

# Brexit Bulletin—EU backtracks on invoking Article 16 of the Northern Ireland Protocol as part of coronavirus (COVID-19) vaccine export authorisation scheme

The European Commission issued a statement on 29 January 2021, announcing measures to address the ‘lack of transparency’ of coronavirus (COVID-19) vaccine exports outside the EU, in light of challenges securing vaccine supply in the quantities required to tackle the spread of the virus throughout the EU. Among the measures announced was a requirement making the export of certain coronavirus vaccines subject to prior authorisation by EU Member States. Commission Implementing Regulation (EU) 2021/111 was adopted accordingly, requiring Member States to seek an advance opinion from the Commission before granting export authorisations for vaccine products covered by Advanced Purchased Agreements. The Commission stated that the intention was to restrict vaccine exports no more than ‘absolutely necessary’ to ensure adequate supply to the EU ‘without impacting on the Union’s international commitments’. However, in introducing the measure, the Commission also announced it would invoke Article 16 of the Northern Ireland Protocol to the Withdrawal Agreement, adopting unilateral safeguards overriding its commitment not to introduce quantitative restrictions on exports moving between the EU and Northern Ireland. Following sharp criticism from the UK and calls for the EU to ‘urgently clarify its intentions’, the Commission reversed its decision to trigger Article 16, promising that the Northern Ireland Protocol would be unaffected in the process of finalising the measures. Laura Rees-Evans, counsel at Fietta LLP, recaps on these developments and their significance in the context of the Withdrawal Agreement.

This analysis was first published on Lexis®PSL on 1 February 2021 and can be found [here](#) (subscription required).

## What was published?

The European Commission update on transparency and authorisation mechanism for exports of coronavirus vaccines is accessible [here](#).

Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation is accessible [here](#).

The Northern Ireland Protocol to the Withdrawal Agreement is accessible [here](#). Article 16 of the Northern Ireland Protocol provides:

### ‘Safeguards

1. If the application of this Protocol leads to serious economic, societal or environmental difficulties that are liable to persist, or to diversion of trade, the Union or the United Kingdom may unilaterally take appropriate safeguard measures. Such safeguard measures shall be restricted with regard to their scope and duration to what is strictly necessary in order to remedy the situation. Priority shall be given to such measures as will least disturb the functioning of this Protocol.

2. If a safeguard measure taken by the Union or the United Kingdom, as the case may be, in accordance with paragraph 1 creates an imbalance between the rights and obligations under this Protocol, the Union or the United Kingdom, as the case may be, may take such proportionate rebalancing measures as are strictly necessary to remedy the imbalance. Priority shall be given to such measures as will least disturb the functioning of this Protocol.

3. Safeguard and rebalancing measures taken in accordance with paragraphs 1 and 2 shall be governed by the procedures set out in Annex 7 to this Protocol.’

The European Commission statement retracting the decision to invoke Article 16 is accessible [here](#).

### **What were the circumstances?**

Rees-Evans outlines the background to the measures:

‘On 29 January, the European Commission [announced](#) that it had adopted a new [implementing regulation](#), subjecting exports of certain COVID-19 vaccines to certain countries to mandatory pre-authorisation by Member States. The regulation covers “exports from companies with whom the EU has concluded Advance Purchase Agreements” (APA), other than those to which a specific exemption applies under Article 1(5). Article 1(5) provides that export authorisations will not be required *inter alia* for supplies for humanitarian aid purposes, for vaccines delivered through COVAX, or for supplies destined for certain of the EU’s neighbouring countries and economies (this includes the member States of the European Free Trade Area (EFTA), Western Balkan States, a number of northern African States, and a number of Middle Eastern countries).

There is no exemption from the requirement for authorisation for exports to countries like the UK, US and Canada. That means that the export of COVID-19 vaccines by an APA counterparty from the EU to one of those countries—or any other non-exempt country—is in principle prohibited without an export authorisation from the “competent authorities of the Member State where products covered by this regulation are manufactured” (Article 1). Article 1 also provides that an export authorisation shall only be delivered “where the volume of exports is not such that it poses a threat to the execution of Union APAs concluded with vaccines manufacturers.”

When the announcement of the regulation was initially made, the EU invoked Article 16 of the Protocol on Ireland/Northern Ireland (part of the Withdrawal Agreement) to justify a departure from Article 5(5) of the Protocol, which prohibits quantitative restrictions on exports moving between the Union and Northern Ireland. Article 16 allows either Party unilaterally to “take appropriate safeguard measures” if application of the Protocol “leads to serious economic, societal or environmental difficulties that are liable to persist”.’

### **What is the legal significance of these measures?**

Although the Commission considered the measures to be justified and proportionate in the circumstances, the announcement of the measures proved controversial, particularly in Northern Ireland. The justification for invoking Article 16 was immediately called into question. Shortly after the announcement, Commission President, Ursula von der Leyen, held follow-up talks with Taoiseach Micheal Martin and Prime Minister Boris Johnson to clarify the situation. The decision to invoke Article 16 was then withdrawn, as Rees-Evans explains:

‘The European Commission justified its resort to Article 16 as necessary “to avert serious societal difficulties due to a lack of supply threatening to disturb the orderly implementation of the vaccination campaigns in the Member States.”

Questions have been and will be asked about whether the required threshold under Article 16 was met in the circumstances. But the way in which the EU invoked Article 16 was also problematic. Article 16(3) provides that safeguard measures are governed by the procedures set out in Annex 7 of the Protocol. Annex 7, in turn, requires a Party considering taking safeguard measures “without delay” to notify the other Party and provide all relevant information. Only when “exceptional circumstances requiring immediate action exclude prior examination” may a Party “apply forthwith the protective measures strictly necessary to remedy the situation”. It is questionable whether such circumstances existed as to justify such swift and unilateral action as that threatened.’

## What happens next?

The Commission has stated that its rollout of the vaccine transparency and export authorisation scheme will not impact the operation of the Northern Ireland Protocol, and it has retracted its decision to invoke Article 16, at least for now. As Rees-Evans comments:

In a [statement](#) issued by the European Commission after reversing its initial decision to invoke Article 16, the Commission confirmed that in finalising the measure, it will “ensure that the Ireland/Northern Ireland Protocol is unaffected” and that it “is not triggering the safeguard clause” (ie Article 16). The Commission’s initial decision appears to have been motivated by a desire to eliminate any possibility that the new regulation could be undermined through the export of vaccines from the EU to the UK (or indeed other non-exempt countries) through Northern Ireland.

In the next paragraph of the same statement, the Commission stated that should “transits of vaccines and active substances toward third countries be abused to circumvent the effects of the authorisation system, the EU will consider using all the instruments at its disposal.” In other words, the Commission seems reluctant to close the door to invoking Article 16, should Northern Ireland be used as a way to bypass the EU’s new vaccine export requirements. The regulation gives it a mechanism to monitor that, since Article 2(1) requires that the request for export authorisation includes information “on the number of vaccine doses of goods covered by this Regulation distributed in the Union since 1st December 2020 [...] as well as information on the number of vaccine doses of goods covered by this Regulation distributed in Northern Ireland since the entry into force of the Regulation.” Presumably, however, the Commission will proceed with more caution before resorting to Article 16 in future.’

Sources:

- [Commission puts in place transparency and authorisation mechanism for exports of COVID-19 vaccines](#)
- [Commission statement on the vaccine export authorisation scheme](#)
- [Commission Implementing Regulation \(EU\) 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation](#)

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