



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 Annual Single Market Report 2022
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission publishes Annual Single Market Report 2022
- COVID-19 Global Action Meeting gathers EU, US, and other partner countries
- Report on EU Exit: UK Border post transition

Medicines and Medical Devices

- EMA publishes new vaccine safety update
- Medical Device Coordination Group publishes revised Guidance on performance evaluation of SARS-CoV-2 *in vitro* diagnostic medical devices
- European Commission publishes call for best practices on non-communicable diseases
- HERA launches first Work Plan

Cybersecurity, Privacy & Data Protection

- European Commission publishes proposed Data Act
- Council updates temporary restriction on non-essential travel into the EU and possible lifting of such restriction

COMPETITION & STATE AID

State Aid

European Commission publishes Annual Single Market Report 2022 (see [here](#))

On 22 February 2022, the European Commission published the Annual Single Market Report 2022, which sets out, in particular, latest developments in industrial ecosystems, the envisaged way forward for recovery from the pandemic, recent challenges in global supply chains, the economic situation of SMEs, and pursuit of the green and digital transition.

On the economic situation of SMEs, the Report notes that SMEs particularly suffered from the COVID-19 crisis, with lockdowns forcing many small businesses to close temporarily.

While the number of bankruptcies of SMEs remains at a lower level than pre-crisis (reflecting, in particular, the impact of various economic support programs and forbearance by lenders and regulators), the Report cautions that overall figures mask significant differences by sector. The situation for the accommodation and food services sector is significantly worse than before the pandemic.

Thus, the Report indicates the Commission's view that when phasing out support measures, it is essential to seek to avoid a cliff-edge for many SMEs. In this context, the Commission decided to prolong the State Aid Temporary Framework until 30 June 2022 and introduced new tools available to Member States to seek to create direct incentives for forward-looking private investment (until 31 December 2022) and solvency support measures (until 31 December 2023) (see also [Jones Day COVID-19 Update No. 68 of 22 November 2021](#)).

On the green and digital transition, the Report refers to the ambitions of the Updated Industrial Strategy of May 2021, which emphasized the need to address strategic dependencies that lead to vulnerabilities of the EU economy (see also [Jones Day COVID-19 Update No. 47 of 12 May 2021](#)). In line with these aims, EU actions deployed include:

- Considering scope for coordinated investment by Member States and industry in the form of new IPCEIs (Important Projects of Common European Interest). The Report notes that certain Member States and companies have jointly expressed interest to engage in additional IPCEIs, such as next-generation Cloud and Edge Infrastructure and Services, hydrogen, health and a second IPCEI on microelectronics. The Commission is monitoring several of these project plans and will assess if and when notified to the Commission under applicable State aid rules.
- Reviewing State aid rules for IPCEIs. In this respect, the revised IPCEI Communication was adopted in November 2021. According to the Commission, the Communication reflects the EU's new key policy objectives of promoting green and digital transitions, as well as strengthening the EU's "open strategic autonomy" (i.e., increasing reliance on its own resources in key strategic areas, but cooperating with partners where necessary) (see also [Jones Day Commentary, EU Revises State Aid Rules for Important Projects of Common European Interest](#), February 2022).

The Report also provided an illustration of investment volumes for nine industrial areas (i.e. raw materials; batteries; solar PV; hydrogen; steel; cement; chemicals; clouds services; and cybersecurity) that are considered to play an enabling role for successful green, digital and resilient transitions. The total cumulative investment volume for the nine selected areas is estimated at some €405 billion for the period up to 2030, or €45 billion annually. The Commission based these figures on data collected and/or estimated through consultations with relevant public stakeholders, industrial associations and alliances.

For further details on the Annual Single Market Report 2022, please see below Section on Trade / Export Controls.

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.

- €120 million Dutch scheme to support companies for their event organizing activity affected by the coronavirus pandemic.
- €6.13 million Cypriot incentive scheme towards airlines affected by the coronavirus pandemic.
- €5 million Belgian scheme to support the events and cultural sectors affected by the coronavirus pandemic.
- Amendment to Dutch scheme, including €1.9 billion budget increase, to further support companies in the context of the coronavirus pandemic.
- €26.23 million Belgian wage subsidy scheme to support the events, nightclubs and indoor recreational activities sectors affected by the coronavirus pandemic.

TRADE / EXPORT CONTROLS

European Commission publishes Annual Single Market Report 2022 (see [here](#))

On 22 February 2022, the European Commission published the Annual Single Market Report 2022, which sets out, in particular, latest developments in industrial ecosystems, the way forward for recovery from the pandemic, and recent challenges in global supply chains.

On [global supply chains](#), the Report highlights that the COVID-19 pandemic exposed vulnerabilities to the Single Market organization in case of unforeseen crises and/or demand or supply shocks.

The Report indicates that for future health crises, the approach taken to tackle the shortage of personal protective equipment and to ramp up COVID-19 vaccines production provides an example of action, which included measures such as:

- Trade instruments, including export transparency mechanisms;
- Close cooperation with non-EU countries to (i) ensure the free flow of goods and avoid disruption of supply chains in a situation of scarce goods and (ii) facilitate the free flow of vaccines and its inputs and

develop vaccine production capacities worldwide.

Towards boosting EU resilience and industrial ecosystems, the Report refers to the findings of the Updated Industrial Strategy of May 2021, which stressed the need to address strategic dependencies that lead to vulnerabilities of the EU economy (see also [Jones Day COVID-19 Update No. 47 of 12 May 2021](#)). In line with these findings, EU actions deployed include developing or updating legislation aimed at providing a regulatory framework to mobilize further investments, addressing technological gaps, and building resilient supply chains in various strategic areas. For example:

- The [draft European Chips Act](#) sets out a strategy for semi-conductors to incentivize manufacturing in the EU and achieve strategic autonomy (see also *Jones Day Commentary, EU Chips Act: The EU's Push for Semiconductor Autonomy*, March 2022, [here](#)); and
- The [draft Regulation on foreign subsidies](#) distorting the internal market seeks to provide further safeguards to preserve the level playing field (see also *Jones Day Commentary, Reining In Foreign Subsidies Distorting the EU Market: The European Commission Takes One Step Closer*, June 2021, [here](#)).

Furthermore, the Report cited the EU's "unwavering support" for its multilateral trading framework and ongoing efforts to reform it, as well as its extensive network of Free Trade and Investment agreements to promote European businesses' integration in global value chains and opportunities for diversification (e.g. for raw materials, the EU signed a strategic partnership to deepen existing cooperation and exchanges with Canada).

Despite the Single Market's signs of recovery, the Report cautions that the depth of the pandemic shock and the volatile recovery require continued vigilance. In this respect, it notes that economic consequences of the COVID-19 crisis as well as speed of recovery vary considerably across industrial ecosystems.

For further details on the Annual Single Market Report 2022, please see above Section on Antitrust & State aid.

COVID-19 Global Action Meeting gathers EU, US, and other partner countries (see [here](#))

On 14 February 2022, the COVID-19 Global Action Meeting gathered leaders from the US, EU (represented by Jutta Urpilainen, Commissioner for International Partnerships), and other partner countries* to discuss a COVID-19 Global Action Plan (GAP).

The meeting, hosted by US Secretary of State Antony Blinken, focused on the GAP's priority areas for responding to acute pandemic needs with concrete actions and global cooperation, in addition to reinforcing future global health threat preparedness.

The EU, which will pursue all GAP priority areas, specifically offered to co-lead with partners to coordinate actions, and in particular to:

- [Bolster supply chain resilience](#) to facilitate reliable supplies of critical products needed to break the pandemic, including establishing mechanisms to identify and remove medical supply chain bottlenecks;
- [Improve vaccine readiness and logistics](#), towards attaining the goal of full vaccinating at least 70% of the population in every country and income category by September 2022; and

- Strengthen global health security architecture, emphasizing the importance of both ending the current pandemic and securing future preparedness for health emergencies at the national, regional and global levels.

The GAP's objective is to bring an end to the pandemic cycle in 2022.

** Participants included the Commonwealth of Australia, Canada, the Republic of Colombia, the French Republic, the Federal Republic of Germany, the Republic of India, the Republic of Indonesia, the Italian Republic, Japan, the Republic of Korea, New Zealand, the Kingdom of Saudi Arabia, the Republic of Senegal, the Republic of South Africa, the Kingdom of Spain, the United Kingdom of Great Britain and Northern Ireland, the African Union/Africa Centres for Disease Control, the European Commission, and the World Health Organization.*

Report on EU Exit: UK Border post transition (see [here](#))

On 9 February 2022, the Report on EU Exit: UK Border post transition was published by the UK House of Commons – Committee of Public Accounts.

The Report studies the impact and future risks of new border arrangements since the Brexit transition period ended on 31 December 2020. During this transition period, the existing rules on trade, travel and business between the UK and the EU continued to apply following the UK's exit from the EU on 31 January 2020.

Since the close of the transition period, the Report notes that trade volumes have been suppressed by the impact of COVID-19, the UK's exit from the EU, and broader global pressures. In particular:

- Total trade in goods between the UK and the EU was 25% less in Q1 2021 and 15% less in Q2 2021 than the equivalent quarters in 2018. While these falls in UK-EU trade are far greater than the falls in the UK's trade with the rest of the world during the same period, the Report also cautions that trade data in general can be "*pretty erratic*" and that it is difficult at this time to be certain of the UK exit's effect on trade.
- The UK's new trading arrangements have impacted UK businesses, which now face additional administration and costs when trading with the EU, and notably with the introduction of customs paperwork for goods moving between the UK and EU. Certain UK industries may also be subject to additional controls (e.g. extra certificates and inspections for exports to the EU of live animals, fresh meat and fish and plants). These additional requirements are particularly challenging for small businesses.

The Report notes the Committee's "*repeatedly raised concerns about the impact of changes to trading arrangements on businesses of all sizes and we remain concerned.*" These include concerns over the UK's ability to apply full import controls as foreseen during the course of 2022 (while the EU introduced full import controls at the end of the transition period), as well as to minimize the current burden on those trading with the EU.

The UK government has two months to respond to the Report.

MEDICINES AND MEDICAL DEVICES

EMA publishes new vaccine safety update (see [here](#) and [here](#))

On 17 February 2022, the European Medicines Agency (EMA) published a new safety update for vaccines granted with marketing authorization in the European Union, in particular concerning COVID-19 vaccines Comirnaty (BioNTech Manufacturing), COVID-19 Vaccine Janssen (Janssen-Cilag International), Nuvaxoid (Novavax CZ), and Vaxzevria (AstraZeneca).

The safety update follows the preceding EMA update of 20 January 2022 (see also [Jones Day COVID-19 Update No. 74 of 10 January 2022](#)). It contains EMA reports on modifications to be made to the concerned vaccines' product information, as well as ongoing assessments of the vaccines, in light of the main assessments of the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) meetings held on 26 January 2022 and 7-10 February 2022.

For COVID-19 vaccine Comirnaty, product information will be updated to reflect accumulated evidence that it can be used during pregnancy and breastfeeding. This follows the absence of negative effects on the pregnancy or newborn baby, based on a large amount of information from pregnant women vaccinated with this vaccine during the second and third semester. The information on pregnant women vaccinated with such vaccine during the first semester is limited, but no change to risk for miscarriage has been observed.

The EMA further noted that the PRAC commenced a further assessment of menstrual disorders following use of mRNA vaccines, following published studies suggesting short-lived changes in menstrual patterns. A previous assessment had been concluded in October 2021 (see [here](#)).

Medical Device Coordination Group publishes revised Guidance on performance evaluation of SARS-CoV-2 *in vitro* diagnostic medical devices (see [here](#))

On 15 February 2022, the European Commission's Medical Device Coordination Group (MDCG) published a revised "*Guidance on performance evaluation of SARS-CoV-2 *in vitro* diagnostic medical devices*" (Guidance). The MDCG is a group of experts appointed by each Member State and chaired by the Commission.

The Guidance concerns the performance evaluation of SARS-CoV-2 *in vitro* diagnostic medical devices (IVDs) (i.e., devices for detection or qualification of SARS-CoV-2 nucleic acid, antigens and antibodies) in the context of conformity assessment under either Directive 98/79/EC (the In Vitro Diagnostic Medical Devices Directive, IVDD) or Regulation (EU) 2017/746 (the In Vitro Diagnostic Medical Devices Regulation, IVDR).

The Guidance, which is non-binding and does not express the Commission's official position, is intended to provide a basis for common specifications for performance evaluation of SARS-CoV-2 IVDs, which the Commission is to adopt in the coming months under Article 9 of the IVDR.

European Commission publishes call for best practices on non-communicable diseases (see [here](#) and [here](#))

On 15 February 2022, the European Commission published a call for best practices on non-communicable diseases as part of the "Healthier Together" – EU Non-Communicable Diseases Initiative (see [here](#)).

The COVID-19 pandemic has shown that people suffering from non-communicable diseases (NCDs) (e.g., cardiovascular diseases, diabetes, chronic respiratory diseases or cancer) can be more affected by other diseases. NCDs are responsible for 80% of the disease burden in EU Member States and the leading cause of premature death.

Towards fostering an EU approach to tackling NCDs, the Commission has invited public and private actors to submit proposals for best practices focusing on prevention and management of NCDs via the EU Best Practice Portal (see [here](#)).

The Portal aims to gather reliable and practical information on implemented practices in the area of health promotion, disease prevention, and management of non-communicable diseases. The Portal only publishes practices evaluated as “best”, and these may be brought to Member State representatives’ attention for further dissemination across the EU.

The call for best practices is open until 15 May 2022.

HERA launches first Work Plan (see [here](#) and [here](#))

On 10 February 2022, the European Health Emergency Preparedness and Response Authority (HERA), published its first Work Plan 2022.

HERA was created to contribute to the EU’s response to the COVID-19 pandemic and pursuit of a robust European Health Union, aiming to improve Europe’s ability to prevent, detect and respond to cross-border health threats and emergencies (see also [Jones Day COVID-19 Update No. 61 of 20 September 2021](#)).

To achieve such aims, the HERA Work Plan 2022 sets out key actions to be implemented throughout 2022 and 2023. These include, in particular:

- Building Europe’s prevention and preparedness for future crises through, e.g., the creation of an IT platform for intelligence gathering with regard to production and availability of medical countermeasures, threat assessment and mapping medical countermeasures, as well as the creation of a stockpile management system.
- Reinforcing Europe’s response capacity by, e.g., promoting wider use of joint EU-level procurement of medical countermeasures, and ensuring close collaboration with global partners to build up resilience and to provide timely and appropriate responses to potential health crises in the future.
- Crisis relevant actions to respond to the ongoing COVID-19 pandemic, e.g., supporting implementation of the EU Vaccines Strategy (particularly in managing Advance Purchase Agreements of COVID-19 vaccines) and the EU Strategy of COVID-19 therapeutics, and continuation of the Expert group on SARS-CoV-2 variants to advise the Commission on categorization of variants and the need to develop new or adapted vaccines to the variants.

A total contribution of €1.3 billion from the EU budget is allocated to HERA in 2022 for preparedness activities and rapidly responding to cross-border health emergencies.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission publishes proposed Data

On 23 February 2022, the Commission published a proposed Data Act (Proposal for a Regulation on harmonised rules on fair access to and use of data).

Act (see [here](#))

The proposed Data Act aims at enhancing data access and use within the EU (see also *Jones Day Alert, European Commission Proposes Legislation Facilitating Data Access and Sharing, February 2022, [here](#)*).

The COVID-19 pandemic, in particular, illustrated the need to access data to address a public emergency. For example, aggregated and anonymized location data from mobile network operators was essential for analyzing the correlation of mobility and the spread of the virus, including informing early warning systems for new outbreaks and taking the right measures to combat the crisis.

The proposed Data Act would be applicable to both personal and non-personal data, and would be relevant for all companies generating, holding or transferring data in the EU, specifically in the Internet of Things (“IoT”) context or for Artificial Intelligence applications. The Proposed Data Act seeks to accomplish the following, for instance:

- Facilitate access to and use of data by businesses and consumers, while preserving incentives to invest;
- Prevent unfair contract terms for data sharing imposed on SMEs;
- Ensure easy switching between cloud, edge and other data processing services;
- Provide for safeguards against unlawful data transfer/access by non-EEA governments;
- Review the Database Directive to exclude machine-generated data from its protection;
- Provide for the access by public sector bodies and EU institutions of data held by enterprises in emergency and other exceptional situations; and
- Provide for the development of interoperability standards for data to be reused between sectors/data spaces, and minimal requirements for smart contracts for data sharing.

The Proposed Data Act must now be adopted by the European Parliament and Council. If adopted, the Data Act will be a Regulation directly applicable in the entire EU, 12 months after its entry into force. It would be enforced by national regulators with the ability to impose fines.

Council updates temporary restriction on non-essential travel into the EU and possible lifting of such restriction (see [here](#))

On 22 February 2022, the Council adopted an updated Recommendation on the temporary restriction of non-essential travel into the EU and the possible lifting of such restriction (Amending Council Recommendation (EU) 2020/912).

The updated Recommendation’s approach takes into account, in particular, the recognition of a growing number of certificates issued by third countries as equivalent to the EU Digital COVID Certificate. It also reflects increasing vaccination uptake and the progressive lifting of travel restrictions worldwide.

The updated Recommendation seeks further coordination to facilitate free movement within, and travel into, the EU. In particular:

- Member States should lift the temporary restriction on non-essential

travel to the EU for travelers:

(a) who have received the last recommended dose of one of the COVID-19 vaccines authorized in the EU at the latest 14 days before entering the EU+ area, provided that less than 270 days have passed since administration of the dose indicated in the vaccination certificate for completion of the primary vaccination series, or an additional dose was received following completion of the primary vaccination series;

(b) who have received the last recommended dose of one of the COVID-19 vaccines that completed the WHO Emergency Use Listing process at the latest 14 days before entering the EU+ area, provided that less than 270 days have passed since administration of the dose indicated in the vaccination certificate for completion of the primary vaccination series, or an additional dose was received following completion of the primary vaccination series; or

(c) who have recovered from COVID-19 within 180 days prior to travelling to the EU.

- In addition to EU Digital COVID certificates, Member States should accept proof of COVID-19 vaccination or recovery if they correspond to certificates recognized by the Commission as equivalent to those issued in accordance with the EU Digital COVID Certificate Regulation (Regulation (EU) 2021/953);
- Where the Commission has not recognized certificates issued by a third country, Member States could accept, in accordance with national law, a proof of testing and vaccination issued by the third country taking into account the need to verify the authenticity, validity and integrity of the certificate and whether it contains all relevant data as provided in the EU Digital COVID Certificate Regulation.

Furthermore, to recall, the Commission recently proposed to prolong application of the EU Digital COVID Certificate Regulation to 30 June 2023. This would imply, in particular, processing of personal data under the Regulation for another year (see [Jones Day COVID-19 Update No. 76 of 9 February 2022](#)). The Commission indicated that it does not propose changes to the Regulation's data protection framework. As such, the GDPR will continue to apply, and personal data contained in the certificates that is processed during their verification must not be retained beyond the verification process.

The updated Recommendation is not a binding instrument and will apply as of 1 March 2022.

The Council also published an accompanying infographic summarizing the COVID-19 restrictions on travel from third countries (see [here](#)).

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