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 2021 General Report on Activities of the European Union
- European Commission comments on Intel's investment plans in the European Union
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- WTO reports compromise on temporary TRIPS waiver on COVID-19 vaccine patents
- European Commission publishes update on Export of COVID-19 vaccines from EU
- European Commission's Directorate-General for Trade issues Management Plan 2022

Medicines and Medical Devices

- EMA starts to review the marketing authorization application for Evusheld submitted by AstraZeneca
- EMA publishes new clinical data for six COVID-19 medicines
- EMA publishes PRAC meeting highlights on safety concerns

Cybersecurity, Privacy & Data Protection

- European Commission adopts second Report on EU Digital COVID Certificate
- EDPB and EDPS publish Joint Opinion on Proposal to amend EU Digital COVID-19 Certificate Regulation

COMPETITION & STATE AID

Competition

European Commission publishes 2021 General Report on Activities of the European Union (see here)

On 9 March 2022, the Commission published "The EU in 2021 – General Report on the Activities of the European Union."

The Report notes that in 2021, following one of the most challenging years in the EU's history, the EU began to launch its recovery from the COVID-19 pandemic. This included the EU's continued and extended efforts to respond to the crisis, with over 2,326 measures adopted in total to provide support since the beginning of the pandemic.

As concerns State aid, in 2021, the Report noted:

- The Commission's continued use of State aid rules as part of its policy response to the pandemic's severe impact on the economy. By end-2021, the Commission had adopted over 730 decisions, approving nearly 900 national measures notified by the Member States, for a total funding amount of €3.17 trillion.

- The Commission's initial response to the urgent need to keep businesses afloat had shifted to fostering robust and sustained recovery, in particular through the sixth amendment to the State Aid Temporary Framework (adopted in November 2021), which aims to enable an EU-wide coordinated phase-out of support while envisaging measures to accelerate the recovery (*see Jones Day COVID-19 Update No. 68 of 22 November 2021*).

The Report also noted the continued role of competition law in supporting Europe's recovery, the green and digital transitions, and a resilient Single Market, as framed by the Communication on Competition Policy Fit for New Challenges of 18 November 2021.

To recall, the Communication, in particular, addressed the comprehensive current review of competition policy and enforcement, which spans over 20 sets of competition rules and guidelines, across all competition instruments (merger, antitrust and State aid control) (*see Jones Day COVID-19 Update No. 68 of 22 November 2021*).

State Aid

European Commission comments on Intel's investment plans in the European Union (see here)

On 15 March 2022, Commission President Ursula von der Leyen welcomed Intel's announced investment plans in the EU as a "*first major achievement*" under the recently proposed EU Chips Act (*see Jones Day Commentary, EU Chips Act: The EU's Push for Semiconductor Autonomy*, March 2022, here).

To recall, the proposed EU Chips Act sets out a planned strategy for semi-conductors to incentivize manufacturing in the EU and achieve strategic autonomy. The proposal follows the Commission's previous assertions that the COVID-19 pandemic has exposed vulnerabilities in certain sectors in Europe due to high dependency on a perceived narrow range of non-EU suppliers, especially for raw materials. The Commission believes that this is particularly the case for the EU industry confronted by semiconductor

	shortages. Although specific new powers and funding mechanisms under the proposed EU Chips Act would require enactment through a regulation by the Parliament and the Council, many of the Commission's policy objectives do not require a change in the law and can already be applied. Crucially, the EC can immediately apply the more lenient interpretation of State aid rules for building new fabs that it announced in this proposal. In total, over €43 billion of public investment (both EU and national investments) would support the EU Chips Act until 2030, in view of attracting tech companies to Europe to invest in cutting-edge chips development and production. President von der Leyen noted that Intel planned as much as an €80 billion investment in the EU over the next decade across the entire semiconductor value chain. As stated by Intel: "*The EU Chips Act will empower private companies and governments to work together to drastically advance Europe's position in the semiconductor sector. This broad initiative will boost Europe's R&D innovation and bring leading-edge manufacturing to the region for the benefit of our customers and partners around the world*." Intel indicated that in an initial phase, it plans to develop two first-of-their-kind semiconductor fabs in Magdeburg, Germany, with construction anticipated in H1 2023 and production planned to come online in 2027, pending European Commission approval.
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. • €44 million Slovenian scheme to support the digital transformation of the economy in the context of the coronavirus pandemic. • Lithuanian scheme, including €25 million budget increase, to support the agriculture and aquaculture sectors affected by the coronavirus pandemic. • Latvian scheme, including €4 million budget increase, to support small farmers affected by the coronavirus pandemic. • €5 million Portuguese scheme to support companies in the Azores in context of coronavirus pandemic. • €2.7 million Danish scheme to support companies affected by the coronavirus pandemic.

TRADE / EXPORT CONTROLS

WTO reports compromise on temporary TRIPS waiver on COVID-	On 16 March 2022, WTO Director-General Ngozi Okonjo-Iweala reported that the EU, India, South Africa and the US had taken a "*major step forward*" in reaching a compromise on a temporary waiver of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") in relation to

19 vaccine patents (see here)	patents on products aimed at combating and preventing COVID-19. The temporary TRIPS waiver, aimed at boosting production and ensuring global access to affordable COVID-19 vaccines, was proposed initially by South Africa and India to the WTO in October 2020 (*see also Jones Day COVID-19 Update No. 67 of 15 November 2021*). Director-General Ngozi Okonjo-Iweala cautioned, however, that full details of the compromise remain to be worked out and that internal domestic consultations within the four WTO members are still ongoing. She further indicated that the discussions must be broadened to include all 164 WTO members. In pursuing a full agreement, Director-General Okonjo-Iweala's team will work with, in particular, the WTO TRIPS Council Chair Ambassador Lansana Gberie (Sierra Leone), who was newly elected at the TRIPS meeting on 9-10 March 2022 (see here).
European Commission publishes update on Export of COVID-19 vaccines from EU (see here)	On 11 March 2022, the European Commission published an update on the export of COVID-19 vaccines from the EU, reflecting information gathered from the Commission's new vaccine monitoring mechanism, applicable since 1 January 2022 (*see Jones Day COVID-19 Update No. 69 of 29 November 2021*). The monitoring mechanism seeks to ensure the ongoing transparency of exports, in particular, by providing the Commission with timely, company-specific vaccine export data. To recall, this monitoring mechanism replaced the COVID-19 vaccines export transparency and authorization mechanism (expired on 31 December 2021), which required the authorization of exports from companies with whom the EU had concluded Advance Purchased Agreements (APAs). Without authorization, such products could not be exported outside the EU. Since November 2020, the EU reports that it has exported 2,053,072,783 vaccine doses (in final form) to 166 countries. The largest export destinations are Japan, the UK, and the US. The Commission indicates that it will pursue ongoing monitoring of the epidemiological situation in view of taking appropriate measures as necessary.
European Commission's Directorate-General for Trade issues Management Plan 2022 (see here)	On 7 March 2022, the European Commission's Directorate-General for Trade (DG Trade) issued its Management Plan 2022, which sets out how DG Trade will seek to pursue its ambitious agenda for this year. The Management Plan notes the role of trade policy in managing the COVID-19 health crisis and notably in ramping up supply chains. The Plan indicates that trade policy will continue to play a decisive role in economic recovery, particularly in terms of supporting economic growth and the pursuit of the EU's open strategic autonomy and the green and digital transformations. The Management Plan's main objectives include: (i) A stronger Europe in the world, in particular, by: – Leading reform of the WTO to preserve rules-based trade. The Commission considers that the WTO is currently facing a crisis whereby it is not providing negotiating outcomes that respond to the challenges of global trade. The Commission seeks, for example, to facilitate the negotiation of

new agreements to address key trade issues, such as agreeing on modern, global rules for digital trade, particularly as the COVID-19 crisis has accelerated the economy's digital transformation. In this respect, the Commission seeks to shape the plurilateral WTO e-commerce negotiations that currently cover over 80 WTO members.

(ii) An economy that works for people, in particular, by:

- Protecting EU companies and citizens from unfair trade and investment by making full use of existing Trade Defence Instruments, developing new tools and focusing on enforcement of existing commitments at an EU or international level. For instance:

  DG Trade notes that the screening of foreign direct investment (FDI) into the EU under the FDI Screening Regulation 2019/452 (in force since October 2020) is all the more vital in the economic context of the COVID-19 crisis, which has brought a growing need for investment encompassing sectors that could trigger security concerns. To recall, the Regulation enables Member States and the European 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*). The Commission will publish its second annual report on the Implementation of the Regulation in 2022.

Additionally, the Management Plan indicates that the Commission will strive to improve the acceptance and understanding of EU trade policy, notably by ensuring that it is pursued in an inclusive and transparent manner through better engagement and communication with the European Parliament, the Council and other stakeholders in view of allowing trade policy to respond to citizens' concerns.

MEDICINES AND MEDICAL DEVICES

EMA starts to review the marketing authorization application for Evusheld submitted by AstraZeneca (see here)	On 15 March 2022, the European Medicines Agency (EMA) started evaluating the marketing authorization application for AstraZeneca's COVID-19 treatment Evusheld (tixagevimab / cilgavimab). EMA's Committee for Medicinal Products for Human Use (CHMP) started the rolling review of Evusheld in October 2021. The preliminary results from clinical studies suggested that Evusheld may help protect against COVID-19 in adults (see here).
EMA publishes new clinical data for six COVID-19 medicines (see here)	Between 7 and 15 March 2022, the EMA published new clinical data for six COVID-19 medicines: • For Kineret (Anakinra), the clinical data supported its extension of indication to include treating COVID-19 adults with pneumonia, requiring supplemental oxygen, and who are at risk of severe respiratory failure; • For Ronapreve (Casirivimab / Imdevimab), a medicine used for treating COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of their disease becoming severe, the

	clinical data supported its initial marketing authorization application; • For Regkirona (Regdanvimab), a medicine used for treating COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of their disease becoming severe, the clinical data supported its initial marketing authorization application; • For Veklury (Remdesivir), an antiviral medicine used to treat COVID-19, further clinical data was published; • For RoActemra (Tocilizumab), the clinical data supported its use in treating COVID-19; andFor Spikevax (mRNA vaccine (Moderna-modified), the clinical data supported the authorization of booster doses.
EMA publishes PRAC meeting highlights on safety concerns (see here)	On 11 March 2022, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) published highlights of the meetings held on 7-10 March 2022, which included, among others, a recommendation to add small vessel vasculitis with cutaneous manifestations to the product information of COVID-19 Vaccine Janssen as a possible side effect of unknown frequency.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission adopts second Report on EU Digital COVID Certificate (see here)	On 15 March 2022, the European Commission adopted the second Report on the EU Digital COVID Certificate and its impact and implementation across the EU. This follows the first Report issued in October 2021 (*see Jones Day COVID-19 Update No. 64 of 18 October 2021*) and was issued pursuant to the EU Digital COVID Certificate Regulation (Regulation (EU) 2021/953). The Report notes that as of 1 March 2022, Member States issued over 1.72 billion EU Digital COVID Certificates, comprised of 1.15 billion vaccination certificates, 511 million test certificates, and 55 million certificates of recovery. As concerns the protection of personal data under the EU Digital COVID Certificate Regulation, the Report noted, in particular: • The Digital COVID Certificate Regulation and implementation are in compliance with the EU data protection rules and principles, particularly in relation to purpose limitation, data minimization, storage limitation and security (e.g., the data collected is limited to what is necessary to achieve their purpose, and personal data accessed in the verification process is not to be retained). • The security of the EU Digital COVID Certificates themselves is considered as shown to be solid. The Report notes that Member States are responsible for ensuring compliance with data protection in the issuance systems, including as concerns information security. While fraudulently issued certificates have been reported (*see next bullet point*), the Report considers that there is no reason to believe that any cryptographic keys used to sign and authenticate EU Digital COVID Certificates were compromised; • Various updated information is provided on latest technical developments related to the EU Digital COVID Certificate system, such as a planned mechanism to facilitate Member State exchanges

	of lists of revoked EU Digital COVID Certificates, and in this respect: – The revocation of certificates seeks to safeguard public health when certificates have been issued erroneously, as a result of fraud or following the suspension of a COVID-19 vaccine batch found to be defective; and – The planned mechanism, expected to be operational in the coming weeks, aims to enable the rapid and secure exchange of certificate revocation lists between Member States via the EU Digital COVID Certificate Gateway. To recall, the EU Gateway is the technical backbone of the COVID Certificate trust framework and enables verification of the digital signatures contained in the QR codes of all COVID certificates, without the processing of personal data (*see Jones Day COVID-19 Update No. 49 of 2 June 2021*). The Report concludes that if certain restrictions to free movement based on public health should remain in place after 30 June 2022, e.g., due to rising infections in H2 2022, EU citizens should continue to have the possibility to use their EU Digital COVID Certificates as an effective and secure means of proving one's COVID-19 status. Thus, the Commission has proposed to extend the EU Digital COVID Certificate Regulation by a year, until 30 June 2023.
EDPB and EDPS publish Joint Opinion on Proposal to amend EU Digital COVID-19 Certificate Regulation (see here)	On 14 March 2022, the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) published Joint Opinion 1/2022 on the Commission Proposal to amend the EU Digital COVID-19 Certificate Regulation (Regulation (EU) 2021/953), issued on 3 February 2022 (see here) (*see also Jones Day COVID-19 Update No. 76 of 9 February 2022*). The Joint Opinion notes that the Proposal is of particular importance due to the major impact on the protection of individuals' rights and freedoms with regard to the processing of their personal data. Concerning the Proposal's impact on the protection of personal data and advice on measures to be taken, the Joint Opinion states, in particular: • The Proposal does not alter substantially the existing provisions of the Regulation with regard to the processing of personal data; • Continuous evaluation is needed of the measures deemed to remain effective, necessary and proportionate for the purpose of combating the COVID-19 pandemic, and data protection principles under Article 5 GDPR must be continuously applied in any personal data processing operation; • Any modification of data fields might require a re-evaluation of the risks to fundamental rights; • Persons participating in clinical trials for the development of COVID-19 vaccines are also eligible to receive a COVID-19 vaccination certificate under the Proposal; thus, it should also clarify whether the vaccination certificate's data categories would add information that a data subject participated in a clinical trial; and • The Commission should assist the Member States in developing technical specifications to improve data minimization, where the Digital COVID Certificate (i.e. where recording the three doses, or any

further possible doses) is used for purposes other than freedom of movement and therefore requires reassessing the necessary categories of personal data included in the QR code.

Given the ongoing legislative process to amend the EU Digital COVID-19 Certificate Regulation, the EDPB and the EDPS emphasized their continued availability to the co-legislators to provide further guidance and to ensure legal certainty for natural persons and the protection of personal data in line with the TFEU, the Charter of Fundamental Rights of the European Union, and EU data protection legislation.

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