



# 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 publishes first Report on implementation of Recovery and Resilience Facility
- European Ombudsman opens case on transparency and accountability of Recovery and Resilience Facility
- EU extends measures to counteract negative economic effects of COVID-19 pandemic on railway undertakings
- European Commission approves new and amended Member State measures to support the economy

### Trade / Export Controls

- European Commission publishes second report on EU strategic dependencies and capacities

### Medicines and Medical Devices

- Council authorizes opening negotiations for International Agreement on Pandemic Prevention, Preparedness and Response
- EMA publishes recommendations for two COVID-19 vaccines

### Cybersecurity, Privacy & Data Protection

- European Commission publishes Communication towards a green, digital and resilient economy: our European Growth Model
- European Commission launches online consultation platform on European Digital Identity Wallets
- European Commission adopts EU Digital COVID Certificate equivalence decisions for Benin and Jordan

## COMPETITION & STATE AID

### State Aid

#### European Commission publishes first Report on implementation of Recovery and Resilience Facility (see [here](#))

On 1 March 2022, the Commission published its first Report to the European Parliament and the Council on implementation of the Recovery and Resilience Facility (RRF). This is the first of the annual reports on implementing the RRF, as required under the RRF Regulation (Regulation (EU) 2021/241 of 12 February 2021).

To recall, the RRF is the key component of NextGenerationEU, the EU's plan for rebounding from the COVID-19 crisis. The RRF will provide up to €672.5 billion to finance reforms and investments (i.e., grants totaling €312.5 billion and €360 billion in loans). In particular, the RRF will support the reforms and public investment projects foreseen for implementation under the Member State recovery and resilience plans (see [Jones Day COVID-19 Update No. 64 of 18 October 2021](#)).

The Report indicates that all Member States (except The Netherlands) have submitted their recovery and resilience plans, and thus far, the Commission and Council have endorsed 22 of these plans.

In evaluating the Member State plans, in particular, the RRF guidelines make clear that the investment projects included in Member State recovery plans must comply with State aid rules. The Commission published practical guidance for swift treatment of projects under State aid rules, as well as a number of sector-specific templates to help Member States design and prepare the State aid elements of their recovery plans (*Jones Day Commentary, "EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, see [here](#)*).

Foreseen as a performance-based program, the Report recalls that the Commission's payments to Member States are based on the deemed completion of milestones and targets indicated in the recovery and resilience plans. In this respect:

- Each Member State must seek to establish an effective control system for its recovery plan (e.g. providing appropriate legal mandates for the bodies in charge of implementing and auditing the funds; adequate administrative capacity of implementing and audit bodies in charge of implementation of the recovery plan; setting out a clear audit strategy and anti-fraud measures).
- The Commission established a monitoring and control framework in 2021 for the RRF, including dedicated audit and legal units, as well as specific control and audit strategies.

To date, the Commission has disbursed EUR 66.6 billion, out of which EUR 56.6 billion in pre-financing to support Member States and the EU as the pandemic continues to impact their economies.

Progress in implementation of the Member State recovery plans can be followed on the Commission's "Recovery and Resilience Scoreboard" platform, launched in December 2021 (see [here](#)).

**European Ombudsman opens case on transparency and accountability of Recovery and Resilience Facility (see [here](#))**

On 24 February, 2022, the European Ombudsman, Emily O'Reilly, opened a case on transparency and accountability of the Recovery and Resilience Facility (RRF), addressing European Commission President Ursula von der Leyen.

The Ombudsman has asked the Commission to respond on how it intends to ensure transparency and accountability in relation to use of the RRF funds to assist Member States in recovering from the pandemic. The Ombudsman, in particular, noted that the public should be reassured that Member States comply with any conditions attached to the RRF funds.

The Ombudsman indicates, for instance, that the Commission should ensure that national control mechanisms are effectively fulfilling Member States' obligations to ensure compliance with EU and national laws. The Ombudsman, in this respect, queries the Commission on what mechanisms are in place to supervise the proper functioning of Member State audit and control mechanisms, and under what circumstances the Commission will request Member States to furnish a detailed account of final recipients of the funds.

Also in pursuit of ensuring transparency on how the RRF funds are spent, the Ombudsman's office, in cooperation with the European Network of Ombudsmen and the OECD, is preparing guidance on "Good Practice Principles for government transparency in the use of recovery funds" to be released in the coming months.

The Commission is due to reply to the Ombudsman by 24 May 2022.

**EU extends measures to counteract negative economic effects of COVID-19 pandemic on railway undertakings (see [here](#))**

On 24 February 2022, as the COVID-19 pandemic continues to negatively impact the level of rail traffic, the EU extended the possibility for Member States to provide relief from certain infrastructure charges for rail companies until 30 June 2022 (adopting Regulation (EU) 2022/312 amending Regulation (EU) 2020/1429 on duration of reference period for application of temporary measures concerning levying of charges for use of railway infrastructure).

In announcing the extension, the European Commissioner for Transport Adina Vălean stated: "*For almost two years now, the pandemic has created extraordinary circumstances that affect the day-to-day activity of transport companies and operators. Extending the possibility for Member States to support the rail sector will help ensure the economic recovery of rail.*"

For instance, subject to compliance with State aid rules, the Regulation allows Member States to authorize infrastructure managers\* to reduce, waive or defer the payment of charges borne by, e.g. freight services and passenger services, in relation to:

- the minimum access package (e.g. use of railway infrastructure; train control such as signaling and dispatching; use of electrical supply equipment for traction current); and
- access to infrastructure connecting service facilities (e.g. passenger stations; freight terminals; maintenance and technical facilities).

Member States shall compensate infrastructure managers for the specific financial loss suffered as a result of applying such relief measures, but without prejudice to the Member States' obligation to ensure that, over a reasonable period (not exceeding five years), the profit and loss account of an infrastructure manager shall remain balanced.

The Regulation will apply retroactively as from 1 January 2022. Furthermore,

given the pandemic's unpredictability, the Commission's power to adopt delegated acts is also prolonged, such that it can extend measures if necessary for a maximum period of six months each time until 31 December 2023.

*\* Infrastructure managers are any body or firm responsible for establishing, managing and maintaining railway infrastructure.*

**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 30 June 2022.

- €100 million Greek scheme to support liquidity of companies affected by coronavirus pandemic.
- €59 million Flemish scheme to support companies affected by the coronavirus pandemic.
- Walloon aid schemes worth €60 million to support companies and self-employed workers affected by the COVID-19 pandemic.
- €2 billion Hungarian investment support scheme towards a sustainable recovery.
- €687 million Italian scheme to compensate commercial rail passenger operators for the damage suffered due to the coronavirus pandemic.
- €7 million Slovenian incentive scheme towards airlines affected by the coronavirus pandemic.
- €100 million Italian scheme to support catering services operators in the context of the coronavirus pandemic.
- €5.7 million Cypriot scheme to support certain farmers active in the livestock sector affected by the coronavirus pandemic.
- Amendment to Swedish scheme, including €189 million budget increase, to support organizers of events affected by the coronavirus pandemic.

## TRADE / EXPORT CONTROLS

**European Commission publishes second report on EU strategic dependencies and capacities (see [here](#))**

On 23 February 2022, the Commission released its second Report on an in-depth review of EU strategic dependencies and capacities.

The Report builds on the Commission's first mapping of strategic dependencies in May 2021, which accompanied the 2021 Updated Industrial Strategy towards Europe's transition to a green, digital, resilient and globally competitive economy in light of lessons learned from the COVID-19 pandemic (see [Jones Day COVID-19 Update No. 47 of 12 May 2021](#)).

The Report indicates that the COVID-19 crisis has demonstrated the relevance of a continued effort to monitor Europe's current and possible future strategic dependencies, consider their impact and risks, as well as to undertake relevant policy measures and business decisions to manage risks.

These in-depth reviews of specific products (or product groups) assess EU dependencies based on various factors (e.g. trade flows, global production concentration, EU production capacities, etc.).

The Report focuses on five targeted areas of dependency. It deepens initial assessments from the first mapping exercise in three priority areas: raw and processed materials (focusing on (i) rare earths and magnesium and (ii) chemicals); (iii) software capacities; and two further areas of strategic importance, (iv) solar panels and (v) cybersecurity.

According to the Report, significant progress has been made to address strategic dependencies identified in the first in-depth review, including through recently launched international partnerships to enable more diversified and resilient supply chains, notably in the area of critical raw materials.

On the role of trade, the Report notes that EU policy measures are reinforcing the EU's position in global value chains by boosting and diversifying external trade and promoting sustainable value chains. For example:

- The **EU/US Trade and Technology Council**, launched in June 2021, seeks cooperation aimed at better resilience across areas included in the EU's in-depth reviews of strategic dependencies (e.g. raw materials, solar panels, active pharmaceutical ingredients, and semiconductors) (see also [Jones Day COVID-19 Update No. 64 of 18 October 2021](#)).
- To address supply challenges and price hikes of **rare earths** and **magnesium** that arose during the COVID-19 crisis, the EU is taking steps to establish partnerships on raw materials with countries with strong legal frameworks to avoid distortions to trade and investment.
- Supply disruptions have seriously impacted the EU's import and deployment of **solar PV (photovoltaic) panels**, given the EU's strategic dependency on imports from Asia and exposure to international and country-specific events. Towards tackling this issue, the Report indicates that fair competition must be ensured between EU PV manufacturers and their foreign competitors. It notes that the EU's main trading partners are also evaluating their strategic supply chain resilience, including in the solar PV sector, and any subsidization initiatives must respect applicable WTO rules to ensure fair trade and investment. The EU, in particular, is cooperating with the US on secure supply chains for PV panels through the above-referred EU/US Trade and Technology Council.

The Commission will continue efforts to identify and assess strategic dependencies, in close collaboration with industry and Member States through, e.g., stakeholder contributions via the Industrial Forum expert group (see [here](#)).

## MEDICINES AND MEDICAL DEVICES

### **Council authorizes opening negotiations for International**

On 3 March 2022, the Council adopted a Decision ("Council Decision") to authorize the opening of negotiations for an International Agreement on Pandemic Prevention, Preparedness and Response ("International Agreement") to be adopted under the World Health Organization ("WHO"). The Agreement would be legally binding under international law.

**Agreement on Pandemic Prevention, Preparedness and Response (see [here](#))**

The Council Decision follows a consensus decision on 1 December 2021 of the WHO's World Health Assembly to launch negotiations for the International Agreement (see [here](#)). The International Agreement will be drafted by an inter-governmental negotiating body established by the World Health Assembly to strengthen pandemic prevention, preparedness and response (see [here](#)).

The COVID-19 pandemic demonstrated the need for enhanced preparedness and closer cooperation at global level, which the International Agreement would seek to address through, e.g., strengthening the early detection of pandemics, improving alerts and response, and promoting general trust in the international health system.

The Council Decision authorizes the Commission, for matters falling within the EU's competence, to represent the EU in the inter-governmental body in charge of developing and negotiating the International Agreement.

The inter-governmental negotiating body will meet by 1 August 2022 to discuss progress on a working draft of the International Agreement, in view of delivering a progress report to the 76th World Health Assembly in 2023 and adopting the International Agreement by 2024.

**EMA publishes recommendations for two COVID-19 vaccines (see [here](#))**

On 25 February 2022, the Human Medicines Committee (CHMP) of the European Medicines Agency (EMA) announced various recommendations concerning COVID-19 vaccines Spikevax (mRNA vaccine (Moderna) and Comirnaty (tozinameran (BioNTech/Pfizer)). The CHMP recommended, in particular, the following:

- Including use of the COVID-19 vaccine Spikevax as a booster dose in people who have previously completed a primary vaccination with another mRNA vaccine or an adenoviral vector vaccine.
- Granting an extension of indication for COVID-19 vaccine Spikevax to include its use in children aged 6 to 11 (see [here](#)). The dose in children from 6 to 11 years of age will be lower than that used in people aged 12 and above (50 µg compared with 100 µg), following a main study in children aged 6 to 11 that showed that their immune response to a lower dose was comparable to that seen in 18-25 year-olds.
- Providing a booster dose of COVID-19 vaccine Comirnaty, where appropriate, to adolescents from 12 years of age, since available evidence is considered sufficient to conclude that their immune response to a booster dose would be at least equal to that in adults (see [here](#)).

The recommendations were announced following the CHMP meeting held from 21 to 24 February 2022. The CHMP also approved an increase in manufacturing capacity for COVID-19 vaccine Spikevax.

## CYBERSECURITY, PRIVACY & DATA PROTECTION

**European Commission publishes Communication**

On 2 March 2022, the Commission published the Communication towards a green, digital and resilient economy: our European Growth Model.

The Communication notes the transformation of the EU economy in a context

**towards a green, digital and resilient economy: our European Growth Model (see [here](#))**

of geopolitical instability and rising global challenges, such as the COVID-19 pandemic, the climate crisis, and spiking energy prices. The pandemic, in particular, has accelerated society's digital transformation.

These developments highlight the need to intensify efforts to pursue the EU's green and digital transition, as well as economic and social resilience and crisis preparedness. The Communication sets out the key investments and reforms viewed as needed to achieve such common objectives of the EU and the Member States. In particular:

- The EU's digital ambitions for 2030, as set out in the Commission's proposed Digital Compass (see [here](#)) will require investments in key digital technologies, such as cybersecurity, cloud computing, artificial intelligence, common European data spaces, blockchain, and semiconductors;
- The EU's digital transformation, according to a 2020 estimate, will require additional investment of some EUR 125 billion per year. While the private sector will provide the bulk of this investment, public intervention will also be needed to spur private investments and help correct market failures;
- Enhancing the EU's technological edge and support its industrial base will require considerably increased EU and Member State investment in European defense and space industries, including in cyber defense; and
- To strengthen risk management and emergency response capabilities, the EU has mobilized additional targeted investment. The European Health Emergency preparedness and Response Authority (HERA) was designed for this purpose (see also [Jones Day COVID-19 Update No. 77 of 23 February 2022](#)). HERA will help anticipate potential health crises, through intelligence gathering and building the necessary response capacities. When an emergency does arise, HERA will assist with ensuring the production and distribution of medicines, vaccines and medical equipment.

The Communication aimed, in particular, to provide input to the discussions on the European economic growth model at the informal European Council meeting of heads of state or government scheduled on 10-11 March 2022.

**European Commission launches online consultation platform on European Digital Identity Wallets (see [here](#))**

On 24 February 2022, the Commission launched an online consultation platform to gather feedback from stakeholders on the planned European Digital Identity Wallets, as set out in the Commission's proposed Regulation of 3 June 2021 on establishing a framework for a European Digital Identity (see [here](#)). The proposed Regulation would amend the eIDAS Regulation (Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions).

To recall, the European Digital Identity Wallet would serve as a personal digital wallet aimed at allowing citizens to digitally identify themselves, store and manage identity data and official documents in electronic format, and maintain full control of their shared data (see also [Jones Day COVID-19 Update No. 74 of 24 January 2022](#)). The Commission notes the urgency of the proposed Regulation, following the COVID-19 pandemic and the sudden need for accessing and using all types of public and private services online.

The online consultation platform seeks to build a virtual community of

stakeholders to provide feedback on the work of the eIDAS Expert Group on a common EU Toolbox for a coordinated approach to the technical aspects of a European Digital Identity Framework. This includes covering at least all aspects of the functionalities and interoperability of the European Digital Identity Wallets, such as eSignatures. The Toolbox is expected by September 2022.

The online consultation platform, accessible upon request for membership, will remain open throughout the legislative negotiations for the proposed Regulation and the Toolbox.

**European Commission adopts EU Digital COVID Certificate equivalence decisions for Benin and Jordan (see [here](#))**

On 16 February 2022, the Commission adopted two new equivalence decisions certifying that COVID-19 certificates issued by Benin and Jordan are equivalent to the EU Digital COVID Certificate (see also [Jones Day COVID-19 Update No. 71 of 13 December 2021](#) for the latest preceding Commission Equivalence Decisions).

In practice, this means that these two countries will be connected to the EU's system and that COVID certificates issued by this country will be accepted in the EU under the same conditions as the EU Digital COVID Certificate.

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

As a result of these two decisions, 62 countries have been connected to the EU's system (see overview of all decisions [here](#)).

The equivalence decisions entered into force on 17 February 2022.

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