
# 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 to phase out State aid COVID Temporary Framework
- European Commission approves new and amended Member State measures to support the economy
- European Commission approves further schemes under State aid Temporary Crisis Framework in context of Russia's invasion of Ukraine

### Trade / Export Controls

- EU-US Trade and Technology Council issue Joint Statement following second ministerial-level meeting
- Affirmed commitment to US-EU Agenda for Beating the Global Pandemic

### Medicines and Medical Devices

- EMA endorses Joint Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness
- European Commission announces agreement with BioNTech and Pfizer on delivery of COVID-19 vaccines

### Cybersecurity, Privacy & Data Protection

- European Parliament and Council provisionally agree on proposed Directive for high common level of cybersecurity across the Union
- European Commission proposes Regulation on European Health Data Space

| COMPETITION & STATE AID | |
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| **State Aid** | |
| **European Commission to phase out State aid COVID Temporary Framework (see here)** | On 12 May 2022, the Commission announced the phasing out of the State aid COVID Temporary Framework, adopted on 19 March 2020, which enabled Member States to remedy a serious disturbance in the economy in the context of the coronavirus pandemic.*<br><br>The Commission confirmed that most measures under the Temporary Framework, as last amended in November 2021, will not be extended beyond the current expiry date of 30 June 2022 (*see also Jones Day COVID-19 Update No. 68 of 22 November 2021*).<br><br>The existing phase-out and transition of the Temporary Framework will remain in place, as set out in the last amendment, which notably includes the below two possibilities for Member States to:<br><br>(i) Create direct incentives for private investments (until 31 December 2022) to spur companies to start filling the investment gap left by the COVID-19 crisis. Member States can use this tool, in particular, to accelerate the green and digital transitions by enabling support for any investments that Member States consider to be important to accelerate economic recovery; and<br><br>(ii) Provide solvency support measures (until 31 December 2023) aimed at easing access to equity finance for smaller companies by enabling Member States to leverage private funds and make them available for investments in SMEs, including start-ups, and small mid-caps.<br><br>On the above two measures, Executive Vice-President and Competition Commissioner Margrethe Vestager commented that these are "*very important to kick-start the economy and crowd-in private investment for a faster, greener and more digital recovery and should therefore remain at the disposal of the Member States for longer than the other measures*."<br><br>Commissioner Vestager remarked, however, that the positive signals of emergence from the pandemic are overshadowed by the war in Europe, which has created a disturbance in the European economy and severely impacts recovery. For this reason, the Commission adopted a Temporary Crisis Framework to enable Member States to address the consequences of this geopolitical crisis and to ensure that the right level of support remains available to hard-hit companies and sectors (*see below item on State aid Temporary Crisis Framework in context of Russia's invasion of Ukraine)*.<br><br>* *Commissioner Vestager indicated that as of 12 May 2022, the Commission had adopted over 1300 decisions in the context of the coronavirus pandemic, approving nearly 950 national measures for an estimate total State aid amount approved of nearly €3.2 trillion. Of the over €3 trillion in aid approved during that period, around €730 billion was actually spent in the period between mid-March 2020 and end-June 2021, based on Member State data.* |
| **European Commission approves new and amended Member** | 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. |

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| **State measures to support the economy (see here and here)** | The Temporary Framework, adopted in March 2020, is currently applicable until 30 June 2022.<br>• Re-introduction of a Slovenian scheme, including €150 million budget increase, to support companies affected by the coronavirus pandemic and the development of coronavirus-relevant products<br>• €2 billion Greek scheme to support investment towards a sustainable recovery in the context of the coronavirus pandemic<br>• €93 million Flemish scheme to support uncovered fixed costs of companies affected by the coronavirus pandemic<br>• €698 million Italian scheme to support the tourism sector in the context of coronavirus pandemic<br>• €380 million Italian scheme to support the tourism and spa sectors in the context of the coronavirus pandemic<br>• €5 million Irish scheme to support Helicopter Emergency Medical Services in the context of the coronavirus pandemic<br>• €129 million Italian scheme to support the tourism sector in the context of the coronavirus pandemic<br>• €119 million Italian scheme to support cabotage and other maritime services in the context of the coronavirus pandemic<br>• €1.9 million Romanian aid measure to compensate TAROM for the damage suffered due to the coronavirus pandemic<br>• €200,000 Maltese scheme to support meat processing and marketing cooperatives affected by the coronavirus pandemic |
| **European Commission approves further schemes under State aid Temporary Crisis Framework in context of Russia's invasion of Ukraine (see here)** | In the first half of May 2022, the Commission approved additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine.<br><br>These are among the first schemes approved under this Crisis Framework, adopted by the Commission on 23 March 2022, which sets out the criteria for Member States to support businesses in the context of Russia's invasion of Ukraine and its serious disruption to the EU economy (see *Jones Day COVID-19 Update No. 80 of 25 March 2022*).<br><br>To recall, in adopting this Crisis Framework, the Commission noted that the conflict had significantly impacted the energy market, and steep rises in energy prices had affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The conflict also disrupted supply chains for both EU imports from Ukraine (in particular, cereals and vegetable oils) and EU exports to Ukraine.<br><br>The latest schemes under the Crisis Framework include:<br>– €152.5 million French aid scheme to support companies in the agriculture, forestry and aquaculture sector in the context of Russia's invasion of Ukraine<br>– €1.8 million Spanish scheme to support private rail freight companies in the context of Russia's invasion of Ukraine |

- €125 million Spanish scheme to support gas intensive sectors in the context of Russia's invasion of Ukraine
- €400 million French aid scheme to support agricultural and fish farms in the context of Russia's invasion of Ukraine
- €450 million Spanish scheme to support private road transport companies in the context of Russia's invasion of Ukraine
- €11 billion German umbrella scheme to support companies across sectors in the context of Russia's invasion of Ukraine

Notably, the Crisis Framework complements the various possibilities for Member States to design measures in line with existing EU State aid rules. For instance, State aid measures under the Crisis Framework may be cumulated with aid granted under the COVID-19 Temporary Framework (*see Jones Day COVID-19 Update No. 68 of 22 November 2021*), provided that their respective cumulation rules are respected.

The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2022. During its period of application, the Commission will keep the Framework under review in light of developments regarding the energy markets, other input markets, and the general economic situation. Prior to the Crisis Framework's end date, and in view of maintaining legal certainty, the Commission will assess whether it should be prolonged.

## TRADE / EXPORT CONTROLS

**EU-US Trade and Technology Council issue Joint Statement following second ministerial-level meeting (see here)**

On 15-16 May 2022, the EU-US Trade and Technology Council (TTC) issued a Joint Statement following its second ministerial-level meeting, emphasizing that strong transatlantic bonds and cooperation on trade, technology, and security-related issues are more critical than ever, particularly in the face of Russia's war against Ukraine.

To recall, the TTC was unveiled in June 2021 and is central to the EU-US partnership. The TCC comprises 10 Working Groups, led by relevant government services to set out deliverables and coordinate technical work. The European Commission's Futurium platform allows stakeholders to join any of these 10 Working Groups, addressing areas such as Secure Supply Chains; Technology Standards; Climate and Clean Tech; and Access to and Use of Digital Tools (*see also Jones Day COVID-19 Update No. 64 of 18 October 2021*).

The Joint Statement outlines outcomes for each of the TTC's 10 Working Groups. In particular:

- Working Group 3 – Secure Supply Chains, which includes a focus on semiconductors, notes that a "perfect storm" of pandemic-related factors led to shortages of certain semiconductors (e.g. surging demand for computers and technology products due to remote working and home schooling, while COVID-19-related shutdowns contributed to supply disruptions).

  To ensure resilient and robust supply chains for semiconductors, the Working Group intends to take action to increase transparency and monitoring of the value chain, create an alert system to share information about possible disruptions, and incentivize increased production while avoiding subsidy races.

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| | • Working Group 10 – Global Trade Challenges, which includes a focus on trade, agriculture, and food security, notes that Russian aggression in Ukraine has vastly increased food insecurity by disrupting trade in key agricultural commodities and inputs such as fertilizers. This is compounding pressure on the agricultural sector, which already faces supply chain disruptions from the COVID-19 pandemic and climate change.<br><br>To address these issues, the Working Group indicates that the EU and US intend to launch a dialogue aimed at promoting more diversified trade in agricultural commodities and inputs and addressing over-reliance on certain trading partners, with the aim of strengthening the resilience of global food production.<br><br>The Joint Statement indicated that ahead of the next TTC ministerial meeting planned before end-2022, all working groups are tasked with building on progress made thus far to implement concrete actions, in consultation with stakeholders. |
| **Affirmed commitment to US-EU Agenda for Beating the Global Pandemic (see here)** | On 12 May 2022, European Commission President von der Leyen and US President Biden issued a Statement on implementation of the US-EU Agenda for Beating the Global Pandemic, Vaccinating the World, Saving Lives Now and Building Back Better Health Security. The Agenda was announced on 22 September 2021 (see here).<br><br>The Statement reaffirms strong EU-US cooperation in seeking to fulfill the Agenda's goals, including further joint action, for example, in strengthening global supply chains and manufacturing.<br><br>In this respect, the Statement recalls that the need to ensure vaccine and therapeutic dose supply and administration in the face of supply chain constraints led to the launch of the joint EU-US COVID-19 Manufacturing and Supply Chain Taskforce in September 2021 (*see Jones Day COVID-19 Update No. 63 of 11 October 2021*). The Taskforce's priority work areas include coordinating efforts to tackle critical supply chain bottlenecks and other disruptive factors for global COVID-19 vaccine and therapeutics production, including regular status updates on any potential import–export issues between the US and EU.<br><br>According to the Statement, the Taskforce is expected to broaden its activities to provide early warning of supply chain bottlenecks that could hinder global availability of vaccines and treatments, as well as to coordinate efforts to support vaccine and therapeutics production capabilities for variants and future pandemics, including in Africa. |

## MEDICINES AND MEDICAL DEVICES

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| **EMA endorses Joint Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and** | On 17 May 2022, the European Medicines Agency ("EMA") endorsed the Joint Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness (Revised 17 May 2022) (see here), issued by the International Coalition of Medicines Regulatory Authorities ("ICMRA") and World Health Organization ("WHO").<br><br>The COVID-19 pandemic's worldwide impact created an unprecedented |

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| **effectiveness (see here)** | level of public interest in vaccines. This has included a spotlight on vaccine development and their regulatory review and safety monitoring, with such coverage largely occurring on mass and social media.<br><br>The Statement recognizes that communicating the importance of COVID-19 vaccination has raised various challenges. For example, reports of adverse side effects have caused delays in or strong opposition to getting vaccinated. Some may see limited value in vaccinating children and young adults, given findings that many in this population are less clinically affected by COVID-19 infection. Therefore, the Statement indicates that clear and consistent communication of evidence and uncertainties is essential to support individuals in making the critical decision to be vaccinated.<br><br>The Statement aims to assist healthcare professionals to respond to questions about the role of regulators in the oversight of COVID-19 vaccines and to reassure medical staff about the safety of COVID-19 vaccines, which undergo rigorous scientific evaluation.<br><br>In particular, the Statement:<br><br>• Explains how regulatory authorities evaluate COVID-19 vaccines, how safety, efficacy and quality evidence is collected prior to potential regulatory authorization, and how safety and effectiveness is monitored post-vaccine approval;<br><br>• Lists the most commonly reported adverse events with COVID-19 vaccines, such as headache, fatigue, and pain at the injection site; and<br><br>• Answers various questions on COVID-19 vaccines, such as:<br><br>– How the vaccines were developed so quickly;<br><br>– How long COVID-19 vaccination will provide protection for immunized people; and<br><br>– Whether to vaccinate children.<br><br>The Statement, last updated in January 2021, follows a series of discussions among ICMRA members and WHO on the importance of public confidence in COVID-19 vaccines. |
| **European Commission announces agreement with BioNTech and Pfizer on delivery of COVID-19 vaccines (see here)** | On 13 May 2022, the Commission reached an agreement with vaccine developers BioNTech and Pfizer to modify originally agreed contractual delivery schedules. The aim is to better match Member State supply and demand for COVID-19 vaccines and to enable Member States to respond to any epidemiological developments later this year.<br><br>In particular, doses originally scheduled for the summer months will now be delivered in autumn/winter 2022, when Member States are more likely to need additional vaccine stocks for national campaigns and for meeting their international solidarity commitments.<br><br>The agreement also provides that Member States will have access to future variant-adapted vaccines that receive authorization by autumn/winter 2022.<br><br>The Commission intends to finalize additional such agreements with the EU's vaccine suppliers in the near future to respond to evolving pandemic needs. |

## CYBERSECURITY, PRIVACY & DATA PROTECTION

**European Parliament and Council provisionally agree on proposed Directive for high common level of cybersecurity across the Union (see here)**

On 13 May 2022, the European Parliament and Council announced a provisional agreement on the proposed Directive on measures for a high common level of cybersecurity across the Union, repealing Directive 2016/1148 ("NIS2 Directive").

During the COVID-19 pandemic, growing security threats emerged, demonstrating the vulnerability of increasingly interdependent societies to low-probability risks (e.g. interdependencies mean that any disruption, even if initially confined to one entity or one sector, can have broader cascading effects, potentially resulting in far-reaching and long-lasting negative impacts in the delivery of services across the EU).

The proposed NIS2 Directive aims to strengthen the resilience and incident response capacities of public and private entities, competent authorities and the EU as a whole, and provides in particular:

Reinforced risk and incident management and cooperation, e.g.:

- Sets the baseline for cybersecurity risk management measures and reporting obligations across all sectors covered by the proposed Directive (e.g., energy, transport, health and digital infrastructure);
- Removes divergences in cybersecurity requirements and in implementation of cybersecurity measures in Member States;
- Lays down mechanisms for effective cooperation among relevant authorities in each Member State;
- Updates the list of sectors and activities subject to cybersecurity obligations;
- Provides for remedies and sanctions to ensure enforcement;
- Formally establishes the European Cyber Crises Liaison Organisation Network, EU-CyCLONe, which will support the coordinated management of large-scale cybersecurity incidents;
- Introduces a peer-learning mechanism to enhance mutual trust and learning from good practices and experiences.

Broadened scope of rules, as well as clarifications/streamlining, e.g.:

- Introduces a size-cap rule, such that all medium-sized and large entities operating within the sectors or providing services covered by the proposed Directive will fall within its scope;
- Clarifies that the proposed Directive will not apply to entities carrying out activities in areas such as defence or national security, public security, law enforcement, the judiciary, parliaments, and central banks;
- Provides legal clarity and ensures coherence with sector-specific legislation (e.g., Regulation on digital operational resilience for the financial sector (DORA) and Directive on the resilience of critical entities (CER));

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| | • Streamlines reporting obligations to avoid over-reporting and excessively burdening concerned entities.<br><br>The proposed NIS2 Directive, which is not yet publicly available, is now subject to approval by the Council and the European Parliament. |
| **European Commission proposes Regulation on European Health Data Space (see here)** | On 3 May 2022, the Commission published its proposed Regulation on the European Health Data Space ("proposed EHDS").<br><br>To recall, the proposed EHDS is one of the EU Legislative Priorities for 2022 (see also *Jones Day COVID-19 Update No. 72 of 10 January 2022*). It seeks to create a common space in which individuals can easily control their electronic health data and to enable researchers, innovators and policy makers use this electronic data in a trusted and secure way.<br><br>The COVID-19 pandemic highlighted, in particular, the importance of digital services in the health area, with the uptake of digital tools increasing significantly during this time. However, the complexity of rules, structures and processes across Member States makes it difficult to access and share health data, especially cross-border.<br><br>Towards addressing these needs and challenges, the proposed EHDS aims to, in particular:<br><br>• Strengthen the rights of natural persons regarding the availability and control of their electronic health data by laying down rules on access to and transmission of personal electronic health data for primary use. This includes mandating Member States to appoint digital health authorities, who will participate in "MyHealth@EU", a central platform to facilitate the exchange of electronic health data between national contact points for digital health;<br><br>• Regulate electronic health record systems ("EHR systems") (i.e., any appliances or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records, which are the collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes). In particular, the proposed EHDS imposes obligations on economic operators of EHR systems (including the affixing of a CE marking), lays down provisions on the interoperability of such systems, and imposes obligations on market surveillance authorities responsible for such systems;<br><br>• Regulate and impose mechanisms that support the secondary use of electronic health data, such as the possibility for any natural or legal person to submit a "data access application" for one of the defined purposes (e.g., scientific research related to the health or healthcare sectors and the provision of personalized healthcare) to a "health data access body". These health data access bodies can then grant a "data permit", if the requested data is used for one of the defined purposes, in closed, secure environments, and without revealing the identity of the individual (only anonymized data can be downloaded);<br><br>• Establish the "HealthData@EU" infrastructure, a cross-border infrastructure to allow accelerating the secondary use of electronic health data while increasing legal certainty, respecting the privacy of natural |

persons, and being interoperable.

On the same date, the Commission published a Communication and Q&A on the proposed EHDS (see here).

The European Parliament and the Member States will now review the Commission's proposal in view of adopting a final text of the Regulation.

## LAWYER CONTACTS


**Kaarli H. Eichhorn**
Partner, Antitrust & Competition Law; Government Regulation; Technology
Brussels
keichhorn@jonesday.com
+32.2.645.14.41

**Cristiana Spontoni**
Partner, Health Care & Life Sciences; Government Regulation
Brussels
cspontoni@jonesday.com
+32.2.645.14.48

**Dr. Jörg Hladjk**
Partner, Cybersecurity, Privacy & Data Protection; Government Regulation; Technology
Brussels
jhladjk@jonesday.com
+32.2.645.15.30

**Rick van 't Hullenaar**
Partner, Government Regulation; Investigations & White Collar Defense
Amsterdam
rvanthullenaar@jonesday.com
+31.20.305.4223



***Lucie Fournier*** *(Associate),* ***Cecelia Kye*** *(Consultant), and* ***Justine Naessens*** *(Associate) in the Brussels Office contributed to this Update.*