authorisation may state that the "final recipient" is located within an exempted trading partner, but that may not be enough to satisfy EU officials reviewing the authorisation request. To verify the identity of the final recipient the officials in question may demand sight of the contract between the vaccine manufacturer and the buyer in the exempted trading partner. Even then, the European officials in question may want to satisfy themselves that the buyer will deploy the vaccines in the exempted trading partners.

In practice, falling outside the new EU export control regime may not afford much protection to a trading partner from disruption to COVID-19 vaccine shipments from the EU. Such disruption is more likely the greater are the delays in the months ahead in vaccine inoculation within the European Union.

Opening Pandora's Box? Five scenarios going forward.

As there are several grounds for concern about the new EU's export control regime for vaccines, attention turns to how other governments might react. Some trading partners may well wait and see how the European Commission and the Member States implement the new export control regime. After all, steps could be taken to address the concerns raised above. Plus, the European Commission may deploy an effective communications strategy that reassures trading partners, which would require describing in detail how the implementation of this control regime won't harm trading partners in practice. The combination of credible,

transparent implementation and convincing communication may prevent a backlash from trading partners and Pandora's Box from opening.

Other governments may be under such pressure from their populations to tackle the COVID-19 pandemic that they will not wait for the European Union to establish its *bone fides*. What trade policy options do they have to secure COVID-19 vaccine or to ensure that contracted vaccines are actually delivered, including those supposed to be delivered from European production facilities? I should make clear right away that the options/scenarios described below are not recommendations. They are not necessarily mutually exclusive either. Most of the options described below would already complicate a fractious debate over the equitable global distribution of COVID-19 vaccines.

My purpose in laying out these options/scenarios is to highlight what is at stake for both the European Union and globally if Pandora's Box is opened—that is, if many governments feel compelled to react to the European Union's new export control regime with their own measures. Surely European policymakers realise that other trading partners face domestic political constraints too and that the availability of vaccines is central to many governments plans for dealing with this public health emergency and associated economic malaise?

If the widespread adoption of export curbs on medical goods and medicines during the first wave of COVID-19 infection is anything to go by, then one must contemplate scenarios where other governments follow the European Commission and take restrictive measures. To recall, at their peak in the second quarter of 2020 a total of 137 curbs on foreign shipments of medical goods and medicines imposed by 72 nations were in force.[11] Arguably, COVID-19 has greater political salience than face masks and other personal protective equipment, a statement that in no way diminishes the importance of the latter in these fraught times.

In identifying options that the trading partners of the European Union could potentially contemplate, it is worth noting that at present a limited number of countries manufacture and export COVID-19 vaccines. This is in contrast to the large number of governments seeking to secure vaccines for their populations. Evidently, one option available to nations with COVID-19 vaccine manufacturers is to introduce some form of export control of their own, compounding the disruption likely to follow from the EU's measure. Governments of other nations may consider limiting exports of ingredients and equipment needed to manufacture, store, or distribute COVID-19 vaccines or confiscate vaccines in transit. In short, vaccine nationalism could spread along the COVID-19 vaccine supply chain.

For governments whose manufactures neither produce COVID-19 vaccines nor associated ingredients and distribution items, two other options exist. The first is to curb the export of other essential goods, such as food, energy, medical goods, medicines, or reagents, to the nations which can export COVID-19 vaccines, for use domestically or for diplomatic leverage.

The second is to take action against the foreign affiliates of trading partners that have impeded the export of COVID-19 vaccine. European multinationals could be hit by discriminatory taxes and regulations or by revocation of their intellectual property, examples of so-called cross-retaliation for which there are precedents in the disputes brought to World Trade Organization. Given the centrality of intellectual property to the business models of Europe's successful companies operating internationally, the potential for such cross-retaliation ought to be a first-order concern in European boardrooms.

[11] Throughout all of 2020 a total of 209 export restrictions on medical goods and medicines were imposed by governments worldwide. For the latest Excel sheet documenting such restrictions please write to me.

The implications for the commercial interests of the European Union of these four scenarios are sketched out in the table below. If opening Pandora's Box looks like it will result in significant collateral damage to European public health (by disrupting the COVID-19 supply chain), access to essential goods, and the commercial viability of overseas investments, then a fifth scenario has to be considered—a rethink by European Union policymakers. This may prompt the European Union to withdraw its export control regime quickly, as it did with the export measures taken on personal protective equipment last year.

The calculus articulated last week by political leaders in the European Union took little account of the risks to European public health and prosperity should foreign governments take stringent measures in response to the new EU export control regime on COVID-19 vaccines. Having dropped the ball on the roll out of COVID-19 vaccines, public health officials should not be allowed to inflict collateral damage on the world trading system. As we have learned from history, when it comes to trade restrictions, all too often governments act in haste and repent at leisure. We would all be well served if the European Union became an exception to that rule, the more so in light of the EUs leadership role in defence of the rules-based global trading system.

Table: Description of the five scenarios.

Scenario	Description	Implications for EU interests	Implications for other nations
Export curbs on COVID-19 vaccines spread.	Other COVID-19 vaccine producing nations would control/limit/ban exports of the manufactured vaccine. Some vaccine producing nations may choose not impose export curbs, instead taking this opportunity to ramp up their "vaccine diplomacy" strategies.	To the extent that the EU's vaccine needs can be met by manufacturing facilities within its borders, then this may not directly affect the rate of inoculation in the EU.	COVID-19 vaccine importing nations will be harmed, including many developing nations. The extent of harm depends on number of COVID-19 producing nations that impose export curbs and on whether "vaccine diplomacy" by China, India, and Russia is ramped up. Such countries are likely to blame the EU for starting this wave of export controls, making it harder for the EU to lead on the trade and health initiative at the WTO.
Export curbs spread along the COVID-19 vaccine supply chain	Nations whose manufacturers produce the ingredients for COVID-19 vaccines or the items necessary to transport, store, or administer effectively the vaccine impose export curbs. These steps could be coupled with demands for access to the vaccine, resulting potentially in **managed trade** along the COVID-19 vaccine supply chain.	COVID-19 vaccine manufacturers in the EU face shortages of ingredients and related goods imported from outside the EU. EU public health bodies may face shortages in medical goods needed to conduct COVID-19 inoculation. COVID-19 vaccine rollout in the EU is further delayed, resulting in greater loss of life and economic recovery is further postponed.	Further threats to the supply of COVID-19 vaccine to importing nations, with adverse implications for COVID-19 vaccine rollout and economic recovery.
Export curbs spread to other "essential goods"	Nations that produce neither the COVID-19 vaccine or goods implicated in its supply chain could curb exports of "essential goods" (including but not limited to food) to the European Union or worldwide. This step could be coupled with demands for access to the vaccine,	Disruption of foreign supply of energy, food, and medicines to the European Union. Clearly, the extent of harm depends on number of trading partners engaging in these export curbs.	Disruption of foreign supply of energy, food, and medicines depends on whether the curbs are directed against the European Union or worldwide.

Scenario	Description	Implications for EU interests	Implications for other nations
	resulting potentially in broader resort to **managed trade**.		
Cross-retaliation against the foreign operations and intellectual property of EU multinationals	Nations that expected to import COVID-19 vaccines from the European Union impose higher taxes on the foreign affiliates of EU multinational companies in their jurisdiction and/or could temporarily or permanently revoke the intellectual property of those affiliates.	Such moves threaten the operations and profitability of the trillions of euros of EU multinational investments abroad.	Lower levels of European multinational investments in developed and developing countries could slow post-COVID-19 economic recovery. Revoking intellectual property could reduce long-term pandemic resilience globally.
Export control regime withdrawn by the EU	In face of threats to European Union commercial interests (including potentially those outlined in the four scenarios above), the European Union abandons its export control regime for COVID-19 vaccine.	The EU could revisit its public-private partnerships to ramp up production of COVID-19 vaccines. Transparent approaches could be taken to split the distribution of additional vaccine production within and outside the European Union. The EU could reclaim its leadership of the trade and health initiative at the WTO.	If abandonment of the export control regime was coupled with greater EU support for production and export (alone or in cooperation with other COVID-19 vaccine producing nations), then the supply of vaccines to third parties may actually increase. Otherwise, the status quo would be restored.