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 adopts revised Guidelines on State aid to promote risk finance investments
- European Commission adopts revised Communication on Short-term export-credit insurance
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission announces new Customs Risk Management System
- EU and WTO members reach landmark agreement to simplify trade in services
- EU-Latin America and Caribbean Leaders' Meeting aims at sustainable post-COVID recovery

Medicines and Medical Devices

- EMA announces ICMRA and WHO Report on review of regulatory flexibilities implemented by authorities worldwide during COVID-19 pandemic
- EMA starts rolling review of Valneva's COVID-19 vaccine (VLA2001)
- European Commission announces Communication on a common and coordinated EU approach to the challenges of COVID-19 resurgence
- European Parliament and Council announce provisional agreement on reinforced role for European Centre for Disease Prevention and Control (ECDC)

Cybersecurity, Privacy & Data Protection

- European Parliament and Council announce provisional agreement on Data Governance Act
- European Commission adopts EU Digital COVID Certificate equivalence decision for El Salvador

COMPETITION & STATE AID

State Aid

European Commission adopts revised Guidelines on State aid to promote risk finance investments (see here and here)

On 6 December 2021, the Commission published its Communication on Guidelines on State aid to promote risk finance investments.

The Communication sets out revised Guidelines on the conditions under which Member States may grant State aid to promote risk finance investment to support innovative start-ups, SMEs and certain types of companies with a medium capitalization (mid-caps). Since these types of businesses may face difficulties in gaining access to finance, particularly in the early stages of their development, the Guidelines seek to address this gap.

The revised Guidelines note, in particular, the Commission's view that through properly targeted State aid, Member State support to improve access to finance can serve to foster recovery from the economic crisis caused by the COVID-19 pandemic and to reinforce the EU's resilience against future crises.

The revisions aim at clarifying and simplifying the rules under which Member States can support and facilitate access to finance by European start-ups, SMEs, and mid-caps, such as by:

- limiting the requirement to provide a funding gap analysis to the largest risk finance schemes and further clarifying the evidence needed to justify the aid, given apparent Member State difficulties in quantifying funding gaps;
- introducing simplified requirements for assessing schemes targeted exclusively at start-ups and SMEs that have yet to make their first commercial sale, such that the Commission may consider more limited evidence as sufficing to demonstrate the existence of market failures that justify the granting of aid to these companies.;
- ensuring consistency between definitions in the Guidelines and in the GBER (General Block Exemption Regulation), e.g. by aligning the Guidelines' definition of "innovative mid-caps" with the GBER's definition of "innovative enterprises" to reconcile current inconsistencies on which companies are considered "innovative" under the two sets of rules.*

The revised Guidelines will apply from 1 January 2022.

* *The Risk Finance aid rules are provided in the GBER (Section 3) and in the Risk Finance Guidelines (for aid subject to notification to the Commission).*

European Commission adopts revised Communication on Short-term export-credit insurance (see here and

On 6 December 2021, the Commission adopted a revised Communication on Short-term export credit insurance ("STEC Communication"), following its assessment of the availability of private short-term export credit insurance capacity for exports to all countries listed as "marketable risk countries" under the 2012 STEC Communication. Export credit insurance shields sellers against risks raised by export credit used by foreign buyers to defer payment of goods and services.

here)	To recall, the STEC Communication indicates that trade within the EU and certain non-EU countries listed in its Annex with a maximum risk period of up to two years constitutes marketable risk and, in principle, should not be insured by the State or State-supported insurers. As private insurers may offer such insurance, the Commission considers that the State is not needed to offer similar insurance. According to the Commission's review of the STEC Communication, the rules have worked well and only needed minor adjustments to reflect market developments. The revised Communication's targeted adjustments include, for example, modifying the eligibility criteria for small and medium-sized enterprises (SMEs), such that those with annual export turnover of up to €2.5 million may benefit from State insurance (up from previous threshold of €2 million). On the issue of phasing out the adjusted list of non-marketable risk countries, to recall, with the COVID-19 outbreak, the Commission decided on 27 March 2020 to temporarily remove all countries from the list of marketable risk countries under the STEC. This derogation enabled Member States to make available public short-term export credit insurance in light of the increasing insufficiency of private insurance capacity for exports to all countries during the current crisis. This amendment to the STEC Communication further expanded the flexibility under the State aid Temporary Framework to support the economy in the context of the COVID-19 outbreak, adopted on 19 March 2020. Such derogation from the list of marketable risk countries was prolonged with subsequent amendments of the Temporary Framework, until the latest amendment of 18 November 2021 (*see Jones Day COVID-Update No. 68 of 22 November 2021*). Following private sector feedback on a return to market normalcy, in this latest amended version of the Temporary Framework, the Commission found no need for a long-term prolongation of the temporary derogation from the list of marketable risk countries. Therefore, the amended Temporary Framework envisages an extension of 3 months (from 31 December 2021 to 31 March 2022), in view of permitting adequate phase out time. The revised STEC Communication will apply from 1 January 2022, with no expiry date.
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. • €400 million Italian scheme to support small and medium-sized enterprises in the context of the coronavirus outbreak. • €10 million Irish scheme to support companies active in the arts and culture sectors in the context of the coronavirus outbreak. • €23.33 million Danish scheme to support travel operators in the context of the coronavirus outbreak. • €12.5 million Belgian scheme to support events businesses in the

	context of the coronavirus outbreak. • €21.9 million Latvian scheme to support companies and self-employed persons in the context of the coronavirus outbreak. • Latest modification to €1.4 billion Swedish scheme to support companies in the context of the coronavirus outbreak, in particular to extend the duration of the scheme until 30 June 2022. • Latest modifications to Irish schemes to support companies in the context of the coronavirus outbreak, and in particular to extend their duration until 30 June 2022, in addition to certain increases in maximum aid amounts per beneficiary and increased aid budget: (*€200 million Irish scheme to support companies (SA.57036); €200 million Irish scheme to support COVID-19 relevant research and development (SA.57453); €2 billion Irish scheme to support companies (SA.57465); €26 million Irish scheme to support airport operators (SA.59709); €55 million Irish scheme to support companies active in the tourism sector (SA.61236); and €25 million Irish scheme to support companies in the live performance sector (SA.63067)*). • Latest modification to a €7 billion French scheme to support Air France in the context of the coronavirus outbreak, in particular to extend the duration of the State guarantee for loans for an additional two years until May 2025.
TRADE / EXPORT CONTROLS	
European Commission announces new Customs Risk Management System (see here)	On 1 December 2021, the European Commission announced a new Customs Risk Management System (CRMS2) to reinforce EU customs controls and to safeguard EU citizens, businesses, and the EU's financial interests. The new CRMS2 will officially start operating on 1 January 2022. The CRMS2 facilitates the real-time exchange of risk-related information between customs administrations, covering a wide range of potential risks (e.g. security risks related to explosives, health-related safety risks, environment or product safety risks, and financial and commercial risks including intellectual property rights and cash controls). The Commission notes that the exchange of information between customs authorities has proved particularly valuable during the COVID-19 pandemic, as large quantities of medical goods must be swiftly checked and cleared for use. CRMS2 connects the customs community of the EU's 27 Member States in addition to, for example, Norway. This includes all international ports, airports, major land border posts and all national risk analysis centers.
EU and WTO members reach landmark agreement to simplify trade in	On 2 December 2021, the World Trade Organization (WTO) published a Declaration announcing the Joint Initiative on Services Domestic Regulation, agreed to by 67 participating WTO members, including the EU (Participants).* The Joint Initiative aims at simplifying regulations and easing procedural

services (see here and here)	burdens by seeking to align licensing requirements and procedures, qualification requirements and procedures, and technical standards affecting trade in services, as set out in the so-called "disciplines" in its Reference Paper (Annex I of Declaration). These disciplines address, for example: – Simplifying the submission of applications for authorization to supply a service, e.g. to avoid requiring an applicant to approach more than one competent authority for each authorization application, to the extent practicable; – Encouraging the use of electronic applications, such that competent authorities shall endeavor to accept applications in electronic format for authorization to supply a service, while taking into account such authorities' competing priorities and resource constraints; and – Establishing open and transparent technical standards, e.g. competent authorities shall adopt technical standards developed through open and transparent processes and shall encourage all bodies (including relevant international organizations) designated to develop technical standards to use open and transparent processes. The European Commission indicated that the adoption and implementation of these disciplines are expected to substantially reduce trade costs for service suppliers and thus help the sector in its post-COVID-19 recovery. The Joint Initiative, announced as covering 90% of global trade in services, is anticipated to reduce the costs of global services trade by over USD 150 billion each year. Participants to the Joint Initiative shall make specific commitments by end-2022 to facilitate trade in services in their markets. They also welcome any other WTO Member to join the Declaration. The new commitments will apply to service suppliers from any other WTO member, based on the so-called most favored nation principle. * *Participants*: *Albania; Argentina; Australia; Bahrain, Kingdom of; Brazil; Canada; Chile; China; Colombia; Costa Rica; El Salvador; European Union; Hong Kong, China; Iceland; Israel; Japan; Kazakhstan; Korea, Republic of; Liechtenstein; Mauritius; Mexico; Moldova, Republic of; Montenegro; New Zealand; Nigeria; North Macedonia; Norway; Paraguay; Peru; Philippines; Russian Federation; Saudi Arabia, Kingdom of; Singapore; Switzerland; The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Thailand; Turkey; Ukraine; United Kingdom; United States; Uruguay.*
EU-Latin America and Caribbean Leaders' Meeting aims at sustainable post-COVID recovery (see here)	On 2 December 2021, leaders of the EU and Latin America and the Caribbean (LAC) held a virtual meeting to relaunch the dialogue between the EU and the LAC at the highest level, after a 6-year hiatus. The meeting focused on the theme of "Joining Forces for a Sustainable post-COVID Recovery." The EU-LAC partnership includes a network of association, trade, political and cooperation agreements between the EU and 27 of the 33 countries in the LAC. The EU is the largest investor in the LAC region. Charles Michel (President of the European Council) chaired the meeting,

representing the EU along with Ursula von der Leyen (President of the European Commission). The LAC was represented by the Heads of State/Government of 7 countries holding the presidencies of regional and sub-regional organizations in 2021 (i.e. Brazil, Colombia, Costa Rica, Ecuador, Guatemala, Mexico, and Suriname).

During the meeting, EU leaders raised issues such as:

- Reaffirming the EU's readiness to increased cooperation to address the COVID-19 pandemic, and in particular, the EU has exported over 130 million vaccine doses to LAC countries and is ready to explore possibilities to support the production and distribution of vaccines in the LAC region.
- Encouraging full use of the broad network of trade and association agreements between both regions to spur economic recovery, job creation, and business and investment opportunities.
- Improving future health preparedness, including the importance of a multilateral response; in particular, the EU invited LAC partners to contribute to work on a new international instrument on pandemic prevention, preparedness and response.

MEDICINES AND MEDICAL DEVICES

EMA announces ICMRA and WHO Report on review of regulatory flexibilities implemented by authorities worldwide during COVID-19 pandemic (see here and here)

On 3 December 2021, the European Medicines Agency (EMA) announced the release of a Report by the International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO) on the review of regulatory flexibilities/agilities as implemented by National Regulatory Authorities (NRAs) during the COVID-19 pandemic.

The EMA notes that in responding to the COVID-19 crisis, NRAs adapted some of their regulatory frameworks in seeking to address both the urgent need for medicines and vaccines to tackle COVID-19, as well as constraints posed by the pandemic, such as lockdowns and travel restrictions.

The Report provides concrete examples of regulatory flexibilities and extraordinary measures implemented by NRAs in different areas of medicines regulation, such as:

- Introducing remote monitoring in clinical trials and remote/virtual inspections for manufacturing and clinical trial sites;
- Expanding the adoption, implementation and use of registration pathways involving reliance and mutual recognition for COVID-19 products;
- Allowing certain medical devices that may not fully meet regulatory requirements, but are manufactured according to comparable standards on the list of medical devices for exceptional importation and sale;
- Implementing flexibilities to encourage manufacturers in early engagement with authorities, such as through pre-submission briefs/meetings and allowing for "rolling submissions" of applications for marketing authorizations; and

	• Introducing the requirement for early notification of potential shortages by manufacturers and other stakeholders. As a next step, NRAs are encouraged to share their experiences and exchange information concerning the effectiveness of their regulatory flexibilities applied during the pandemic following an adequate period of implementation. Such feedback is expected to assist in identifying best practices for future public health crises, and where appropriate, even ordinary regulatory activities. Additionally, the WHO/ICMRA are examining certain practices more closely, such as remote inspections and virtual approaches; acceleration of timelines for approvals (regulatory activities); and emergency procedures for access to medicines.
EMA starts rolling review of Valneva's COVID-19 vaccine (VLA2001) (**see here**)	On 2 December 2021, the EMA announced the start of a rolling review of VLA2001, a COVID-19 vaccine developed by Valneva. A rolling review is a regulatory tool enabling the EMA to review clinical data as soon as they become available, in order to decide whether the benefits of the vaccine outweigh the risks. The decision to start the rolling review is based on preliminary results from laboratory studies (non-clinical data) and early clinical studies in adults. These studies suggest that the vaccine triggers the production of antibodies that target SARS-CoV-2, the virus that causes COVID-19, and may help protect against the disease. The rolling review will continue until enough evidence is available for a formal marketing authorization application.
European Commission announces Communication on a common and coordinated EU approach to the challenges of COVID-19 resurgence (see here and here)	On 1 December 2021, the Commission released a Communication on addressing together current and new COVID-19 challenges, which announces a common and coordinated EU approach to tackle the challenges from the recent resurgence of COVID-19 in many Member States. The Communication indicates the need for urgent action, given spiking case numbers and renewed pressure on hospitals, in addition to the Omicron variant's new potential threat. Among other initiatives, the Commission calls for: • The EU and Member States to continue to implement a joint strategy to limit the entry of the Omicron variant into the EU, with day-by-day reviews of essential travel restrictions, including testing and quarantine measures; • Member States to rapidly deploy booster doses to maintain strong levels of protection against the virus including the Omicron variant, starting with the most vulnerable groups; • Member States to run renewed campaigns to target unvaccinated people in all eligible age groups, with targeted national strategies to address vaccine hesitancy; • Member States to increase genomic sequencing capacity and

	surveillance of the Omicron and any other variants of concern, including through widespread wastewater testing, with the Commission helping to ensure that samples and results are shared swiftly; • HERA (EU Health Emergency Preparedness and Response Authority, launched in September 2021) to work with vaccine manufacturers to ensure the swift adaptation of vaccines to the new variant if necessary and guarantee sufficient vaccine production capacity; • The European Parliament and the Council to adopt the European Health Union proposals and the HERA crisis regulation by end-2021. In addition, the Commission recalls that the EU Vaccines Strategy (see here) remains the EU's primary tool for ending the pandemic, as complemented by the EU strategy on COVID-19 therapeutics (see here).
European Parliament and Council announce provisional agreement on reinforced role for European Centre for Disease Prevention and Control (ECDC) (see here)	On 29 November 2021, the European Parliament and the Council reached a Provisional Agreement on the proposed Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC) (see here). The ECDC is tasked with supporting the EU in combating infectious diseases through epidemic intelligence, scientific advice, and training activities, among other areas. Reinforcing the ECDC's role is one component of the EU's response to the COVID-19 pandemic and pursuit of constructing a European Health Union to continue decisively addressing COVID-19 and to improve Europe's ability to respond to cross-border health threats and emergencies *(see also Jones Day COVID-19 Update No. 27 of 18 November 2020)*. The renewed and updated mandate would enable ECDC to take a stronger role in supporting the EU and its Member States in preventing and controlling communicable disease threats and in improving European preparedness for future health challenges. In particular, the ECDC would: • Coordinate the standardization of data collection procedures, data validation, analysis and dissemination of data at EU level; • Establish an EU Health Task Force of experts to assist with preparedness and response planning as well as with local response to outbreaks, in coordination with the European Union Civil Protection Mechanism* and other international mechanisms; • Develop risk assessments and maintain databases for epidemiological surveillance and work towards harmonized approaches to data collection and modelling in order to produce comparable EU-wide data; • Work in close cooperation with international organizations in the field of public health, in order to avoid duplication of efforts, including working more closely with WHO (World Health Organization) to monitor and report on trends in communicable disease and unusual epidemic phenomena; • Provide technical and scientific assistance to national authorities to develop their capacity to detect and sequence the genomes of infectious

agents;

- Monitor the uptake of vaccination against major communicable diseases across the EU, taking into account the specificities of national and regional vaccination schedules; and
- Facilitate the fight against misinformation on vaccination and the causes of vaccine hesitancy.

The Parliament and Council negotiators also agreed to reinforce data protection provisions, such that personal data will not be processed or communicated except in cases where strictly necessary for fulfilling ECDC's mission.

The Provisional Agreement between the European Parliament and Council is not publicly available. The Agreement is part of inter-institutional negotiations, facilitating the formal adoption of the proposed Regulation.

* *The EU Civil Protection Mechanism aims at strengthened cooperation between the EU Member States and 6 Participating States (Iceland, Norway, Serbia, North Macedonia, Montenegro, and Turkey) on civil protection to improve prevention, preparedness and response to disasters. Since 2001, the Mechanism has been activated over 420 times to respond to emergencies in Europe and worldwide.*

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Parliament and Council announce provisional agreement on Data Governance Act (see here and here)

On 30 November 2021, the Parliament and Council reached a Provisional Agreement on the proposed Regulation on European Data Governance (Data Governance Act) (see here).

The proposed Data Governance Act seeks to contribute to creating a single market for data, which is the objective of the European Strategy for Data (see here). Such single market for data aims to ensure increased access to data, which is particularly important in situations where EU coordinated action is necessary, such as the COVID-19 crisis.

As stated by Boštjan Koritnik, President of the Council: *"The Data Governance Act is a major milestone that will boost the data-driven economy in Europe in the years to come.* […] *Data-powered innovations will help us address a range of societal challenges and drive economic growth, which is so important for the post-COVID recovery*."

In particular, the Data Governance Act aims to:

- Create a mechanism to enable the safe reuse of certain categories of public-sector data that are subject to the rights of others (e.g. trade secrets, personal data, and data protected by intellectual property rights), thereby complementing the Open Data Directive of 2019, which does not cover such types of data;
- Create a framework to promote a new business model for data intermediation services, which is intended to provide a secure environment where companies or individuals can share data (e.g. digital platforms to support voluntary data-sharing between companies or data wallet apps to share personal data with others, based on the data holder's consent and rights under the GDPR);
- Facilitate the ability of individuals and companies to make data

	voluntarily available for the common good, such as for medical research projects (e.g. entities seeking to collect data for general interest objectives may request, where fulfilling certain rules, to be listed in a national register of recognized data altruism organizations that would be recognized across the EU); • Create safeguards against unlawful international transfer of or governmental access to non-personal data with respect to public-sector data, data intermediation services and data altruism organizations (e.g. the Commission, through secondary legislation, may adopt adequacy decisions declaring that specific non-EU countries provide appropriate safeguards for the use of non-personal data transferred from the EU; such decisions would resemble adequacy decisions relating to personal data under the GDPR). The Provisional Agreement between the European Parliament and Council is not publicly available. The Agreement is part of inter-institutional negotiations, facilitating the formal adoption of the proposed Regulation.
European Commission adopts EU Digital COVID Certificate equivalence decision for El Salvador (see here)	On 30 November 2021, the Commission adopted a new equivalence decision certifying that COVID-19 certificates issued by El Salvador are equivalent to the EU Digital COVID Certificate (*see also Jones Day COVID-19 Update No. 69 of 29 November 2021 for the latest preceding Commission Equivalence Decisions*). In practice, this means that El Salvador 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, El Salvador has accepted EU Digital COVID Certificates for travel to its country. The European Commissioner for Justice, Didier Reynders stated: "*We keep increasing the figures of countries now connected to the EU Digital COVID Certificate system: 52 countries and territories in five continents so far and we are expecting more soon*." The equivalence decision entered into force on 1 December 2021.

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