COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 76 | 9 February 2022

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 proposes Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (European Chips Act) and adopts accompanying Communication
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission proposes Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (European Chips Act)

Medicines and Medical Devices

- EMA evaluates booster dose of COVID-19 vaccine Comirnaty in adolescents
- EMA publishes further clinical data for two COVID-19 medicines

Cybersecurity, Privacy & Data Protection

- European Commission publishes proposal to modify and prolong application of EU Digital COVID-19 Certificate Regulation
- European Commission announces new EU Strategy on Standardisation in support of a resilient, green and digital EU single market
- European Parliament publishes infographic on Cybersecurity: main and emerging threats in 2021

COMPETITION & STATE AID

State Aid

European Commission proposes Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (European Chips Act) and adopts accompanying Communication (see here and here)

On 8 February 2022, the Commission presented the proposed Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (European Chips Act). The proposal is part of the Commission's package of measures (see here) aimed at ensuring the EU's security of supply and technological leadership in the field of semiconductors.

The Commission has previously contended that the COVID-19 crisis has exposed vulnerabilities in certain sectors in Europe due to high dependency on an allegedly 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 and the emergence of fake semiconductor chips on the market that compromise the security of electronic devices and systems.

Towards tackling these challenges, the proposed Regulation presents three main pillars:

(i) The Chips for Europe Initiative will support large-scale technological capacity building and innovation throughout the EU to enable the development and deployment of cutting-edge semiconductor and quantum technologies. This will include pooling resources from the EU, Member States and third countries associated with the existing Union programs, as well as the private sector, with €11 billion to be made available to strengthen existing research, development and innovation.

(ii) A framework to ensure security of supply that seeks to spur investments and enhanced production capacities in semiconductor manufacturing, including through a Chips Fund intended to facilitate access to finance for start-ups to help them mature their innovations and attract investors.

(iii) A monitoring and crisis response coordination mechanism between the Member States and the Commission that aims at monitoring the supply of semiconductors, estimating demand, and anticipating shortages.

The accompanying Commission Communication, in particular, notes that in line with the recent Communication on a Competition policy fit for new challenges (Nov. 2021, see here), the Commission may assess cases that do not fall under existing guidelines and in this respect:

"*it may be justified to cover with public resources up to 100% of a proven funding gap, if such facilities would otherwise not exist in Europe. Such cases are to be assessed by the Commission directly under Article 107(3)(c) TFEU. Under this provision, the Commission may consider aid to facilitate the development of certain economic activities or of certain economic areas to be compatible with State aid rules, where it does not adversely affect trading conditions to an extent contrary to the common interest, weighing the positive effects of such State aid against its likely negative impact on trade and competition*".

As concerns the funding of "first-of-a-kind" facilities,* Executive Vice-President and Competition Commissioner Margrethe Vestager commented that these require large investments that private investors cannot fund on their own, such that the Commission believes that it may be justified to cover up to 100% of a proven funding gap with public resources. She specified the

	Commission's view that such funding does not require creating new, modified, or "bended" rules. Rather, the Commission must assess projects directly on the Treaty in seeking to avoid any competition distortions and to avoid a subsidy race in Europe and elsewhere. Thus, Commissioner Vestager cited the following considerations as relevant: (i) such facilities must be "first-of-its-kind"; (ii) the aid must be targeted, proportionate, and limited to only what is needed; and (iii) the projects will need to benefit Europe as a whole, without discrimination. The Commission estimates that the Chips Act itself should result in additional public and private investments of over €15 billion. Combined with existing EU programs and announced Member State support, the Commission anticipates that in total, over €43 billion of policy-driven investment will support the Chips Act until 2030, which it expects will be broadly matched by long-term private investment. The European Parliament and the Member States shall discuss the Commission's proposal for a European Chips Act, and if adopted, the Regulation will be directly applicable across the EU. Additionally, the Commission is conducting a stakeholder survey, open until 20 March 2022 (see here), to gather information on current and future chip demand towards better understanding the chip shortage's impact on European industry. * *According to the proposed Regulation, "'first-of-a-kind facility' means an industrial facility capable of semiconductor manufacturing, including front-end or back-end, or both, that is not substantively already present or committed to be built within the Union, for instance with regard to the technology node, substrate material, such as silicon carbide and gallium nitride, and other product innovation that can offer better performance, process innovation or energy and environmental performance."* *For further details on the proposed European Chips Act, please see below Section on Trade.*
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. • €10 million Italian scheme to support breweries in the context of the coronavirus pandemic. • €300 million Austrian scheme for package travel organizers and facilitators of linked travel services in the context of the coronavirus pandemic. • €43.63 million aid to compensate CFR Calatori, the largest public service operator of rail passenger transport in Romania, for the damage suffered due to the coronavirus outbreak. • €435 million Lithuanian scheme to support the liquidity and investments of companies affected by the coronavirus pandemic. • €31.5 million Greek scheme to support certain agricultural producers

affected by the coronavirus pandemic.

- €509 million Czech scheme to support the self-employed and partners in small limited liability companies affected by the coronavirus pandemic.
- €48.62 million Finnish aid measure to compensate Finnair for the damage suffered due to the coronavirus pandemic.

TRADE / EXPORT CONTROLS

European Commission proposes Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (European Chips Act) (see here)

On 8 February 2022, the European Commission presented the proposed Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (European Chips Act). The proposal is part of the Commission's package of measures (see here) aimed at ensuring the EU's security of supply and technological leadership in the field of semiconductors.

The Commission has previously claimed that the COVID-19 crisis has exposed vulnerabilities in certain sectors in Europe due to high dependency on an allegedly 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 and the emergence of fake semiconductor chips on the market that compromise the security of electronic devices and systems.

The proposed Regulation's three main pillars include (i) the Chips for Europe Initiative to support large-scale technological capacity building; (ii) a framework to ensure security of supply by spurring investments and enhanced production capacities; and (iii) a monitoring and crisis response coordination mechanism in relation to the semiconductor value chain and disruptions to the supply of semiconductors.

In support of the proposed Regulation's objectives, a European Semiconductor Board is foreseen. This EU-level governance mechanism (composed of Member State representatives and chaired by the Commission) would advise the Commission on consistent application of the proposed Regulation, as well as facilitate cooperation among Member States and the exchange of information on issues relating to the Regulation.

In relation to the above-referred objective of monitoring and crisis response, the Commission notes that:

- On forecasting and preparing for future disruptions to the semiconductor value chain in the EU, the Commission should, as assisted by the European Semiconductor Board, identify early warning indicators in the EU risk assessment, such as the effect of trade policies, tariffs, export restrictions, trade barriers and other trade related measures; the availability of raw materials; price surges exceeding normal price fluctuation; and the effect of accidents, attacks, natural disasters or other serious events. Member States are to monitor these early warning indicators.
- Upon activation of the crisis stage, where there is serious and reliable evidence of a semiconductor crisis, measures should be implemented to mitigate such crisis. Such appropriate and proportionate measures should be undertaken without prejudice to possible continued international engagement with relevant partners. The Commission, in particular, should be able to require certain production facilities and foundries to accept and prioritize an order for the production of crisis-

	relevant products. In addition, the European Semiconductor Board may advise on the necessity of introducing an export control regime pursuant to Regulation (EU) 2015/479 on common rules for exports . The European Parliament and the Member States shall discuss the Commission's proposal for a European Chips Act, and if adopted, the Regulation will be directly applicable across the EU. Additionally, the Commission is conducting a stakeholder survey, open until 20 March 2022 (see here), to gather information on current and future chip demand towards better understanding the chip shortage's impact on European industry. *For further details on the proposed European Chips Act, please see above Section on Competition & State Aid.*
MEDICINES AND MEDICAL DEVICES	
EMA evaluates booster dose of COVID-19 vaccine Comirnaty in adolescents (see here)	On 8 February 2022, the Human Medicines Committee (CHMP) of the European Medicines Agency (EMA) started the evaluation of the application for use of a booster dose of COVID-19 vaccine Comirnaty (BioNTech/Pfizer) in adolescents aged 12 to 15 years. The CHMP is also currently evaluating use of a booster dose of Comirnaty in adolescents aged 16 to 17 (see here). The CHMP will carry out an accelerated assessment of data submitted by BioNTech/Pfizer, which includes results from real world evidence from Israel. The EMA will communicate the result of its assessment in due course.
EMA publishes further clinical data for two COVID-19 medicines (see here)	On 2 February 2022, the EMA published further clinical data for two COVID-19 medicines in relation to the following: • The authorization of booster doses of COVID-19 vaccine Comirnaty (BioNTech/Pfizer) in adults. Further clinical data and information on the vaccine is available on the EMA corporate website (see here). • Veklury (remdesivir), an antiviral medicine used to treat COVID-19. Further clinical data and information on this medicine is available on the EMA corporate website (see here).
CYBERSECURITY, PRIVACY & DATA PROTECTION	
European Commission publishes proposal to modify and prolong application of EU Digital COVID-19 Certificate Regulation	On 3 February 2022, the Commission published a proposal to amend the EU Digital COVID-19 Certificate Regulation (Regulation (EU) 2021/953). To recall, the EU Digital COVID-19 Certificate, which seeks to facilitate the free movement of citizens within the EU Member States during the pandemic, serves 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. 72 of 10 January 2022*). The Regulation is currently applicable until 30 June 2022. However,

(see here)	particularly in light continuing uncertainties (e.g. potential emergence of new COVID-19 variants), the Commission has proposed to enable Member States to continue to require EU citizens exercising their right to free movement to present proof of COVID-19 vaccination, testing or recovery until 30 June 2023. Additionally, the Commission also proposed certain limited modifications to the Regulation, such as: • Broadening the definition of an antigen test to include high-quality laboratory-based rapid antigen tests such as lateral flow immunoassays that give results in less than 30 minutes; • Clarifying that the vaccination certificate must include information about the total number of doses administered to the holder, regardless of the Member State in which a dose was administered; and • Clarifying that Member States may also issue vaccination certificates to persons participating in clinical trials for vaccines against COVID-19 and that other Member States may accept such vaccination certificates. The Commission notes that by prolonging the application of the Regulation, the proposal implies processing of personal data, as set out under the Regulation, by another year. The Commission indicates that it does not propose changes to the Regulation's data protection framework. In particular, the GDPR will continue to apply, and personal data contained in the certificates that is processed during their verification must not be retained beyond the verification process. Additionally, on the same day, the Commission set forth a parallel proposal to amend the EU Digital COVID-19 Certificates Regulation (Regulation (EU) 2021/954) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (see here). The Parliament and Council must now adopt the proposals before the current end date of the EU Digital COVID Certificate Regulations, i.e., 30 June 2022.
European Commission announces new EU Strategy on Standardisation in support of a resilient, green and digital EU single market (see here)	On 2 February 2022, the Commission presented a new approach to EU standards, as set out in its Communication on an EU Strategy on Standardisation: Setting global standards in support of a resilient, green and digital EU single market. Harmonized EU standards provide the technical specifications needed for a product to respect EU law, thereby granting products the presumption of compliance with EU law and promoting the inter-operability of products and services. The Commission indicated, in particular, that the COVID-19 pandemic illustrated standardization urgencies with regard to COVID-19 vaccines and medicines production. The Commission also noted the critical role of standards in facing the current challenges of EU industries and the need for standards for the data economy, e.g. to enable data inter-operability for robots, autonomous cars or machinery. Under the new Standardisation Strategy, the Commission seeks to treat standardisation as more than a merely technical matter and to place

	standards as the focus of EU policy. For instance, new technologies must reflect EU values, such as the safeguarding of data protection standards. The Communication sets out key actions under the EU Strategy on Standardisation, such as: • Supporting the EU's leading position in key technologies, in order to shape international standards in line with EU values and interests, for example by fostering the development and deployment of international standards for a free, open, accessible and secure global Internet and establishing an EU internet standards monitoring website. • Anticipating and prioritizing standardization in areas where standards are needed in order to avoid strategic dependencies and to manifest the EU's global leadership in green and technical technologies, such as in the areas of: – COVID-19 vaccine and medicine production; – Semiconductor chips certification; and – Data standards enhancing data interoperability, data sharing and data re-use in support of the Common European Data Spaces. As concerns data, in particular, Executive Vice-President for a Europe Fit for the Digital Age, Margrethe Vestager emphasized: *"Ensuring that data is protected in artificial intelligence or ensuring that mobile devices are secure from hacking, rely on standards and must be in line with EU democratic values."* The Communication is accompanied by a Proposal for a Regulation amending Regulation (EU) No 1025/2012 as regards the decisions of European standardisation organisations concerning European standards and European standardization deliverables, which aims in particular to extend the Commission's powers to request one or several European standardization organizations to draft a European standard or European standardization deliverable within a set deadline (see here). Additionally, the Commission released a Report on the implementation of Regulation (EU) No 1025/2012 from 2016 to 2020 (see here).
European Parliament publishes infographic on Cybersecurity: main and emerging threats in 2021 (see here)	On 27 January 2022, the Parliament published an infographic setting out what it viewed as the main and emerging cybersecurity threats in 2021. The Parliament notes that the COVID-19 crisis had a strong impact on cybersecurity threats. For instance, cybercriminals took advantage of the pandemic by targeting organizations and companies working remotely. On cybersecurity threats, the infographic illustrates, in particular: • Digital service providers and the healthcare/medical sectors are among the most affected sectors; • Among the prime security threats, these include data breaches involving a human element; and the use of COVID-19 as the main focus of disinformation campaigns and email-related attacks; and • Ransomware (i.e., malicious software designed to prevent a user or an organization from accessing files on their computer and

demanding a ransom payment to reestablish access), is considered the most worrying threat at present. The EU Agency for Cybersecurity cited data showing that the highest ransomware demand grew from €13 million in 2019 to €62 million in 2021, and the average ransom pay doubled from €71,000 in 2019 to €150,000 in 2020.

Parliament further noted the adoption of its position on a new Directive on Network and Information Security (so-called NIS2 Directive), which sets out measures for a high common level of cybersecurity across the EU that seek to reflect how cybersecurity threats have evolved and that introduce harmonized measures across the EU, including on the protection of essential sectors.

LAWYER CONTACTS

Kaarli H. Eichhorn
Partner, Antitrust & Competition Law; Government Regulation; Technology
Brussels
keichhorn@jonesday.com
+32.2.645.14.41

Cristiana Spontoni
Partner, Health Care & Life Sciences; Government Regulation
Brussels
cspontoni@jonesday.com
+32.2.645.14.48

Dr. Jörg Hladjk
Partner, Cybersecurity, Privacy & Data Protection; Government Regulation; Technology
Brussels
jhladjk@jonesday.com
+32.2.645.15.30

Rick van 't Hullenaar
Partner, Government Regulation; Investigations & White Collar Defense
Amsterdam
rvanthullenaar@jonesday.com
+31.20.305.4223