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 expresses views on IAG's (aborted) intended acquisition of Air Europa, including in light of impact of COVID-19 restrictions
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- Continued pursuit of US-EU Agenda for Beating the Global Pandemic
- Joint Declaration published on EU Legislative Priorities for 2022, including the role of trade in building a stronger Europe

Medicines and Medical Devices

- European Commission agreement with BioNTech-Pfizer to accelerate deliveries of vaccine doses to Member States
- Update on EMA announcements on medicines and vaccines for treating or preventing COVID-19
- Council of the European Union publishes political agreement on proposed Regulation on emergency framework regarding medical countermeasures
- Joint Declaration published on EU Legislative Priorities for 2022, including the building of a strong European Health Union

Cybersecurity, Privacy & Data Protection

- European Commission adopts rules on validity period of vaccination certificates issued under EU Digital COVID Certificate framework
- European Commission adopts EU Digital COVID Certificate Equivalence Decisions for Uruguay, Tunisia, Thailand, Taiwan, and Montenegro
- EBA consults on draft Guidelines on the Use of Remote Customer Onboarding Solutions
- Council of the European Union publishes political agreement on proposed Regulation on

emergency framework regarding medical countermeasures, including data protection-related items

- Joint Declaration published on EU Legislative Priorities for 2022, including building a Europe fit for the digital age

COMPETITION & STATE AID

Competition

European Commission expresses views on IAG's (aborted) intended acquisition of Air Europa, including in light of impact of COVID-19 restrictions (see here)

On 16 December 2021, the European Commission commented on IAG and Globalia's decision to abandon their proposed agreement for IAG to acquire Air Europa (see here). In Spain, IAG is the largest airline (including ownership of Iberia and Vueling), and Air Europa is the third largest airline.

The Commission had opened an in-depth investigation into the proposed transaction on 29 June 2021. The Commission confirmed its view that discussions with the companies and the proposed remedy package had not adequately addressed its competition concerns.

Competition Commissioner and Executive Vice-President Margrethe Vestager stated: "*IAG and Air Europa are … key providers of connectivity between Spain, the rest of Europe and Latin America….The in-depth analysis carried out during the phase II investigation indicated that the merger would have negatively affected competition on some domestic, short-haul and long-routes within, to and from Spain.*"

In particular, Commissioner Vestager indicated the Commission's position that its "*assessment fully took into account the impact of covid restrictions on the markets affected. Competitive transport markets offer connectivity with a wide offering of affordable flights. This should be preserved for when demand returns fully and travelling picks up once again*."

State Aid

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.

- €7.5 million Greek scheme to support companies in Mantoudi-Limni-St. Anna and Istiaia-Aidipsos in the context of the coronavirus outbreak.
- €9 million Latvian rent compensation scheme to support companies in the context of the coronavirus outbreak.
- €6 million Italian scheme to support Calabrian airports in the context of the coronavirus outbreak.
- €4 million Slovenian scheme to support micro-enterprises in the context of the coronavirus outbreak.
- €12.7 million Belgian scheme to support Walloon airports in the context of the coronavirus outbreak.
- €800,000 Romanian scheme to support sport clubs in the municipality of Sfântu Gheorghe in the context of the coronavirus outbreak.

- €64 million Latvian wage subsidy scheme to support employers, self-employed individuals and patent fee payers in the context of the coronavirus outbreak.
- €10 million Italian scheme to support entertainment agencies and tourist villages in the context of the coronavirus outbreak.
- €2 million Italian scheme to support management bodies of speleological sites and caves in the context of the coronavirus outbreak.
- €49 million Polish scheme to support Poczta Polska in the context of the coronavirus outbreak.
- €23.74 million Belgian scheme to support the commercial passenger and freight rail operators in the context of the coronavirus outbreak.
- €50 million Latvian scheme to support shopping and sports centers, cultural, recreational and entertainment sites in the context of the coronavirus outbreak.
- €3.6 million Greek scheme to support port authorities affected by the coronavirus pandemic.
- €10.3 million Romanian scheme to support airport operators in the context of the coronavirus pandemic.
- €71.4 million Portuguese aid measure to further support TAP Air Portugal in the context of the coronavirus pandemic.
- €88 million German support to compensate Deutsche Bahn for damages suffered by its subsidiary DB Cargo due to the coronavirus outbreak.
- €9.8 million Belgian measure to recapitalize Brussels South Charleroi Airport in the context of the coronavirus outbreak.
- €2.55 billion Portuguese restructuring aid in favor of TAP Group and €107 million compensation for damages suffered due to coronavirus pandemic.
- €125,000 Lithuanian tax deferral scheme to support businesses affected by the coronavirus pandemic.
- €25.5 million Flemish scheme to support companies affected by the coronavirus pandemic.

TRADE / EXPORT CONTROLS

Continued pursuit of US-EU Agenda for Beating the Global Pandemic (see here)	On 22 December 2021, EU-US discussions (led by Björn Seibert (Head of Cabinet of European Commission President Ursula von der Leyen) and Jon Finer (US Principal Deputy National Security Advisor)) took place on advances and next steps in fulfilling the US-EU Agenda for Beating the Global Pandemic Vaccinating the World, Saving Lives Now, and Building Back Better Health Security, announced on 22 September 2021 (see here). Both sides affirmed the significance of the Transatlantic partnership and leadership in ending the pandemic and reinforcing long-term global health

	security. Discussion areas included, among others, sustained efforts to donate and deliver over 1.7 billion vaccine doses worldwide by mid-2022; joint health threat assessments and R&D; and cooperating on strengthening COVID-19 supply chains and increasing global production of vaccines and critical supplies (*see also launch of US-EU Joint COVID-19 Manufacturing and Supply Chain Taskforce in September 2021, Jones Day COVID-19 Update No. 63 of 11 October 2021*). The EU and US delegations also emphasized the need for decisive action in preparing for future health emergencies, including the planned creation in early 2022 of a Financial Intermediary Fund (FIF) for global health security and pandemic preparedness with sustainable capitalization, to be achieved in particular with EU Member States, the G20, lower-middle income countries, the World Bank, and the World Health Organization (WHO).
Joint Declaration published on EU Legislative Priorities for 2022, including the role of trade in building a stronger Europe (see here)	On 16 December 2021, the three EU institutions (European Parliament; Council; and European Commission) signed the Joint Declaration on EU Legislative Priorities for 2022. The Joint Declaration aims at further guiding the EU's recovery from the COVID-19 crisis, while pursuing the opportunities of the green and digital transitions. Together with the EU's Joint Conclusions on policy objectives and priorities for 2020-2024, adopted in December 2020 (see here), the Joint Declaration sets out the EU's political and legislative agenda for recovery and growth between now and 2024. The Joint Statement highlights key legislative proposals currently in the hands of the co-legislators or to be presented by the European Commission by Fall 2022. The accompanying Working Document, in this respect, lists some 138 key legislative proposals (see here). On the role of trade in building a stronger Europe in the global arena, in 2022, the EU institutions will focus on: – Strengthening supply chains and advocating a robust trade policy. This will include promoting a rules-based trade system that aims at ensuring a level playing field and fair trade practices, as well as new trade agreements. – Deterring extra-territorial third-country sanctions and better shielding EU operators from these sanctions by amending and reinforcing the Blocking Statute Regulation (Council Regulation 2271/96). The results of the public consultation on revising the Blocking Statute, published on 17 December 2021 (see here), generally reflect the view that the extra-territorial application of third-country sanctions has negatively impacted the EU and its operators. – Protecting the EU and its Member States from economic coercion by third countries in a newly proposed Regulation published on 8 December 2021 (*see Jones Day COVID-19 Update No. 71 of 13 December 2021*). The three EU institutions will work together on the basis of the Joint Declaration and accompanying Working Document, in view of progressing as far as possible on these objectives by end-2022. *For further details on the Joint Declaration, see below Sections on Medicines and Cybersecurity*.

MEDICINES AND MEDICAL DEVICES

European Commission agreement with BioNTech-Pfizer to accelerate deliveries of vaccine doses to Member States (see here)	On 19 December 2021, the Commission announced its agreement with BioNTech-Pfizer to accelerate the delivery of its mRNA vaccine to Member States. In Q1 2022, BioNTech-Pfizer will deliver an additional 20 million vaccine doses, which supplement the already scheduled 195 million doses. In addition, the Commission and Member States activated the possibility to order over 200 million doses with BioNTech-Pfizer, which may cover vaccines adapted to the Omicron variant, should these vaccines become available. Deliveries of these over 200 million doses are expected to take place as from Q2 2022, and would supplement the already scheduled 450 million doses planned to be delivered in 2022. This will bring the total number of deliveries by BioNTech-Pfizer to 650 million doses in 2022.
Update on EMA announcements on medicines and vaccines for treating or preventing COVID-19	The European Medicines Agency (EMA) issued recent announcements on potential COVID-19 treatments and vaccines: – On 16 December 2021, the EMA recommended authorization of the monoclonal antibody Xevudy (sotrovimab) for the treatment of COVID-19 (see here). The applicant is GlaxoSmithKline Trading Services Limited, who developed the medicine together with Vir Biotechnology. The Commission's final decision on the marketing authorization, which would apply to all Member States, is now expected. – On 16 December 2021, EMA announced its recommendation to extend the indication of the medicine Kinere (ankinra), marketed by Swedish Orphan Biovitrum AB (publ), to include treatment of COVID-19 in adult patients with pneumonia requiring supplemental oxygen and who are at risk of developing severe respiratory failure (see here). – On 16 December 2021, EMA issued advice on the use of Paxlovid for the treatment of COVID-19 (see here). Such advice aims to support national authorities who may decide on possible early use of the medicine prior to marketing authorization, for example in emergency use settings, in the light of rising rates of infection and deaths due to COVID-19 across the EU. The EMA started a rolling review in parallel to providing this advice. To recall, such rolling review is a regulatory tool enabling the EMA to review clinical data as soon as they become available. The rolling review will continue until enough evidence is available for the company to submit a formal marketing authorization application. – On 15 December 2021, the EMA issued a recommendation on the booster dose of the COVID-19 Vaccine Janssen (see here) such that the booster dose may be considered at least two months after the first dose in people aged 18 years and above and may be given after two doses of one of the mRNA vaccines authorized in the EU, Comirnaty (from Pfizer/BioNTech) or Spikevax (from Moderna). At national level, public health bodies may issue official recommendations on the use of booster doses, either following one dose of COVID-19 Vaccine Janssen or two doses of the mRNA vaccines, taking into account the local epidemiological situation,

	availability of vaccines, and emerging effectiveness and the limited safety data for the booster dose.
Council of the European Union publishes political agreement on proposed Regulation on emergency framework regarding medical countermeasures (see here)	On 17 December 2012, the Council published the political agreement on the proposed Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. The European Commission's proposal for the Regulation in September 2021 underlined the EU's inadequate readiness in the face of the COVID-19 pandemic to ensure efficient development, manufacturing, procurement and distribution of crisis-relevant medical countermeasures. The political agreement adds, in particular, that the proposed Regulation aims at establishing an instrument of economic policy that is fundamental to avoiding the adverse economic consequences of health crises (e.g. unemployment, market disruptions, and impediments to swift manufacturing), which surged with the COVID-19 pandemic. The proposed Regulation establishes a framework for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency, which would include, in particular: • Establishing a Health Crisis Board, which should ensure the coordination of the actions by EU and Member State bodies by giving guidance to the Commission preparing and implementing medical countermeasures; • Monitoring, procurement and purchase of crisis-relevant medical countermeasures and crisis-relevant raw materials; • Activating emergency research and innovation plans, including the use of EU-wide clinical trial networks and data sharing platforms; • Emergency EU funding and financing; and • Measures concerning the production, availability and supply of crisis-relevant medical countermeasures, including the establishment of an inventory of crisis-relevant production and production facilities, raw materials, consumables, equipment and infrastructure, and including measures aiming at increasing their production in the EU. The political agreement makes several contributions to the proposal regarding the Health Crisis Board. In particular: • The Health Crisis Board shall be co-chaired by the Commission and the Member State holding the rotating presidency of the Council; • The Commission shall consult the Health Crisis Board in a timely manner, whenever possible before taking action, and shall take the utmost account of the result of deliberations within the Health Crisis Board; • The Health Crisis Board may issue opinions, upon request of the Commission or on its own initiative. In case the Commission does not follow the opinion of the Health Crisis Board, it shall explain the reasons for its action to the Health Crisis Board, without prejudice to

	the Commission's right of initiative; and • The Health Crisis Board shall advise the Commission on the need to use a purchasing mode where the Commission acts as a central purchasing body on behalf of Member States, either in conjunction with other available instruments or as an autonomous procurement mode. In addition, the political agreement aims to strengthen the role of the Member States by allowing them to mandate the Commission to act as a central purchasing body to procure crisis-relevant medical countermeasures and raw materials on their behalf. The final text based on the political agreement is expected to be submitted to the Council for adoption in early 2022. *For further details on the proposed Regulation, see below Section on Cybersecurity*.
Joint Declaration published on EU Legislative Priorities for 2022, including the building of a strong European Health Union (see here)	On 16 December 2021, the three EU institutions (European Parliament; Council; and European Commission) signed the Joint Declaration on EU Legislative Priorities for 2022 (*for further details on the Joint Declaration, see above Section on Trade and below Section on Cybersecurity)*. The Joint Declaration aims at further guiding the EU's recovery from the COVID-19 crisis, while pursuing the opportunities of the green and digital transitions. Together with the EU's Joint Conclusions on policy objectives and priorities for 2020-2024, adopted in December 2020 (see here), the Joint Declaration sets out the EU's political and legislative agenda for recovery and growth between now and 2024. Its accompanying Working Document, in this respect, lists some 138 key legislative proposals (see here). With respect to the building a strong European Health Union to reinforce the EU's preparedness and resilience in the face of future health crises, in 2022, the EU institutions will prioritize work on, for example: – the proposed Regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU ("Cross-border Health Threats Decision"), aimed at a stronger and more comprehensive legal framework for the EU to react rapidly and trigger the implementation of preparedness and response measures to cross-border threats to health across the EU, with inter-institutional discussions on the proposal anticipated to continue in early 2022; and – a proposal for a Regulation on a European health data space, anticipated for Q1 2022, aimed at promoting access to health data for research on new strategies for prevention, diagnosis, and treatment solutions, as well as providing individuals with greater control over their health data (see also *Jones Day COVID-19 Update No. 46 of 5 May 2021*). The three EU institutions will work together on the basis of the Joint Declaration and accompanying Working Document, in view of progressing as far as possible on these objectives by end-2022.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission adopts rules on validity period of vaccination certificates issued under EU Digital COVID Certificate framework (see here)	On 21 December 2021, the Commission adopted rules relating to the EU Digital COVID Certificate, establishing a binding acceptance period of 9 months (i.e. 270 days) of vaccination certificates for the purposes of intra-EU travel (*see Draft Commission Delegated Regulation amending the Annex to Regulation (EU) 2021/953 on the acceptance period of vaccination certificates issued in the EU Digital COVID Certificate format indicating the completion of the primary vaccination series (Delegated Regulation),* here). To recall, the EU Digital COVID Certificate is to serve as proof that a person: (i) is vaccinated against COVID-19; (ii) received a negative test result; or (iii) recovered from COVID-19 (*see Jones Day COVID-19 Update No. 51 of 15 June 2021*). When the COVID Certificate was launched, insufficient data was available regarding the duration of protection resulting from completion of the primary series of a COVID-19 vaccine. As Member States were free to determine the validity of the vaccination certificates, this raised the potential of causing significant disruptions to citizens and businesses arising from diverging measures. Under the new harmonized rules, Member States must accept any vaccination certificate issued less than nine months since the administration of the last dose of the primary vaccination. Member States cannot provide for a shorter or longer acceptance period. As concerns booster doses, no standard acceptance period will apply at this time to certificates issued, in view of the current lack of sufficient data on the period of protection. The European Data Protection Supervisor delivered formal comments on the Delegated Regulation on 14 December 2021, following its consultation in accordance with Regulation 2018/1725 on data protection obligations for EU institutions and bodies when they process personal data and develop new policies (see here). The Draft Decision will apply as from 1 February 2022.
European Commission adopts EU Digital COVID Certificate Equivalence Decisions for Uruguay, Tunisia, Thailand, Taiwan, and Montenegro	On 21 December 2021, the Commission adopted five new equivalence decisions certifying that COVID-19 certificates issued by Uruguay (see here), Tunisia (here), Thailand (here), Taiwan (here), and Montenegro (here) 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 five 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 five countries have accepted EU Digital COVID Certificates for travel to their countries. To recall, the COVID Certificate can be used as proof of vaccination, recent negative test result, or recovery from the virus. Each EU Digital COVID Certificate contains a QR code with a digital signature to protect it against falsification. To ensure proper verification of the certificates across the EU, the

	Commission also developed a secure digital infrastructure to connect the national systems, which went live on 1 June 2021. As of end-December 2021, some 807 million COVID Certificates were issued in the EU, with 60 countries and territories across five continents that have joined the system. These latest equivalence decisions entered into force on 21 December 2021.
EBA consults on draft Guidelines on Use of Remote Customer Onboarding Solutions (see here and here)	On 10 December 2021, the European Banking Authority (EBA) launched a public consultation on its draft Guidelines on the use of Remote Customer Onboarding Solutions under Article 13(1) of Directive (EU) 2015/849 ("Anti-money Laundering Directive," Art. 13 (1) on Customer due diligence measures). In the face of restrictions on movement caused by COVID-19, financial sector operators are accelerating the implementation of new methods for the remote onboarding of new customers. The EBA notes the growing reliability of digital tools to identify and verify that customers are who they claim to be. Still, it cautions that financial sector operators must provide safeguards to mitigate money laundering / terrorist financing risks and impersonation fraud risks when performing initial customer due diligence. The draft Guidelines aim to establish a common understanding by competent authorities of the steps that financial sector operators should take to ensure safe and effective remote customer onboarding practices. At the same time, operators must respect applicable legislation on anti-money laundering and countering the financing of terrorism, as well as the EU's data protection framework. For instance, as concerns data protection: • On identifying customers, where financial sector operators do not resort to digital identity issuers, they should ensure that the images, video, sound and data are stored according to the GDPR (Regulation (EU) 2016/679) and remain available to the financial sector operator; • Where outsourcing all or parts of the remote customer onboarding to an outsourcing provider, financial sector operators shall ensure that only necessary customer's data is collected and stored with a clearly defined retention period; access to the data is strictly limited and registered; and appropriate security measures are implemented to ensure that the stored data is protected where the outsourcing provider stores customer's data; • Financial sector operators should carry out a pre-implementation assessment for the end-to-end customer onboarding solution it intends to use, which should include tests to assess fraud risks including impersonation fraud risks and other the information and communication technology (ICT) and security risks; • Financial sector operates should ensure that when a customer is onboarded using their digital identity, this occurs in a secure environment and, where possible, strong authentication is applied when verifying their digital identity; • Financial sector operators should use secure communication channels to interact with the customer during the remote customer

	onboarding process. Secure protocols and strong and widely recognized encryption techniques should be used to safeguard the confidentiality, authenticity and integrity of the exchanged data at rest and in transit; and • Ongoing monitoring of the remote customer onboarding solution should be carried out by financial sector operators, including steps to check the quality, accuracy and adequacy of data collected during the remote customer onboarding process. Following the public consultation, which runs until 10 March 2022, the EBA will finalize the Guidelines. Once adopted, these Guidelines will apply to all financial sector operators that are within the scope of the Anti-money Laundering Directive.
Council of the European Union publishes political agreement on proposed Regulation on emergency framework regarding medical countermeasures, including data protection-related items (see here)	On 17 December 2021, the Council published the political agreement on the proposed Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. The political agreement adds data protection-related provisions to the proposed Regulation, and in particular: • Personal data shall not be processed or communicated except in cases where this is strictly necessary to the purposes of the Regulation and, in such cases, in compliance with both the GDPR (Regulation (EU) 2016/679) and data protection obligations for EU institutions and bodies when they process personal data and develop new policies (Regulation (EU) 2018/1725); • Where processing of personal data is not strictly necessary to the fulfilment of the mechanisms established in the Regulation, personal data shall be rendered anonymous such that the data subject is not identifiable; and • The Commission shall adopt detailed rules to ensure full compliance with data protection requirements under EU legislation concerning the role of actors involved in the collection and processing of personal data. *For further details on the proposed Regulation, see above Section on Medicines*.
Joint Declaration published on EU Legislative Priorities for 2022, including building a Europe fit for the digital age (see here)	On 16 December 2021, the three EU institutions (European Parliament; Council; and European Commission) signed the Joint Declaration on EU Legislative Priorities for 2022 (*for further details on the Joint Declaration, see above Sections on Trade and Medicines)*. The Joint Declaration aims at further guiding the EU's recovery from the COVID-19 crisis, while pursuing the opportunities of the green and digital transitions. Together with the EU's Joint Conclusions on policy objectives and priorities for 2020-2024, adopted in December 2020 (see here), the Joint Declaration sets out the EU's political and legislative agenda for recovery and growth between now and 2024. Its accompanying Working Document, in this respect, lists some 138 key legislative proposals (see here). On building a Europe fit for the digital age, in 2022, the EU institutions will

prioritize initiatives on, for example:

- digital services and digital markets (e.g. Proposal for a Regulation on contestable and fair markets in the digital sector (Digital Markets Act), to undergo inter-institutional discussions in Q1-Q2 2022);
- artificial intelligence (e.g. proposed Regulation on harmonized rules on artificial intelligence (Artificial Intelligence Act), currently undergoing inter-institutional discussions);
- data (e.g. anticipated proposal for a Data Act to encourage data sharing among businesses and between businesses and government, with the Commission conducting a more in-depth analysis of the results of a public consultation released in Dec. 2021 (see here); and
- improved cyber resilience (e.g., proposal for a European Cybersecurity Resilience Act anticipated for Q3 2022, aiming at establishing common standardization standards for cybersecurity products).

The three EU institutions will work together on the basis of the Joint Declaration and accompanying Working Document, in view of progressing as far as possible on these objectives by end-2022.

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