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 prolongs and further expands Temporary Framework to support economy in context of coronavirus outbreak
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission affirms compatibility of COVID-19 export authorization mechanism with international obligations
- European Commission publishes latest list of Member State mechanisms screening foreign direct investments, reflecting various COVID-19 related measures
- Expansion of EU-Japan Economic Partnership Agreement welcomed as instrument to rebuild growth following the COVID-19 pandemic

Medicines, Medical Devices, and Personal Protective Equipment

- EMA starts rolling review of Regeneron/Roche COVID-19 vaccine
- European Commission adopts Implementing Regulation on the authorisation mechanism for exports of COVID-19 vaccines
- EU approves AstraZeneca's COVID-19 vaccines

Cybersecurity, Privacy & Data Protection

- Guidelines on proof of vaccination for medical purposes - basic interoperability elements

COMPETITION & STATE AID

State Aid	
European Commission prolongs and further expands Temporary Framework to support economy in context of coronavirus outbreak (see here)	In light of the continued economic uncertainty due to the prolonged pandemic, the European Commission decided to extend all measures set out in the State aid Temporary Framework (adopted 19 March 2020) until 31 December 2021. The Commission has also substantially increased the aid ceilings set out in the Temporary Framework to: – €225,000 per company active in the primary production of agricultural products (previously €100,000) – €270,000 per company active in the fishery and aquaculture sector (previously €120,000) – €1.8 million per company active in all other sectors (previously €800,000) – up to €10 million (previously €3 million) for contributing to the portion of fixed costs not covered by revenues, for companies with turnover losses of at least 30% as compared to the same period in 2019. Furthermore, recapitalization measures, originally set to expire on 20 September 2021, are also prolonged until 31 December 2021. To recall, these recapitalization measures respond to the constricted ability of European companies to supply goods and services due to the pandemic, provoking losses that have diminished their equity and their ability to borrow on the markets. The Temporary Framework's expansion in May 2020 thereby included facilitating public interventions in the form of recapitalization aid to non-financial companies, along with safeguards to preserve competition (*see Jones Day COVID-19 Update No. 7 of 8 May 2020*). Until 31 December 2022, the Commission will also enable Member States to convert certain repayable instruments (e.g. guarantees, loans, repayable advances) into other forms of aid, such as direct grants, provided the conversion does not exceed the new ceilings. This measure should incentivize Member States to construct their aid as repayable instruments from the outset. Member States seeking to modify existing aid measures, towards extending their duration until 31 December 2021, expanding their budget, or aligning such measures with the now-amended Temporary Framework (including higher aid ceilings per company), may notify such modifications in a block notification. This is intended to minimize Member States' administrative burdens.
EU approves new and amended Member State measures to support the economy (see here and here)	Since the onset of the coronavirus outbreak, the European 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 most recent measures adopted to support the economy and companies affected by coronavirus outbreak include: • €230 million Czech scheme to support companies affected by the coronavirus outbreak.

	• €66.9 million Swedish scheme to support package travel organizers affected by the coronavirus outbreak. • €10.2 million Cypriot scheme to support self-employed and enterprises affected by the coronavirus outbreak. • €200 million Belgian scheme to support companies in Flanders affected by the coronavirus outbreak. • €5 million Slovenian scheme to support the Fraport Slovenija (the operator of Jože Pučnik Ljubljana Airport) for damages caused by the coronavirus outbreak.
TRADE / EXPORT CONTROLS	
European Commission affirms compatibility of COVID-19 export authorization mechanism with international obligations (see here)	The European Commission recently adopted a Regulation establishing an export transparency and export authorization mechanism for COVID-19 vaccines, addressing exports outside of the EU market. This is a temporary measure and is not an export ban (*for further details, see below Section on Medicines*). Addressing the Regulation's compatibility with WTO and G20 commitments, the Commission specifies that it fully adheres to the EU's international obligations and commitments. The Commission emphasizes that the Regulation respects the principle that any measures deemed necessary to prevent or relieve critical shortages are implemented in a targeted, transparent, proportionate, temporary manner and in line with WTO obligations. The Commission further specifies that the export authorization mechanism is also fully compatible with the EU's position in the context of the WTO trade and health initiative, as the Regulation takes careful consideration of the interests of poorer and developing countries. The Regulation, in this respect, ensures the unimpeded operation of the COVAX facility, a global procurement mechanism to ensure rapid and fair access to COVID-19 vaccines for all countries. The Commission further stated the EU's commitment to ensure transparency about the export authorization measure towards its trading partners at the WTO. Furthermore, as concerns Northern Ireland, the Commission stated that the Ireland / Northern Ireland Protocol would unaffected by the export authorization mechanism.
European Commission publishes latest list of Member State mechanisms for screening foreign direct investments, reflecting various COVID-19 related measures (see here)	On 14 January 2021, the Commission published the latest list of screening mechanisms notified by Member States, pursuant to the Regulation on screening foreign direct investments into the EU (Regulation (EU) 2019/452 of 19 March 2019). The list of screening mechanisms for such foreign direct investment includes measures spurred by the COVID-19 pandemic. For example, Slovenia's Act Determining the Intervention Measures to Mitigate and Remedy the Consequences of the COVID-19 Epidemic of 29 May 2020 indicates that foreign direct investment in certain sectors will be prohibited if determined to pose a threat to security or public policy of the Republic of Slovenia. Such sectors encompass the supply of critical inputs (including

	medical and protective equipment) as well as critical infrastructure (including the health sector) and critical technologies (including health, medical and pharmaceutical technologies).
Expansion of EU-Japan Economic Partnership Agreement welcomed as instrument to rebuild growth following the COVID-19 pandemic (see here)	The second anniversary of the EU-Japan Economic Partnership Agreement (EPA) took place on 1 February 2021. To mark this occasion, the EU and Japan agreed to significant improvements to the Agreement. In particular, the EU and Japan will each see 28 additional Geographical Indications (GIs) protected (i.e. concerning various agri-food products), and trade in the key sectors of wine and vehicles will be further facilitated. As stated by Executive Vice-President and Commissioner for Trade Valdis Dombrovskis: "*The EU-Japan Economic Partnership Agreement is one of our most important deals. Together, the EU and Japan make up for a quarter of the world's GDP and our bilateral trade reaches some €170 billion a year. This deal has made trading easier and cheaper for both EU and Japanese producers….This is very welcome as we work to rebuild economic growth following the Covid-19 pandemic*."

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

EMA starts rolling review of Regeneron/Roche COVID-19 vaccine (see here)	On 1 February 2021, the European Medicines Agency (EMA) started the "rolling review" of the potential COVID-19 vaccine developed by Regeneron Pharmaceuticals and Hoffman-La Roche (REGN-COV2 antibody combination (casirivimab/imdevimab). To recall, in view of the expedited development and authorization of medicinal products and vaccines for the treatment and prevention of COVID-19, the EMA will rely on such rolling reviews (enabling the agency in emergency contexts to assess data as they become available for very promising applications) (*see Jones Day COVID-19 Update No. 7 of 8 May 2020*). The present rolling review covers an initial set of non-clinical data coming from laboratory and animal studies. Following the provision of further sufficient evidence during the course of the rolling review, Regeneron Pharmaceuticals and Hoffman-La Roche may formally file a marketing authorization application (MAA) with the EMA.
European Commission adopts Implementing Regulation on the authorisation of exports of COVID-19 vaccines (see here)	On 30 January 2021, the European Commission published Implementing Regulation (EU) 2021/111 on making the exportation of certain products subject to the production of an export authorization ("Regulation"). This Regulation follows in the wake of the vaccine supply problem announced recently by the Commission (*see Jones Day COVID-19 Update No. 33 of 29 January 2021*). As stated by the Commission, the Regulation is aimed at ensuring timely access to COVID-19 vaccines for all EU citizens and rectifying the present lack of transparency of vaccine exports outside the EU. The Regulation provides for an export authorization for COVID-19 vaccines, as well as for the active substances used for the manufacture of such vaccines. The scheme only applies to exports from companies with whom the EU has concluded Advance Purchased Agreements (APAs). Without authorization, such products cannot be exported outside the European Union.

	Export authorization can be granted "*only where the volume of exports is not such that it poses a threat to the execution of Union APAs concluded with vaccines manufacturers*" by the competent authorities of the Member State where the vaccine and the substances are manufactured. Member States must immediately notify requests for exportation and their draft decision to the Commission. In case of disagreement with the draft decision, the Commission must issue an opinion on the basis of an evaluation of the impact of export on the execution of the relevant APAs. The Member State must decide on the request for authorization in accordance with the Commission's opinion. Additionally, the authorization requirement includes a range of exemptions, based on the principle of solidarity. These include, in particular, exports to various non-EU countries (e.g. EFTA countries (Iceland, Norway, Liechtenstein, and Switzerland), Israel, Morocco, Ukraine, etc.), as well as to poorer and emerging economies worldwide to ensure rapid and equitable access to COVID-19 vaccines. The Commission will make information publicly available on authorizations granted and refused, in compliance with confidentiality rules on the data provided by the applicants. The Regulation applied from 30 January 2021, with a limited validity of six weeks given its adoption as an emergency response. The Commission intends to propose an extension of this measure until end-March 2021. The Commission has issued a Q&A on the authorization mechanism (see here).
EU approves AstraZeneca's COVID-19 vaccines (see here)	On 29 January 2021, the European Commission granted a conditional marketing authorization (CMA) to the COVID-19 vaccine manufactured by AstraZeneca. This is the third COVID-19 vaccine authorized in the EU. The CMA was granted on the basis of positive results (around 60% of efficacy) coming from large clinical trials involving over 24,000 people. The vaccine is authorized for the prevention of COVID-19 infection in persons 18 years and older. The vaccine is given as two injections, with the second dose to be given between 4 and 12 weeks after the first dose. Under AstraZeneca's contract with the European Commission, signed on 27 August 2020, it will deliver a total amount of 400 million doses throughout 2021. These will add to the 600 million doses of the vaccine by BioNTech-Pfizer and the 160 million doses of the vaccine by Moderna.

CYBERSECURITY, PRIVACY & DATA PROTECTION

eHealth Network publishes Guidelines on proof of vaccination for medical purposes - basic interoperability	On 27 January 2021, the eHealth Network published Guidelines on proof of vaccination for medical purposes - basic interoperability elements ("Guidelines"). The eHealth Network, established under the aegis of the European Commission, is a voluntary network that provides a platform of Member States' competent authorities dealing with eHealth. The Guidelines aim at supporting interoperability between proof of vaccination certificates (i.e., a "*reliable and verifiable proof of vaccination that can be*

elements (see here)	*presented by its holder upon request*"), to the extent that Member States or other parties decide to implement these. The Guidelines are based on the principle of rigorous protection of personal data, which requires developing proper instruments. In particular, the Guidelines stress that the design of the vaccination certificate system should allow the data subject to control the use of the certificate data. The Guidelines set out the basic elements of interoperability of certificates, which consist of a minimum dataset (e.g. person's name; name of vaccine medicinal product; date and location of vaccination; issuer of certificate; etc.). Each certificate for a partial or completed vaccination procedure/course that takes place in EU Member States must be identified by a unique identifier for vaccination certificates ("UVCI"). With respect to the UVCI, the Guidelines recommend that it should not comprise personal data, as its primary purpose is to be a unique 'primary key' which allows health authorities of Member States to verify an individual's vaccination status.

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