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 Temporary Crisis Framework to support economy in context of Russia's invasion of Ukraine
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- Third Joint Committee Meeting under EU-Japan Economic Partnership Agreement
- European Commission contemplates Task Force to mitigate high energy prices

Medicines and Medical Devices

- EMA publishes CHMP meeting highlights
- EMA recommends authorization of COVID-19 treatment Evusheld
- Commissioner for Health and Food Safety answers questions from Members of European Parliament on COVID-19 matters

Cybersecurity, Privacy & Data Protection

- European Commission facilitates exchange of lists of revoked EU Digital COVID Certificates
- European Commission launches open consultation on extending applicability of EU Digital COVID Certificate to third-country nationals

COMPETITION & STATE AID

State Aid

European Commission adopts Temporary Crisis Framework to support economy in context of Russia's invasion of Ukraine (see here)

On 23 March 2022, the Commission adopted a Communication on a Temporary Crisis Framework for State Aid measures, which sets out the criteria for Member States to support businesses in the context of Russia's invasion of Ukraine and its serious disruption to the EU economy.

The Communication notes that the conflict has significantly impacted the energy market, and steep rises in energy prices have affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The conflict has also disrupted supply chains for both EU imports from Ukraine (notably, cereals and vegetable oils) and EU exports to Ukraine.

Under the Crisis Framework, based on Article 107(3)(b) of the Treaty on the Functioning of the European Union ("TFEU"), Member States, in particular, may:

(i) grant a limited amount of aid to companies affected by the current crisis or by related sanctions and counter-sanctions, with up to €35,000 for companies affected by the crisis active in the agriculture, fisheries and aquaculture sectors and up to €400,000 per company affected by the crisis active in all other sectors;

(ii) guarantee the availability of sufficient liquidity for companies through (i) subsidized State guarantees to ensure that banks continue to provide loans to all companies impacted by the crisis; and (ii) public and private loans with subsidized interest rates; and

(iii) compensate companies for additional costs due to exceptionally high gas and electricity prices, and in particular for energy-intensive businesses, such that:

- Support can be granted in any form, including direct grants, with overall aid per beneficiary not exceeding 30% of eligible costs, up to a maximum of €2 million.
- For companies incurring operating losses, further aid may be necessary to ensure the continuation of an economic activity, such that Member States may grant aid exceeding the above-referred ceilings, with up to €25 million for energy-intensive users, and up to €50 million for companies active in specific sectors (e.g., production of aluminum and other metals, pulp, fertilizer or hydrogen and many basic chemicals).

Towards ensuring a level playing field, the Crisis Framework also foresees certain safeguards in relation to, e.g.:

- Proportionality, such that the amount of aid that can be granted to businesses should be linked to the scale of their economic activity and exposure to the economic effects of the crisis, in light of their turnover and energy costs; and
- Eligibility conditions, and in particular, defining "energy-intensive"

	users by reference to the Energy Taxation Directive (Article 17(1)(a)), i.e., those businesses for which the purchase of energy products amounts to at least 3% of their production value. Cumulated aid. The Crisis Framework complements the various possibilities for Member States to design measures in line with existing EU State aid rules. For instance, State aid measures under the Crisis Framework may be cumulated with aid granted under the COVID-19 Temporary Framework (*see Jones Day COVID-19 Update No. 68 of 22 November 2021*), provided that their respective cumulation rules are respected. The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2022. During its period of application, the Commission will keep the Framework under review in light of developments regarding the energy markets, other input markets, and the general economic situation. Prior to the Crisis Framework's end date, and in view of maintaining legal certainty, the Commission will assess whether the Crisis Framework should be prolonged.
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. • €200 million Italian scheme to support the retail trade sector in the context of the coronavirus pandemic. • €50 million Irish scheme to support the beef sector affected by the coronavirus pandemic. • €13.9 million Croatian scheme to support fishery and aquaculture sector in the context of the coronavirus pandemic. • €3 million Slovak scheme to support airlines affected by the coronavirus pandemic. • €12.78 million Bulgarian scheme to support tour operators in the context of the coronavirus pandemic. • Latvian scheme to support arts, entertainment and recreation companies affected by the coronavirus pandemic, re-introducing a measure that expired on 31 December 2021, including a number of amendments, such as an extension of the loan period by 30 months with a grace period of 24 months. • €30.7 million Bulgarian scheme to support air carriers affected by the coronavirus pandemic. • Italian scheme to support companies active in road passenger transport affected by the coronavirus pandemic, re-introducing a measure that expired on 31 December 2021, with public support to take the form of direct grants.

TRADE / EXPORT CONTROLS

Third Joint Committee Meeting under EU-Japan Economic Partnership Agreement (see here)	On 25 March 2022, Executive Vice-President and European Commissioner for Trade Valdis Dombrovskis and Japanese Minister of Foreign Affairs Yoshimasa Hayashi co-chaired the third Joint Committee under the EU-Japan Economic Partnership Agreement (EPA). To recall, the EPA is a trade agreement applicable since 1 February 2019 that seeks 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 (*see Jones Day COVID-19 Update No. 71 of 13 December 2021 for the Second EU-Japan EPA Progress Report of 8 December 2021*). On the occasion of the third Joint Committee meeting, the Commission stated that trade in goods between the two partners recovered to pre-pandemic levels in 2021 (rising to €125 billion), with the EPA serving as the "bedrock" of the EU-Japan economic relationship. In responding to the pandemic, the EU and Japan affirmed their commitment to international solidarity. Japan is the largest export destination for EU-made COVID-19 vaccines, with over 340 million doses exported since November 2020. The Joint Committee also discussed areas such as improving market access (e.g., import conditions in Japan for certain categories of EU agricultural products). Furthermore, the EU and Japan (together with other international partners) are closely coordinating their sanctions against Russia and Belarus. Japan also recently demonstrated solidarity with Europe by directing its surplus of Liquified Natural Gas to the EU, and the two partners confirmed their continued cooperation on energy security, including through trade and investment in renewable energy capacities.
European Commission contemplates Task Force to mitigate high energy prices (see here)	On 23 March 2022, the European Commission announced a contemplated Task Force on common gas purchases at EU level, in view of building EU partnerships with third countries to collectively purchase gas, LNG, and hydrogen towards improving the EU's energy resilience and lowering prices. The Commission indicated that such eventual Task Force would be inspired by experience from the COVID-19 pandemic, where EU wide action was viewed as crucial to ensuring adequate supplies of vaccines. By pooling demand, the Commission considers that such a Task Force would enhance the EU's international outreach to suppliers to help secure well-priced imports ahead of next winter. The Task Force would be supported by Member State representatives in a Steering Board, with the Commission leading a joint team to negotiate with gas suppliers. Additionally, the European Council's conclusions of its meeting of 24 - 25 March 2022 stated that Member States and the Commission will "urgently" work together on the voluntary common purchase of gas, LNG and hydrogen, in view of making optimal use of the EU and Member States' collective political and market weight to lower prices in negotiations. The Council further indicated that a common purchases platform would also be open for Western

	Balkan countries and the three associated Eastern Partners (Armenia, Moldova, and Ukraine).
MEDICINES AND MEDICAL DEVICES	
EMA publishes CHMP meeting highlights (see here)	On 25 March 2022, the Human Medicines Committee (CHMP) of the European Medicines Agency (EMA) published highlights of the meeting held on 21-24 March 2022. These included, among others: – the recommended approval of five new medicines, including a positive CHMP opinion for COVID-19 treatment Evusheld (*see below for further details*), and – the approval of an increase in manufacturing capacity for COVID-19 vaccine Cominarty (tozinameran (BioNTech/Pfizer)).
EMA recommends authorization of COVID-19 treatment Evusheld (see here)	On 24 March 2022, the CHMP recommended granting a marketing authorization for AstraZeneca's monoclonal antibody treatment Evusheld for the prevention for COVID-19 in adults and adolescents from 12 years of age weighing at least 40 kg. The CHMP's conclusion is based on data from a study of over 5,000 participants that showed that Evusheld (given as two injections of 150 mg tixagevimab and 150 mg cilgavimab) reduced the risk of COVID-19 infections by 77%, with an estimated duration of protection from the COVID-19 virus of at least six months. However, since the above-referred study data was obtained before the emergence of the Omicron variant, the EMA will assess data in the coming weeks to evaluate whether an alternative dosing regimen could be appropriate for preventing COVID-19 resulting from emerging variants. The CHMP will now send its recommendation to the European Commission for a rapid decision applicable in all EU Member States to authorize Evusheld.
Commissioner for Health and Food Safety answers questions from Members of European Parliament on COVID-19 matters (see here and here)	On 16 and 21 March 2022, Stella Kyriakides, Commissioner for Health and Food Safety provided a written answer to two Parliamentary questions on COVID-19 related matters: (i) Addressing a regulatory gap regarding air purifiers under Medical Devices Regulation ("MDR", Regulation (EU) 2017/745) This question concerned diverging Member State views on air purification devices and whether these can mitigate the spread of COVID-19, noting that "*many manufacturers claim their devices can eradicate harmful viruses like COVID-19, among others, from the air.*" Given contradictory national regulations, the Parliamentary question asked, in particular, whether the European Commission intended to classify air purifiers as medical devices under the MDR. On March 21, Commissioner Kyriakides replied (see here) that the Commission does not intend to seek to modify the MDR concerning this matter. She noted the qualification of a given product as a medical device under the MDR falls within the competence of the Member States (subject to exceptions under Article 4, MDR).

As Member State interpretations of EU legislation may diverge, Commissioner Kyriakides referred to the Medical Devices Coordination Group's specific Working Group to facilitate dialogue among national regulators in relation to product qualification. The Working Group's non-legally binding agreements in the "Manual on borderline and classification in the community regulatory framework for medical devices" includes an entry on air purifiers and air decontamination units, which indicates that such products are not considered as medical devices, but rather products for the general environment.

(ii) Inciting sharing of genomic sequences of COVID-19 vaccines

This question raised the concern that genomic information of COVID-19 vaccines is viewed as crucial to furthering the scientific community's understanding of the potential impact of a particular substance approved by the EU and national authorities. However, only one COVID-19 vaccine manufacturer has thus far shared such genomic sequence.

The Parliamentary question therefore asks whether the Commission intends to initiate negotiations and/or legal steps to encourage pharmaceutical companies from which it has purchased COVID-19 vaccines to publish the genomic sequence of such vaccines.

On March 16, Commissioner Kyriakides replied (see here) that its current purchasing contracts with pharmaceutical companies for COVID-19 vaccines do not include sharing the genomic sequence of such vaccines. Thus, the Commission can only encourage these companies to publish the genomic sequence of such vaccines, but it has no grounds for taking any legal steps.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission facilitates exchange of lists of revoked EU Digital COVID Certificates (see here)

On 25 March 2022, the European Commission adopted an amending Implementing Decision* on technical specifications and rules for implementing the trust framework (EU Gateway) for the EU Digital COVID Certificate. The amendments seek to enhance the EU Gateway by supporting the bilateral exchange of certificate revocation lists between Member States in order to safeguard public health when certificates are issued erroneously, e.g., due to fraud or the suspension of a COVID-19 vaccine batch found to be defective.

The EU Digital COVID Certificate, since becoming applicable on 1 July 2021, has given rise to a significant number of forged certificates as well as authentic certificates that are unlawfully issued (e.g. based on false documentation, unauthorized access, or with fraudulent intent).

Forged certificates can be immediately revealed through the EU Digital COVID Certificate system. However, authentic certificates that are unlawfully issued cannot be detected in other Member States unless lists of revoked certificates generated at national level are exchanged between Member States.

Thus, the amended Implementing Decision enhances the EU Digital COVID Certificate trust framework by establishing a communication infrastructure on behalf of the Member States to enable the secure and reliable exchange of revocation lists between Member States via the EU Gateway.

As concerns the protection of personal data in the exchange of certificate revocation lists via the EU Gateway, in particular:

	– the processing of such data will be limited to the purpose of supporting the exchange of revocation information and will only be used for the purpose of verifying the revocation status of EU Digital COVID Certificates issued within the scope of the EU Digital COVID Certificate Regulation (Regulation (EU) 2021/953). – Information submitted by Member States to the EU Gateway will comprise the pseudonymized unique certificate identifiers of revoked EU Digital COVID Certificates, as well as an expiry date for the submitted certificate revocation lists. – The Commission will act as the data processor and will process the personal data contained in the EU Gateway in accordance with the documented instructions from the Member States, which act as data controllers. The amending Implementing Decision, which is addressed to Member States, entered into force on 28 of March 2022 and will apply four weeks following that date. * *Implementing Decision (EU) 2022/483, of 21 March 2022 amending Implementing Decision (EU) 2021/1073 on technical specifications and rules for implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953*
European Commission launches open consultation on extending applicability of EU Digital COVID Certificate to third-country nationals (see here)	On 17 March 2022, the European Commission launched an open consultation on the Proposal for a Regulation amending the EU Digital COVID Certificate Regulation with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (Regulation (EU) 2021/954). The Proposal, adopted on 3 February 2022 (*see Jones Day COVID-19 Update No. 76 of 9 February 2022*), seeks to align the expiration date of Regulation (EU) 2021/954 with that of Regulation (EU) 2021/953 on use of the EU Digital COVID Certificate by EU nationals, such that both Regulations would apply for the same period of time. Extension of the expiration date of Regulation (EU) 2021/953 until 30 June 2023 (instead of 30 June 2022) is currently under review by the Council and European Parliament, following the European Commission's adoption of a proposal to amend Regulation (EU) 2021/953 (see *Jones Day COVID-19 Update No. 76 of 9 February 2022*). The Proposal seeks to ensure that third-country nationals legally staying or residing in a Member State will have the possibility to make use of the EU Digital COVID Certificate beyond 30 June 2022, the current expiration date contained in Regulation (EU) 2021/954. As concerns data protection, the Explanatory Memorandum to the Proposal notes that GDPR Regulation (EU) 2016/679 will continue to apply under the Proposal and that no derogation from the EU's data protection regime is envisaged. The Proposal further provides that the European Data Protection Supervisor and the European Data Protection Board will have been consulted on its provisions. The public consultation is open until 12 May 2022.

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