



COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

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This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

LATEST KEY DEVELOPMENTS

Competition & State Aid

- European Commission comments on transatlantic relations in post-pandemic world, including building resilient supply chains
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- Executive Vice President and European Commissioner for Trade comments on access to COVID-19 vaccines ahead of WTO Ministerial Conference

Medicines and Medical Devices

- EMA ends rolling review of antibodies for treating COVID-19 following withdrawal by developer

Cybersecurity, Privacy & Data Protection

- European Commission adopts Delegated Regulation to the Radio Equipment Directive to strengthen cybersecurity
- European Commission adopts EU Digital COVID Certificate Equivalence Decisions for Armenia and the United Kingdom

COMPETITION & STATE AID

European Commission comments on transatlantic relations in post-pandemic world, including building resilient supply chains (see [here](#))

On 12 November 2021, Executive Vice-President and Competition Commissioner Margrethe Vestager addressed EU-US relations, particularly in view of emerging from the COVID-19 crisis and the need for resilient supply chains.

Commissioner Vestager reminded that at the pandemic's peak, European vaccine manufacturers were unable to source components from the US, creating shortfalls in production. To address EU dependencies in strategic sectors, in May 2021, the Commission assessed 5,200 products imported into the EU in sensitive sectors (see [here](#)). It is focusing on 34 of these products where the EU is considered to have strategic dependencies from third countries (notably in raw materials, chemicals and pharmaceutical ingredients) and where the Commission believes that the market cannot be expected to solve dependencies on its own through diversification.

Similarly, the US also undertook a supply chain review, which identified vulnerable areas that largely overlapped with those identified by the European Commission.

Commissioner Vestager's comments focused on the field of semiconductors, where she indicated that a serious current shortage is undermining recovery from the pandemic. She noted that both the EU and the US have set targets to expand innovative capacities in the design and manufacture of semiconductors. On EU initiatives, Commissioner Vestager referred in particular to:

- A [proposal for a European Chips Act](#), expected in the first half of 2022, which would aim to make Europe more competitive by promoting a state-of-the-art European chip ecosystem by strengthening innovation, production capacity, as well as security of supply through a framework for international cooperation and partnership. The proposed Act would also aim at coordinating EU and national investment along the value chain.
- Investment through [Important Projects of Common European Interest \(IPCEI\)](#). IPCEIs are intended to facilitate, within the State aid framework, the emergence of large-scale cross-border projects of significant benefit to the EU economy and its citizens by addressing perceived market failures in strategic value chains. A second IPCEI concerning semiconductors is under preparation, following the first IPCEI, approved by the Commission on 18 December 2018 following a joint notification by France, Germany, Italy and the UK to give €1.75 billion in public support to a joint research and innovation project in microelectronics, to be completed by 2024 (see [here](#)).

Commissioner Vestager also emphasized the importance of avoiding a detrimental subsidies race. State aid may be justified only if it is deemed necessary to get a project off the ground and provided that competition distortions are sought to be minimized and that benefits are to be shared widely and without discrimination across the European economy. In this respect, she indicated that the anticipated European Chips Act would seek to provide a coordinated EU approach.

Finally, Commissioner Vestager referred to the Summit on Global Supply Chain Resilience chaired by US President Biden on 31 October 2021 in the context of the G20 Summit (see [here](#)), which she viewed as a “good start” towards “*building more common ground... and find[ing] agreements that will*

outlast the crises of tomorrow.”

European Commission approves new and amended Member State measures to support the economy (see [here](#) and [here](#))

Since the onset of the coronavirus outbreak, the Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the Temporary Framework.

The Temporary Framework, adopted in March 2020, is currently applicable until 31 December 2021.

- €73 million Italian scheme to support bus operators in the context of the coronavirus outbreak.
- €15.34 million Bulgarian scheme to support the tourism sector in the context of the coronavirus outbreak.
- €51 million Bulgarian wage compensation scheme to support companies and self-employed persons in the context of the coronavirus outbreak.
- €4.5 billion Italian scheme to support companies and the economy in the context of the coronavirus outbreak.
- €245 million Italian scheme to support the textile, fashion and accessories sector in the context of the coronavirus outbreak.
- €208 million German federal ‘umbrella’ scheme to support companies active in trade fairs and congress sector for damage suffered in the context of the coronavirus outbreak.
- €800,000 Maltese scheme to support fishers in the context of the coronavirus outbreak.
- Latest modification to €868 million Italian scheme to support private employers in the tourism, spas, commerce and cultural or recreational sectors, in particular to extend its sectoral scope.
- Latest modification to €122.5 million Dutch scheme to support special transport providers, in particular to extend the eligible period to cover the period from 14 October 2020 to 30 September 2021 and to increase the overall budget by €402.5 million.
- Latest modification to €200 million Slovak scheme (SA.57599) and €100 million Slovak scheme to support undertakings (SA.59996), in particular to extend the duration of the schemes until 31 December 2021 and to increase the cumulation ceiling of the second scheme to EUR 1.8 million.

TRADE / EXPORT CONTROLS

Executive Vice President and European Commissioner for Trade comments on access to COVID-19 vaccines ahead of WTO Ministerial Conference (see

On 11 November 2021, Executive Vice President and European Commissioner for Trade, Valdis Dombrovskis provided remarks following the Foreign Affairs Council (Trade) meeting of the Council of the European Union.

In particular, Commissioner Dombrovskis commented on preparations for the 12th World Trade Organization (WTO) Ministerial Conference from 30 November to 3 December 2021 in Geneva. He reiterated that a strong WTO is vital for the global trading system, which is why the EU is actively engaged

[here](#))

in the run-up to the Ministerial Conference.

Commissioner Dombrovskis indicated that the EU has a particular interest in the issue of trade and health. Universal and fair access to COVID-19 vaccines is a top priority for the EU, which is engaged in intensive discussions on this issue.

He emphasized the EU's view that intellectual property (IP) should not be a barrier to ramping up vaccine production, which could be achieved by facilitating the use of compulsory licenses (see also [Jones Day COVID-19 Update No. 51 of 15 June 2021](#)).

The Foreign Affairs Council (Trade) indicated that the issue of how to provide a common IP response to COVID-19 would be part of the discussions at the WTO Ministerial Conference (see [here](#)). The two main proposals under discussion in anticipation of the Ministerial Conference are:

- the revised Trade Related Aspects of Intellectual Property Rights (TRIPS) waiver proposal, first put forward by South Africa and India (see [here](#)); and
- the EU proposal for a draft General Council Declaration on the TRIPS Agreement and Public Health in the circumstances of a pandemic, focusing on the measures related to intellectual property, as provided for in the TRIPS Agreement, in the circumstances of the COVID-19 pandemic and other pandemics (see [here](#)).

In addition, a draft Ministerial declaration on trade and health, crisis preparedness and resiliency may also be issued.

The Foreign Affairs Council (Trade) will meet again in the margins of the Ministerial Conference in view of setting out the position to be taken on behalf of the EU.

MEDICINES AND MEDICAL DEVICES

EMA ends rolling review of antibodies for treating COVID-19 following withdrawal by developer (see [here](#))

On 2 November 2021, EMA announced the end of its rolling review of bamlanivimab and etesevimab for an eventual marketing authorization application after the developer of the treatment, Eli Lilly Netherlands BV, informed EMA that it would no longer pursue a marketing authorization application for the treatment.

Bamlanivimab and etesevimab are antibodies designed to treat COVID-19 by attaching to SARS-CoV-2.

The reason for ending the rolling review is that EMA's human medicines committee (CHMP) determined that prospective concurrent validation is required for the submission of a formal marketing authorization application. However, Eli Lilly stated that it is not in a position to generate such required data due to current demand from EU Member States, as the company anticipates that no additional manufacturing campaigns will be needed for the foreseeable future.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission adopts Delegated Regulation to the Radio Equipment Directive to strengthen cybersecurity (see [here](#))

On 29 October 2021, the Commission adopted a Delegated Regulation to the Radio Equipment Directive* to strengthen cybersecurity and privacy when “internet-connected radio equipment” (i.e. certain wireless devices) are sold on the EU market. In recent years and particularly due to the COVID-19 pandemic, reliance on radio equipment devices connected to the internet for professional and personal purposes has greatly increased, such as the use of smartphones, electronic cameras, and tablets.

The Radio Equipment Directive establishes a regulatory framework for placing radio equipment on the EU market. Article 3 of the Directive sets out essential requirements for the construction of radio equipment. Article 3(3) of the Directive empowers the Commission to adopt a Delegated Regulation which specifies categories or classes of radio equipment for which additional requirements apply.

More particularly, as concerns data privacy, fraud prevention, and network security, the Delegated Regulation requires that:

- Radio equipment capable of processing personal data, traffic or location data must incorporate safeguards to ensure that the personal data and privacy of the user and the subscriber are protected; and
- Inter-connected radio equipment that enables the holder or user to transfer money, monetary value or virtual currency must be constructed such that it supports certain features ensuring protection from fraud; and
- Wireless devices and products must incorporate features to avoid harming communication networks and prevent the possibility that these are used to disrupt website or other services functionality.

The Commission will call upon the European Standardisation Organisation to develop relevant standards to support manufacturers in complying with the new legal requirements.

Following the Commission's adoption, the European Parliament and the Council will have two months to examine the proposed Delegated Regulation. If no objection is raised, the delegated act will be published, and a 30-month transitional period is foreseen in view of seeking to enable manufacturers to adapt to its provisions.

The Delegated Regulation will be complemented by a Cyber Resilience Act, covering additional products and looking at the products' whole life cycle (see [here](#)). The Delegated Regulation and Cyber Resilience Act are part of the new EU Cybersecurity Strategy presented in December 2020 (see [here](#)).

The accompanying Q&A (see [here](#)) and impact assessment report (see [here](#)) provide further details on the adopted Delegated Regulation.

* *Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC*

European Commission adopts EU Digital COVID Certificate Equivalence Decisions for Armenia (see [here](#)) and the United Kingdom (see [here](#))

On 28 October 2021, the Commission adopted two decisions to ensure that COVID-19 certificates issued by Armenia and the United Kingdom are considered equivalent to the EU Digital COVID Certificate (see also *Jones Day COVID-19 Updates* [No. 55 of 12 July 2021](#), [No. 58 of 2 August 2021](#), and [No. 60 of 6 September 2021](#) for previous *Commission Equivalence Decisions*).

In particular, these decisions mean that Armenia and the United Kingdom will be connected to the EU's system and that COVID certificates issued by these countries will be accepted in the EU under the same conditions as the EU Digital COVID Certificate.

In return, these countries have accepted EU Digital COVID Certificates for travel to their countries.

European Commissioner for Justice, Didier Reynders, stated: *"Safer travel is a reality thanks to the EU Digital COVID Certificate, which is now the leading global standard: 45 countries in four continents are connected to the system and more will follow in the coming weeks and months. We are open to other countries to join our system."*

The two decisions entered into force on 29 October 2021.

LAWYER CONTACTS

Kaarli H. Eichhorn

Partner, Antitrust & Competition Law;
Government Regulation; Technology
Brussels

keichhorn@jonesday.com

+32.2.645.14.41

Dr. Jörg Hladjk

Partner, Cybersecurity, Privacy & Data
Protection; Government Regulation;
Technology
Brussels

jhladjk@jonesday.com

+32.2.645.15.30

Cristiana Spontoni

Partner, Health Care & Life Sciences;
Government Regulation
Brussels

cspontoni@jonesday.com

+32.2.645.14.48

Rick van 't Hullenaar

Partner, Government Regulation;
Investigations & White Collar Defense
Amsterdam

rvanthullenaar@jonesday.com

+31.20.305.4223