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 State aid Scoreboard 2021
- European Commission posts timeline for State aid policy reviews 2020-2024
- European Commission adopts first amendment of Ukraine Temporary Crisis Framework
- European Commission approves further schemes under Ukraine Temporary Crisis Framework
- European Commission announces phase out of COVID Temporary Crisis Framework, with certain exceptions
- European Commission approves further schemes under COVID Temporary Crisis Framework

Trade / Export Controls

- European Commission publishes Second Annual Report on screening of foreign direct investments
- 9th EU-China High-Level Economic and Trade Dialogue

Medicines and Medical Devices

- EMA and ECDC issue Joint Statement on booster vaccination with Omicron adapted bivalent COVID-19 vaccines
- European Commission publishes 2022-2026 workplan of ACT EU initiative
- EMA adopts measures concerning medicines shortages in the EU
- Provisional agreement reached on Regulation on serious cross-border threats to health
- European Commission and the US Department of Health and Human Services sign cooperation arrangement on preparedness and response to public health threats

Cybersecurity, Privacy & Data Protection

- Provisional agreement reached on 2030 Policy Programme: Path to the Digital Decade

- EDPB and EDPS publish Joint Opinion on Proposal for a Regulation on the European Health Data Space
- European Commission adopts equivalence decisions for EU Digital COVID certificates of Bahrain, Ecuador, the Republic of Korea, Kosovo, and Madagascar
- European Parliament and Council of the European Union adopt extension of the EU Digital COVID Certificate

COMPETITION & STATE AID

State Aid

European Commission publishes State aid Scoreboard 2021 (see here)

On 8 September 2022, the Commission published the State aid Scoreboard 2021.

The Scoreboard, in particular, explains State aid expenditure in 2020 by the 27 EU Member States and the UK*, which together spent €384.33 billion in State aid for all objectives (or some 2.43% of their combined 2020 GDP), excluding aid to railways and Services of General Economic Interest (SGEI).

Total expenditure for COVID-19 measures in 2020 amounted to €227.97 billion (approx. 59% of total State aid spending). In this respect, notably:

- The majority of Member States provided most of their COVID-19 crisis support via non-repayable instruments. Direct grants accounted for over 50% of support in Bulgaria, Ireland, Malta, Slovenia, Czechia, Hungary, Cyprus, Austria, Slovakia, Denmark, Sweden, The Netherlands, and the United Kingdom.
- Tax advantage measures represented a much lower share of total COVID-19 support.

Total non-COVID related public support measures in 2020 amounted to €156.36 billion (approx. 41% of total spending), and in this respect:

- State aid expenditure remained within pre-pandemic ranges, increasing by €9.12 billion compared to 2019 (average annual increase from 2015 – 2019 was €9.80 billion per year).
- Also in line with previous years, Member States spent by far the most on environmental protection and energy savings (€77 billion, with Germany and Denmark spending the most), followed by regional development (€18.30 billion) and research and development, including innovation (€16.40 billion).

According to the Scoreboard, State aid measures actually implemented by Member States have largely correlated to the economic damage suffered during the COVID crisis. The Scoreboard also indicated it found no evidence of Member States granting an excessively larger amount compared to the others.

State aid expenditure data gathered by DG Competition is available on its data repository webpage hosted by EUROSTAT (see here).

* *Until 31 January 2020 and the entry into force of the withdrawal agreement, the UK was an EU Member State and therefore included in the scope of the State aid Scoreboard. Aggregate statistics are disclosed at the EU27 level, plus the UK.*

European Commission publishes timeline for State aid policy reviews 2020-2024 (see here)

In August 2022, the Commission published a timeline for State aid policy reviews 2020-2024. Amongst other developments, the timeline denotes:

- The adoption of the Ukraine Temporary Crisis Framework in Q1 2022 (*see further details below*);
- The phasing out of the State aid COVID Temporary Framework on

	30 June 2022 (*see further details below*). – The anticipated adoption of the Regulation on foreign subsidies distorting the internal market in Q4 2022; and – The anticipated adoption of Regulation on Exemptions for small amounts of aid (de minimis aid) in Q2 2022.
European Commission adopts first amendment of Ukraine Temporary Crisis Framework (see here)	The Commission adopted the first amendment of the State aid Temporary Crisis Framework to support the economy in the context of Russia's invasion of Ukraine on 20 July 2022. 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 amendment, in particular, broadens the Crisis Framework to include additional types of aid measures (which may be granted until 30 June 2023) in view of accelerating: – Renewable energy rollout: Member States can establish schemes for investments in renewable energy (e.g., renewable hydrogen, biogas and biomethane, storage and renewable heat) with simplified tender procedures aimed at swift implementation; and – Diversification of energy supplies through decarbonization of industrial processes: Member States can support investments to phase out fossil fuels (e.g., through electrification, energy efficiency and use of renewable and electricity-based hydrogen), either through (i) new tender based schemes, or (ii) directly supported projects, without tenders, with certain limits on the share of public support per investment. The amended Crisis Framework also expands on the existing types of support that Member States can give to companies in need. For example, it increases the amount of aid that Member States may grant to companies affected by the current crisis or by the subsequent sanctions and countersanctions up to €62,000€ and €75,000 in respectively the agriculture, and fisheries/aquaculture sectors, and up to €500,000 in all other sectors. The current amendment also notably clarifies the conditions under which Member States may grant aid to cover the recent rise in gas and electricity costs for companies (e.g., aid may cover only up to 70% of the beneficiary's gas and electricity consumption during the same period of the preceding year.)
European Commission approves further schemes under Ukraine Temporary Crisis Framework (see here)	The Commission continues to approve additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine. The Crisis Framework, adopted by the Commission on 23 March 2022, 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*). 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. Among the latest schemes under the Crisis Framework (until August 2022): – €90 million Lithuanian scheme to help companies reduce fossil fuel consumption and foster the use of renewables in the context of Russia's invasion of Ukraine – €407 million Italian scheme to support companies of certain municipalities in the context of the coronavirus pandemic and Russia's invasion of Ukraine – €61 million Lithuanian scheme to support companies in context of Russia's invasion of Ukraine – €10 million Latvian scheme to support companies processing agricultural products in the context of Russia's invasion of Ukraine – €260 million Italian scheme to support companies in Friuli Venezia Giulia in the context of Russia's invasion of Ukraine – €30 million Greek scheme to support companies in the context of Russia's invasion of Ukraine – €110 million Austrian scheme to support agricultural producers in context of Russia's invasion of Ukraine – €407 million Italian scheme to support companies of certain municipalities in the context of the coronavirus pandemic and Russia's invasion of Ukraine – €181.5 million Latvian schemes to support companies in 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, 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.
European Commission announces phase out of COVID Temporary Crisis Framework, with certain exceptions (see here)	The Commission announced (as previously indicated in May 2022) the expiry on 30 June 2022 of the State aid COVID Temporary Crisis Framework, with certain exceptions and notably the below two possibilities for Member States to: (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 (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. Additionally, the Temporary Framework already provides for a flexible transition, in particular for the conversion and restructuring options of debt instruments (e.g., loans and guarantees) into other forms of aid, such as direct grants, until 30 June 2023. The Commission indicated that it will continue to closely monitor future developments and will take swift action again as needed. The Commission noted, in this respect, that the positive signs of recovery from the COVID crisis are overshadowed by Russia's war against Ukraine, which has created a disturbance in the European economy and led to the Commission's adoption of the Ukraine Temporary Crisis Framework on 23 March 2022. As of 30 June 2022, under the COVID Temporary Framework (adopted on 19 March 2020) the Commission had taken over 1350 decisions approving around 980 national measures notified by all 27 Member States for an estimate total State aid amount approved of some €3.2 trillion. A summary infographic of the COVID Temporary Framework is available here.
European Commission approves further schemes under COVID Temporary Crisis Framework (see here and here)	The Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the State aid COVID Temporary Crisis Framework adopted in March 2020. With certain exceptions, the Temporary Framework applied until 30 June 2022.* Among the latest schemes (until August 2022): • €358 million Romanian scheme to support companies affected by the coronavirus pandemic • €407 million Italian scheme to support companies of certain municipalities in the context of the coronavirus pandemic and Russia's invasion of Ukraine • €215 million German support to compensate Deutsche Bahn for damages suffered by its subsidiaries due to the coronavirus pandemic • €500 million Irish scheme to support investment towards a sustainable recovery from coronavirus • €475 million Dutch scheme to support event organizers affected by the coronavirus pandemic • €104 million Italian scheme to support companies affected by the coronavirus pandemic ** Exceptions notably include the possibility for Member States to (i) create direct incentives for private investments (until 31 December 2022) and (ii) provide solvency support measures (until 31 December 2023) aimed at easing access to equity finance for smaller companies*

TRADE / EXPORT CONTROLS

European Commission publishes Second Annual Report on screening of foreign direct investments (see here)

On 1 Sept 2022, the European Commission published the Second Annual Report on the screening of foreign direct investments (FDI) into the Union.*

The Report assesses the application of the FDI Screening Regulation 2019/452, which became fully applicable in October 2020. To recall, the Regulation enables Member States and the Commission to identify and address security concerns related to specific investments from outside the EU (*see Jones Day COVID-19 Update No. 69 of 29 November 2021*). Since the creation of the cooperation mechanism, the Commission has screened over 740 FDI transactions.

The Report determined that overall, the FDI Regulation has worked efficiently, providing useful information and preventing investments posing security risks, while not restricting the flow of foreign investment:

- The vast majority of FDI poses no problem from a security/public order perspective and is approved quickly (both at Member State level and under the FDI Regulation).
- The Commission completed the assessment of FDI transactions notified by Member States very quickly, with 86% assessed in 15 calendar days.

On FDI trends and figures, the Report indicated the following, in particular:

- In 2021, global FDI recovered from the COVID-19 slow-down in 2020. Global inflows reached €1.5 trillion in 2021, or a +52% increase with respect to 2020 and a +11% increase with respect to the pre-COVID-19 levels of 2019.
- Cumulated flows of foreign transactions have trended upwards in the 27 EU Member States, despite the slow-down caused by the COVID-19 pandemic, with an average rise of over 2100 acquisitions and 3200 greenfield investments per year from 2015-2021. The US was the leading foreign investor in 2021 (accounting for 32.3% of all acquisitions and 39.4% of greenfield investments), followed by the UK (25.6% and 20.9%, respectively).
- Foreign transactions in the EU gained new momentum in all the main sectors compared with 2020, reaching or even surpassing pre-COVID-19 levels in certain categories. Acquisitions of equity stakes in ICT, Professional and Scientific activities, and Construction sectors, for example, increased respectively by +27%, +8.3% and +10% in 2021 compared to 2019.
- The Commission cautioned, however, that prospects for 2022 for cross-border M&A and greenfield activities remain uncertain and heavily dependent on the behavior of the pandemic and on Russia's war on Ukraine.

On legislative developments in the EU Member States, the Report noted that the global pandemic and recent disruptions in global supply chains exposed the criticality of certain key industries (e.g., healthcare and energy). Many EU Member States responded by either adopting new national screening mechanisms, or updating or expanding existing ones.

	In total, in 2021, two-thirds of all EU Member States had an FDI screening legislation in place, and FDI screening is increasingly gaining momentum in the EU. The Commission expects that all 27 EU Member States will soon have a national FDI screening mechanism in place. * *The Report was adopted simultaneously with the Second Annual Report on Dual Use Export Controls (see here), which addresses dual-use exports i.e., items that may be used for civilian and military purposes. The Commission considers both FDI Screening and Export Controls as key tools for strategic trade and investment controls to ensure EU security.*
9th EU-China High-Level Economic and Trade Dialogue (see here)	The 9th EU-China High-Level Economic and Trade Dialogue, held on 19 July 2022, focused on global economic challenges and was co-chaired by EU Executive Vice-President Valdis Dombrovskis and China's Vice-Premier Liu He. As background to the Dialogue, the European Commission noted that the EU and China are major trading partners. In 2021, China was the third largest partner for EU exports of goods (10.2%) and the largest partner for EU imports of goods (22.4%). EU imports from China were respectively €363 billion and €472 billion in 2019 and 2021. EU exports to China were respectively €198 billion and €223 billion in 2019 and 2021. The Commission reported on the Dialogue's key topics and outcomes, such as the following: – The EU and China agreed on the importance of preventing supply chain disruptions and increasing transparency and exchanging information on the supply of certain critical raw materials and other products. – The EU addressed further cooperation in managing the COVID-19 pandemic, and in particular, encouraged China to review its so-called "circuit breaker" policy (i.e., suspending flight routes when incoming international flights are found to exceed limits for carrying COVID-19 positive passengers onboard), which hampers air services between the EU and China. – The EU emphasized the importance of EU and China working together in addressing the challenges caused by Russia's aggression against Ukraine. The EU noted China's willingness to cooperate on ensuring the stability of global markets and alleviating global food insecurity, including through fertilizer exports. – The EU and China welcomed the positive outcomes of the 12th Ministerial Conference of the World Trade Organization (WTO), with the EU and China agreeing to work jointly on WTO reform in that context. The EU also emphasized the need to address global distortions (e.g., concerning industrial subsidies and overcapacities). The EU and China anticipate holding the next Dialogue in 2023.

MEDICINES AND MEDICAL DEVICES

EMA and ECDC issue Joint Statement on booster vaccination with Omicron adapted bivalent COVID-19 vaccines (see here)

On 6 September 2022, the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) published a Joint Statement on booster vaccination with Omicron adapted bivalent COVID-19 vaccines.*

The Joint Statement follows the EMA's human medicines committee's (CHMP) recommendation on 1 September 2022 to authorize two adapted vaccines that provide a wider protection against COVID-19 in light of new variants (see here).

The Joint Statement includes public health considerations on use of adapted COVID-19 vaccines to support the planning of the autumn and winter vaccination campaigns. It is based on the assessment of current epidemiological trends and available scientific evidence. In particular, the Joint Statement addresses:

- Recommended population groups for booster doses: As a priority, the adapted COVID-19 vaccines should be directed to those at a higher risk of developing a severe disease (e.g., people aged 60 years and above, the immunocompromised, pregnant women and vulnerable people), residents and staff in long-term care homes, and healthcare workers; and

- Interval between booster doses: Regulatory approval allows administering additional booster doses with an interval as short as 3 months after the previous dose, if deemed needed. While real-world evidence indicates that a high level of protection against severe disease is maintained for at least 4 months after the dose was provided, it may be possible to consider longer intervals. This should be balanced with diminishing protection and the local epidemiological situation.

- Booster doses only. The adapted COVID-19 vaccines are currently approved solely for use as booster doses in individuals that completed at least a primary series, regardless of the vaccines used for the primary series. Presently, use of these adapted vaccines should remain limited to booster use.

The Joint Statement further notes that, importantly, the clinical studies supporting the approval of these adapted vaccines were focused on data related to safety and immunogenicity (i.e. priming of immune response); thus, real-world evidence will be essential to measure the impact of these vaccines in preventing infection and disease.

* "*Bivalent" COVID-19 vaccines target two versions of the coronavirus, i.e., the original strain and the Omicron subvariant(s).*

European Commission publishes 2022-2026 workplan of ACT EU initiative (see here)

On 30 August 2022, the European Commission, Heads of Medicines Agencies (HMA), and EMA published the 2022-2026 workplan of the initiative on Accelerating Clinical Trials in the EU (ACT EU).

Launched on 13 January 2022, to recall, ACT EU is an initiative co-led by the Commission and HMA. It intends to strengthen the EU as a hub for clinical research, enhance the development of high quality and effective medicines and better streamline clinical research in the European health system. The

	initiative, in particular, responded to the COVID-19 pandemic, which highlighted the relative absence of EU-wide impactful multi-state clinical trials, as well as the complications and inefficiencies of a preponderance of small single Member State studies. (*see Jones Day COVID-19 Update No. 73 of 17 January 2022*). Among the 2022-2026 workplan's priority actions and related key deliverables expected for 2023, these include: – Successful implementation of the Clinical Trials Regulation (CTR), including by launching a scheme to support large multinational clinical trials; – Developing a multi-stakeholder platform involving all stakeholders to support a more holistic discussion across the clinical research landscape; – Gathering the key actors in scientific advice on clinical trials in the EU (e.g., through enhancing intra-network information exchange), with the aim of assessing the existing landscape in line with stakeholder needs; and – Maximizing the value of clinical trials data analytics, including by developing an EU clinical trials dashboard.
EMA adopts measures concerning medicines shortages in the EU (see here and here)	In June and July 2022, EMA adopted different measures to tackle medicines shortages in the EU. These include in particular: • On 15 July 2022, EMA published a Good Practice Guidance for Patient and Healthcare Professional Organizations on the Prevention of Shortages of Medicines for Human Use (see here). In light of the growing issue of medicine shortages as well as availability issues, as amplified by the COVID-19 pandemic, the Guidance seeks to set out key principles and examples of good practices for shortage prevention and management, such as: – Recommendations on fair distribution and measures to control distribution (e.g., (e.g. restrictions placed on paracetamol dispensing during the COVID-19 pandemic); – Member State practices to prevent and notify shortages (e.g., in Italy, the military pharmaceutical industry has started to produce certain drugs needed to treat COVID-19 patients). • On 7 July 2022, EMA's Medicines Shortages Steering Group (MSSG) adopted the list of the main therapeutic groups of medicines (see here). In particular: – The list forms the basis on which EMA will prepare concrete lists of critical medicines required to deal with a specific "public health emergency" or a "major event" (i.e., likely to pose a serious risk to public health in relation to medicines in more than one EU Member State); – The medicines on such concrete lists are closely monitored because of a potential increased risk of shortages. If

	necessary, EMA can coordinate rapid actions across Member States to ensure continued supply. • On 7 June 2022, MSSG adopted the list of critical medicines for the COVID-19 public health emergency (see here) in particular: – The medicines included in the list comprise all approved vaccines and therapeutics in the EU to prevent or treat COVID-19, and their supply and demand will be closely monitored to identify and manage potential or actual shortages; – Marketing authorization holders (MAHs) of medicines included in the list must regularly update EMA with relevant information, including data on potential or actual shortages and available stocks, forecasts of supply and demand. Member States will also provide regular reports on estimated demand for critical medicines at national level. These measures respond to the EMA's reinforced role in case of a major event to public health emergency at EU level. In such event, EMA facilitates an EU-level coordinated response by monitoring and mitigating the risk of shortages of critical medicines and medical devices, providing advice, and coordinating clinical trials (*see Jones Day COVID-19 Update No. 75 of 1 February 2022*).
Provisional agreement reached on Regulation on serious cross-border threats to health (see here)	On 23 June 2022, the European Parliament and the Council of the EU reached a provisional agreement on the proposed Regulation on serious cross-border threats to health (see here). In light of the lessons learned from the COVID-19 pandemic, the proposal aims at a stronger and more comprehensive legal framework to enable the EU and Member States to react rapidly and to trigger the implementation of preparedness and response measures to cross-border threats to health across the EU (*see Jones Day COVID-19 Update No. 72 of 10 January 2022*). The provisional agreement covers various measures that intend to reinforce action at EU level to support cooperation among the EU Member States. In particular: • The Commission may now formally recognize a public health emergency at EU level, in view of triggering stronger intra-EU cooperation and enabling the timely development, stockpiling and joint procurement of medical countermeasures; • The ECDC (European Centre for Disease Prevention and Control) will carry out regular assessments of prevention, preparedness and response planning at Member State level. This measure responds to the Parliament's efforts to place prevention at the core of the combat against health threats and to secure reinforced mechanisms to prepare for and respond to health crises; and • In the event of EU-level joint procurement of medical countermeasures, Member States may be limited in carrying out parallel procurement and negotiation activities. To safeguard transparency, the Commission will be required to inform Parliament about all joint procurement measures and to make the contracts

	accessible to the Members of the Parliament. The Parliament and Council will now need to adopt the Commission's proposal before it can enter into force.
European Commission and the US Department of Health and Human Services sign cooperation arrangement on preparedness and response to public health threats (see here)	On 9 June 2022, the Commission and the US Department of Health and Human Services signed a cooperation arrangement on preparedness and response to public health threats (Cooperation Arrangement). The Cooperation Arrangement enables the Commission and the US to jointly tackle health emergencies, and in particular, to counter the COVID-19 pandemic. As stated by Stella Kyriakides, European Commissioner for Health and Food Safety: "*Today's first transatlantic arrangement on cooperation in the area of health is an important step in our already close working relationship with the US to counter COVID-19.*" The Cooperation Arrangement covers different action areas, such as: – Identifying a public health threat per year on which to collaborate on; – Sharing secured data for global surveillance to allow early detection of emerging health threats; – Supporting procurement activities; – Coordinating support for R&D of innovative medical countermeasures; and – Tackling mis- and disinformation on health threats by exchanging good practices and initiating joint actions. The Cooperation Arrangement will be coordinated on the EU side by the European Commission Health Emergency and Preparedness Response Authority (HERA) and the Directorate-General for Health and Food Safety, and on the US side by the Department of Health and Human Services. The Cooperation Arrangement is a deliverable of the US-EU Agenda for Beating the Global Pandemic, announced on 22 September 2021, and also complements the US–Commission Joint Statement announced the same day on the launch of the Joint COVID-19 Manufacturing and Supply Chain Taskforce (*see Jones Day COVID-19 Update No. 63 of 11 October 2021*).

CYBERSECURITY, PRIVACY & DATA PROTECTION

Provisional agreement reached on 2030 Policy Programme: Path to the Digital Decade (see here)	On 14 July 2022, the European Parliament and the Council of the EU reached a provisional agreement on the proposal for a Decision establishing the 2030 Policy Programme: Path to the Digital Decade (see here). To recall, the COVID-19 crisis exposed many vulnerabilities and dependencies of the EU and its Member States. In particular, the crisis demonstrated the vital role of technology for economic and health resilience and the critical importance of EU's digital transformation and sovereignty. The Digital Decade Policy Programme aims at addressing these issues by setting out concrete objectives and targets to be achieved by 2030.

	Beyond addressing the deficiencies in Europe's digital capacities, the Programme aims at a successful digital transformation to reinforce its competitiveness and ability to shape universal standards. The Programme, in particular, provides for a novel cooperation mechanism between the EU institutions and its Member States, such as through the following: • Setting trajectories for each target at the EU and national levels. The EU trajectories, developed by the Commission together with the Member States, will help assess progress towards the digital targets on a yearly basis. The Member States, in turn, shall propose national strategic roadmaps, outlining their national projected trajectories and actions to achieve the EU objectives and targets, including planned regulatory measures and investments; • The Commission will publish a yearly report on the "State of the Digital Decade". The report will serve as a yearly assessment of the digital transformation in Europe and progress on achieving digital targets and objectives. Member States and the Commission shall closely cooperate to identify ways to address deficiencies in areas where progress was insufficient to achieve one or more of the digital targets or where significant gaps and shortages were identified based on the results of the report; and • Member States may propose multi-country projects to facilitate the achievement of the targets for digital transformation. These are large-scale projects that channel coordinated investments between the EU, Member States and, where appropriate, other public or private stakeholders. The Commission has identified an initial list of areas where cooperation among Member States is necessary to reach the Digital Decade targets (i.e., the European Common Data Infrastructure and Services; a pan-European deployment of 5G corridors; a Connected Public Administration). The provisional agreement is now subject to formal approval by the European Parliament and the Council of the EU before the Digital Decade Policy Programme enters into force.
EDPB and EDPS publish Joint Opinion on Proposal for a Regulation on the European Health Data Space (see here)	On 12 July 2022, the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) published Joint Opinion 03/2022 on the Commission Proposal for a Regulation on the European Health Data Space (EHDS) *(see also Jones Day COVID-19 Update No. 84 of 17 May 2022*). To recall, the Proposal aims at creating a common space in which individuals can easily control their electronic health data. It also purports to establish a reliable and efficient framework to use health data for research, innovation, policy-making and regulatory activities. The Proposal notes, in particular, that the COVID-19 pandemic highlighted the necessity of digital services in the health area and the importance of timely access to health data for research and policy purposes. The Joint Opinion raises a number of overarching concerns regarding the Proposal and urges the European Parliament and the Council to address

	these. In particular, the Joint Opinion highlights that while the Proposal may contribute to public and individual data subjects/patients' interests by facilitating the use of electronic health data, it may also weaken the protection of privacy and data protection rights. Among the Joint Opinion's main concerns, it considers that: • The Proposal adds another layer to the already complex EU and national legislation relating to the processing of health data; • The Proposal erroneously provides for an exception to the right to be informed under Article 14 GDPR. However, the scope of GDPR exceptions relating to the data subject's rights should not be extended. • The Proposal erroneously considers that personal data gathered through wellness applications and other digital health applications constitutes a secondary use of health data. However, these applications can be highly invasive and do not have the same data quality requirements of those generated through medical devices, and thus should not be considered as a secondary use of data. Furthermore, the Proposal should better specify and circumscribe the purposes for which secondary use of health data is allowed. • In relation to the infrastructure created by the Proposal for the exchange of data (i.e. HealthData@EU), the Proposal should require storing personal electronic health data in the EU/EEA, in view of the large quantity of data that would be processed, their highly sensitive nature and the risk of unlawful access. The Proposal is currently under review by the European Parliament and the Council.
European Commission adopts equivalence decisions for EU Digital COVID certificates of Bahrain, Ecuador, the Republic of Korea, Kosovo, and Madagascar (see here)	On 29 June 2022, the European Commission adopted five new equivalence decisions certifying that COVID-19 certificates issued by Bahrain, Ecuador, the Republic of Korea, Kosovo, and Madagascar are equivalent to the EU Digital COVID Certificate (*see also Jones Day COVID-19 Update No. 81 of 5 April 2022 for the latest preceding Commission Equivalence Decisions*). Holders of certificates issued by these five countries will be able to use them under the same conditions as holders of an EU Digital COVID Certificate do. As a result of these five decisions, 69 countries are now connected to the EU's system (see overview of all decisions here). The Commission's Decisions entered into force on 1 July 2022.
European Parliament and Council of the European Union adopt extension of the EU Digital COVID Certificate (see here)	On 28 June 2022, the European Parliament and the Council of the EU adopted an amendment of the Regulation establishing the EU Digital COVID certificate extending its application by one year, i.e. until 30 June 2023. To recall, the Regulation was adopted on 14 June 2021 (see also *Jones Day COVID-19 Update No. 51 of 15 June 2021*). The Regulation, intended to facilitate free movement during the COVID-19 pandemic, applied since 1 July 2021 and was to expire on 30 June 2022.

The adopted extension of the Regulation will allow persons to continue using their certificate to travel across the EU until 30 June 2023. It may be repealed earlier in case the health situation allows it.

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