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

- Executive Vice-President and Competition Commissioner Margrethe Vestager speaks at U.S. Chamber of Commerce's Transatlantic Business Works Summit
- European Commission approves new and amended Member State measures to support the economy

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- European Commission proposes Anti-Coercion Instrument
- European Commission releases second EU-Japan EPA Progress Report

Medicines and Medical Devices

- European Commission announces adoption of Regulation on Health Technology Assessment
- ICMRA highlights need for continued focus on developing COVID-19 therapeutics
- EMA and ECDC adopt recommendations on “mix and match” vaccination courses against COVID-19

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- European Commission releases Annual Report on Application of EU Charter of Fundamental Rights – Protecting Fundamental Rights in the Digital Age
- European Commission adopts EU Digital COVID Certificate equivalence decisions for Cabo Verde, Lebanon, and the United Arab Emirates

COMPETITION & STATE AID

Competition

Executive Vice-President and Competition Commissioner Margrethe Vestager speaks at U.S. Chamber of Commerce's Transatlantic Business Works Summit (see here)

On 9 December 2021, Executive Vice-President and Competition Commissioner Margrethe Vestager spoke at the U.S. Chamber of Commerce's Transatlantic Business Works Summit. She focused on the prominence of technology, both in serving to recover from the pandemic and in raising complexities in safeguarding competition, individuals, and democratic values.

In Commissioner Vestager's view, immense investment in innovation is essential to enable democracies to retain a technological edge. In this respect, she referred to the EU's Recovery and Resilience plan to re-ignite the Europe's economy following the pandemic (providing up to €672.5 billion to finance reforms and investments, *see also* *Jones Day COVID-19 Update No. 64 of 18 October 2021*). Commissioner Vestager stated that the Recovery plan targets unprecedented levels of funding on innovation from 5G and fibre rollout to advanced digital skills, and she further noted the US's similar ambitions.

Commissioner Vestager also commented that the EU and US must create a framework for technology to serve their people and democracies, referring to the perceived need for "better digital regulation."

In this respect, she referred to the EU's proposed Digital Markets Act (DMA), which would recognize what it considers as the special role and responsibility of those deemed as so-called large "gatekeeper" platforms. The proposed DMA would impose certain obligations on such "gatekeepers" with the stated aim of preserving competition, protecting small digital players, and ensuring value and choice for consumers (*see also* *Jones Day COVID-19 Update No. 68 of 22 November 2021*).

In Commissioner Vestager's view, the EU was making good progress towards passing the proposed DMA, and she felt a "strong convergence" with the US in shared concerns over digital markets.

Finally, Commissioner Vestager referred to the new EU-US Joint Technology Competition Policy Dialogue, launched on 7 December 2021 (see here), which seeks to help the EU and US to address common perceived challenges in technology and digital markets.

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.

- €133 million Swedish scheme to support rail freight and passenger operators in the context of the coronavirus outbreak.
- €5.5 million Estonian scheme to support dairy and pork meat

producers in the context of the coronavirus outbreak.

- €52.7 million Dutch scheme to support zoos in the context of the coronavirus outbreak.
- €155.6 million Italian scheme to support companies in the context of the coronavirus outbreak.
- €3.6 million Greek scheme to support port authorities in the context of the coronavirus outbreak.
- €10.3 million Romanian scheme to support airport operators in the context of the coronavirus outbreak.
- Latest modification to €1.4 billion Dutch scheme (SA.57712) to support companies in the context of the coronavirus outbreak, and in particular to increase the overall budget by €1.9 billion, to extend the period and criteria for eligibility, and to modify the maximum aid amount per beneficiary.
- Latest modification to €650.000 Latvian scheme (SA.64033) to support companies active in microgreen production, fishery and aquaculture sectors in the context of the coronavirus outbreak, and in particular to increase the overall budget by €7 million and to extend the period and criteria for eligibility.
- Latest modification to €9.1 billion Swedish scheme (SA.56860) and €4.9 billion Swedish scheme (SA.61486) to support companies in the context of the coronavirus outbreak, and in particular to extend the maximum term of guarantees to a period of five years.

TRADE / EXPORT CONTROLS

European Commission proposes Anti-Coercion Instrument (see here)

On 8 December 2021, the European Commission published a proposed Regulation on the protection of the Union and its Member States from economic coercion by third countries (so-called Anti-Coercion Instrument (ACI)).

The proposed ACI is a new tool aimed at counteracting third-country economic coercion against the EU or any of its Member States. Such coercion restricts trade or investment (or threatens to), with the aim of pressuring the EU or Member States into making certain policy choices in areas such as climate change, taxation or consumer security.

The Commission notes the specific need for an anti-coercion instrument to aid in navigating rising global tensions, aggravated by the COVID-19 crisis, with trade increasingly “weaponized” in a geo-economic context. In this respect, the Commission cites cases of “vaccine diplomacy”, where certain countries reportedly accompanied COVID-19 vaccine supplies with soft power messages to support their standing or positions, or withheld such vaccines subject to changing a policy position.

As the EU legislative framework currently lacks an instrument specifically addressing coercion, the proposed ACI would seek to fill this gap. With deterrence as its primary goal, the proposed ACI would empower the Commission to apply trade, investment or other restrictions towards any non-EU country deemed as unduly interfering in the policy choices of the EU or its Member States. This framework is intended to enable the Commission to

	respond to cases of economic coercion in a structured and uniform manner to ensure predictability and transparency. A wide range of potential measures would be available under the proposed ACI in seeking the cessation of economic coercion, such as: – new or increased customs duties and quantitative restrictions on the export and import of goods; – restrictions on intellectual property rights or their commercial exploitation in relation to right-holders who are nationals of the third country concerned; – restrictions on foreign direct investment into the EU; and – restrictions on access to EU-funded research programs. The proposed ACI will now undergo discussion by the European Parliament and the Council of the European Union. Until 7 February 2022, stakeholders and citizens may also provide further feedback on the proposal (see here), which the Commission will present to the European Parliament and Council in view of contributing to the legislative debate.
European Commission releases second EU-Japan EPA Progress Report (see here)	On 8 December 2021, the European Commission released the second EU-Japan EPA Progress Report, which presents the results of the second year of implementation (i.e. 1 February 2020 to 31 January 2021) of the EU-Japan Economic Partnership Agreement (EPA) Facility Instrument. The EPA, which entered into force on 1 February 2019, is a trade agreement seeking to further facilitate trade between the EU and Japan, notably by removing tariffs and other trade barriers and assisting in shaping global trade rules in line with both parties' values. Japan is the EU's second-biggest trading partner in Asia after China. Despite a temporary trade reduction in 2020 due to the COVID-19 crisis, the Report indicates that Japan was the seventh largest EU trading partner in terms of both exports and imports. In 2020, EU exports to Japan fell to a low of €12.6 billion in Q3 but recovered to €13.9 billion in Q4. EU imports from Japan reached a low of €12.5 billion in Q2, recovering to €14.4 billion in Q4. In light of increased customs and trade facilitation efforts of both the EU and Japan, the Report indicates substantial progress, in particular, in the use of the tariff preferences stipulated under the EU-Japan EPA in 2020. The Report further notes amendments to Japanese laws and practices that reflect the commitments made by Japan in the EPA (e.g. completing the authorization of certain additives to wine), in addition to non-legislative measures that accelerate or facilitate the EPA's implementation (e.g. Japan Customs encouraging Japanese exporters to register in English on the corporate number publication website of the National Tax Agency, to enable EU customs authorities to easily confirm corporate numbers appearing in statements on origin).
MEDICINES AND MEDICAL DEVICES	
European Commission announces	On 13 December 2021, the Commission announced the adoption of the proposed Regulation on Health Technology Assessment (see here). The Regulation aims to expand the availability of vital and innovative health

adoption of Regulation on Health Technology Assessment (see here and here)	technologies (e.g., new medicines, medical devices and equipment, and prevention and treatment methods) by ensuring the efficient use of resources and strengthening the quality of health technology assessment (HTA) across the EU. An HTA is a multidisciplinary comparative assessment process that evaluates available evidence about the clinical and non-clinical issues related to the use of a health technology. The outcome of such assessments is used to inform decisions concerning the allocation of budgetary resources in the field of health (e.g. to establish pricing or reimbursement levels of health technologies). These assessments can assist Member States in creating sustainable healthcare systems and stimulating innovation. The Regulation establishes a support framework and procedures for cooperation on HTA at EU level. In particular, it lays down harmonized rules for the clinical assessments of medicinal products and medical devices conducted by competent authorities of the Member States. As stated by the European Commissioner for Health and Food Safety, Stella Kyriakides: "*With COVID-19, we have seen the importance of producing safe and efficient treatments and medical devices for all Europeans. The new rules will secure inclusiveness and transparency in the assessment process and increase predictability for Member States' authorities and for the industry*." The Regulation will enter into force in January 2022 and will apply from January 2025. The Regulation is a key deliverable of the European Pharmaceutical Strategy and an important building block for a European Health Union *(see also Jones Day COVID-19 Update No. 27 of 18 November 2020)*.
ICMRA highlights need for continued focus on developing COVID-19 therapeutics (see here)	On 12 December 2021, the International Coalition of Medicines Regulatory Authorities (ICMRA) issued a statement on the important ongoing need for developing additional therapeutics to treat and prevent COVID-19. ICRMA recognizes the tremendous progress in developing health products to combat COVID-19, such as new testing devices, a variety of disinfectants, sanitizers, and personal protective equipment, as well as several vaccines successfully brought to market and deployed globally, with others under development. However, ICRMA emphasizes the need for sustained efforts to increase the availability and accessibility of effective treatments across the disease spectrum. This is especially important in view providing complements to vaccination, such as: • treatment options for persons unable to be vaccinated or with lower immune response to vaccines; and • tackling break-through infections, the emergence of SARS-CoV-2 variants with some level of vaccine resistance, and dwindling immunity. ICMRA calls on researchers, industry, healthcare professionals, and others to collaborate and to focus development efforts on therapeutics addressing the full range of the COVID-19 disease in all populations (and in particular, underserved populations such as pediatric patients and pregnant individuals).

	Finally, ICMRA affirmed its continued support of international collaboration on pharmacovigilance and post-approval systems to equip regulators with data and information that promotes well-informed and timely action.
EMA and ECDC adopt recommendations on "mix and match" vaccination courses against COVID-19 (see here)	On 7 December 2021, the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) issued recommendations on (i) use of two different COVID-19 vaccines for the first and second doses of a primary course (heterologous primary vaccination) and (ii) use of a third dose of a different COVID-19 vaccine as a booster 3 to 6 months after a primary vaccination course (heterologous boosting). Studies on heterologous vaccination suggest that combining viral vector vaccines and mRNA vaccines, whether in a primary or booster regimen, produces good levels of antibodies against the COVID-19 virus and a higher T-cell response than using the same vaccine (homologous vaccination). Less well-studied is the use of a viral vector vaccine as a second dose in primary vaccination schemes, or use of two different mRNA vaccines. EMA's and ECDC's recommendations are intended to help decision-makers for national vaccination campaigns to ensure that the maximum number of EU citizens are vaccinated and protected as quickly as possible.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission releases Annual Report on Application of EU Charter of Fundamental Rights – Protecting Fundamental Rights in the Digital Age (see here)	On 10 December 2021, the Commission released the 2021 Annual Report on the Application of the EU Charter of Fundamental Rights. The EU Charter, which is binding EU law, protects a broad range of rights linked to human dignity, freedom, equality and solidarity, including requiring that any restrictions to fundamental rights must be necessary and proportionate. The 2021 Report is the first to follow last year's strategy to strengthen the application of the EU Charter of Fundamental Rights, including through annual reports with thematic focuses. The Report focuses on the challenges of protecting fundamental rights in the digital age, and in particular, how the COVID-19 pandemic has tested the protection and guarantees of fundamental rights and freedoms. In relation to data protection and privacy, the Report notes that the COVID-19 pandemic has highlighted urgent issues such as the following: • Responding to the pandemic has frequently involved the processing of personal data, including health data, which is subject to further rules under the GDPR due to its sensitive nature. In this respect, the Commission has provided guidance to Member States, for example, through a Communication on apps to fight the pandemic in relation to data protection (see here). • The importance of encryption to protect the confidentiality of information, given the growing use of digital tools during the pandemic and the corresponding rise in cyberattacks that have seriously harmed companies and critical services, as well as jeopardized

	people's rights. As encryption also enables criminals to conceal their identities and the contents of their communications, the Commission intends to present a proposal in 2022 to address the issue of lawful access to encrypted information in the context of criminal investigations, based on mapping how Member States deal with encryption together with a multi-stakeholder process to weigh the concrete options (legal, ethical and technical). • The rise of online educational tools during the COVID-19 pandemic, including the use of commercial digital learning solutions and software to monitor students taking exams remotely, has raised concerns that their design might leverage user data for profitmaking, rather than meaningful educational practices. To address these concerns, the European Digital Education Hub (launch expected by end-2021) will serve as a forum to develop measures, in particular, for quality assurance and respect for data protection and privacy. The Commission calls on the European Parliament, the Council and Member States to use the Report to engage in exchanges about the challenges and opportunities for protecting fundamental rights in the digital age.
European Commission adopts EU Digital COVID Certificate equivalence decisions for Cabo Verde, Lebanon, and the United Arab Emirates (see here)	On 10 December 2021, the Commission adopted three new equivalence decisions certifying that COVID-19 certificates issued by Cabo Verde, Lebanon, and the United Arab Emirates (UAE) are equivalent to the EU Digital COVID Certificate (*see also Jones Day COVID-19 Update No. 70 of 6 December 2021 for the latest preceding Commission Equivalence Decisions*). In practice, this means that these three 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 three countries have accepted EU Digital COVID Certificates for travel to their countries. The European Commissioner for Justice, Didier Reynders stated: "*The EU Digital COVID Certificate is unique and that's why 55 countries and territories in five continents have joined the system so far with more than 750 million certificates issued*." The equivalence decisions entered into force on 10 December 2021.

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