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

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- Air passenger rights during COVID-19 pandemic: Key rights not protected – Special Report by European Court of Auditors
- European Commission adopts positive assessments of Recovery and Resilience Plans from an additional 2 Member States
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission prolongs COVID-19 export authorization mechanism until 30 September 2021
- European Commission 2020 Annual Burden Survey includes proposed Single Window customs initiative

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- European Commission identifies five promising candidate therapeutics for treating COVID-19 and associated conditions

Cybersecurity, Privacy & Data Protection

- EU Digital COVID Certificate enters into application in EU
- European Commission revises EU rules on product safety and consumer credit, including response to digitalization accelerated by the pandemic
- European Commission publishes reports by online platforms on combating coronavirus disinformation

COMPETITION & STATE AID

State Aid

Air passenger rights during COVID-19 pandemic: Key rights not protected – Special Report by European Court of Auditors (see here)

On 29 June 2021, the European Court of Auditors ("ECA") released its Special Report 15/2021: Air passenger rights during the COVID-19 pandemic: Key rights not protected despite Commission efforts.

Member States granted unprecedented levels of State aid in response to the pandemic to enable air carriers and package-tour operators to continue operating and to shield them from bankruptcy. The ECA reports that the European Commission approved 54 State aid decisions and nearly €35 billion of public money between March 2020 and April 2021.

In the early months of the pandemic, the ECA also reported that many passengers were obliged to accept vouchers and were denied their right to reimbursement under EU law (Regulation 261/2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights; and Directive 2015/2302 on package travel and linked travel arrangements).

The ECA highlighted that while the Commission could not require reimbursing passengers as a condition for approving State aid, the Commission did clearly indicate that Member States could subject aid to airlines to passenger reimbursement. The ECA reports that Member States, instead, did not condition the aid on complying with passenger reimbursement rules, which led to divergent treatment of air passengers across the EU.

In this respect, the ECA notes that contrary to EU law, 15 Member States (including Belgium, France, the Netherlands, and Portugal) even adopted derogations from the obligation to reimburse under the above-referred Directive on package travel. In addition, two Member States (Italy and Greece) adopted similar derogations from the above-mentioned Regulation on air passenger rights.

In response to these derogations, the Commission opened various infringement actions on 2 July 2020 against national legislation authorizing the suspension of reimbursement rights. The infringement actions were largely subsequently closed as national laws were brought back in line with EU law, or because national measures were repealed/amended, or expired/not renewed.

In light of its findings, the ECA set out specific recommendations to the European Commission, such as:

- Strengthening air passenger rights (by end-2022), including eventual legislation (e.g. establishing an EU-wide standardized reimbursement form, similar to the rail sector; mitigating the risk of a liquidity crisis or the insolvency of carriers for example by reviewing the rules on the financial fitness of airlines; etc.); and

- More coordination of national measures and better linking State aid to airlines to passenger reimbursement (by end-2021).

	The ECA presents its special reports to the European Parliament and the Council of the EU, as well as to other interested parties such as national parliaments and various stakeholders. The ECA indicates its view that the vast majority of recommendations made in these reports are put into practice.
European Commission adopts positive assessments of Recovery and Resilience Plans from an additional 2 Member States (see here)	As of 5 July 2021, the Commission had adopted 2 additional positive assessments of the Recovery and Resilience Plans of the below-listed Member States. These plans set out the reforms and public investment projects foreseen for implementation with the support of the Recovery and Resilience Facility (RRF): – Lithuania (€2.2 billion) – Slovenia (€2.5 billion) These approvals are a key step towards disbursing funds to these Member States under the RRF, the key component of NextGenerationEU, the EU's plan for rebounding from the COVID-19 crisis. The RRF will provide up to €672.5 billion to finance reforms and investments (i.e., grants totaling €312.5 billion and €360 billion in loans). The following 12 Member State plans have already received the Commission's approval: Austria (€3.5 billion); Belgium (€5.9 billion); Denmark (€1.5 billion); France (€39.4 billion); Germany (€25.6 billion); Greece (€30.5 billion); Italy (€191.5 billion); Latvia (€1.8 billion); Luxembourg (€93 million); Portugal (€16.6 billion); Slovakia (€6.3 billion); and Spain (€69.5 billion). The Council will have, in principle, four weeks to adopt the Commission's proposals. 10 Member State plans remain pending approval (see here), with the following total amounts requested under the RRF: Croatia (€6.4 billion); Cyprus (€1.2 billion); Czechia (€7.1 billion); Estonia (€982.5 million); Finland (€2.1 billion); Hungary (€7.2 billion); Ireland (€1 billion); Poland (€23.9 billion); Romania (€29.3 billion); and Sweden (€3.2 billion). Commission assessment of plans. In evaluating the Member State plans under the criteria set out in the RRF Regulation, notably, the RRF guidelines make clear that the investment projects included in Member State recovery plans must comply with State aid rules. The Commission published practical guidance for swift treatment of projects under State aid rules, as well as a number of sector-specific templates to help Member States design and prepare the State aid elements of their recovery plans (*Jones Day Commentary, "EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, see here*). The Commission's appraisal of Member State plans will also, in particular, determine whether the plans dedicate at least 37% of expenditure to investments and reforms that pursue climate objectives and 20% to the digital transition. In terms of timing, the RRF Regulation envisages two months for assessing the Recovery and Resilience plans and for translating their contents into legally binding acts. However, the Regulation also specifies that, if necessary, the Member State concerned and the Commission may agree to extend the deadline for assessment by a reasonable period. Member State plans pending submission. The Commission will continue to closely engage with the 3 remaining Member States (i.e. Bulgaria, Malta, The Netherlands) to deliver robust national recovery plans. While Member States

	were invited to notify their plans before 30 April 2021, they may do so until mid-2022.
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 most recent measures adopted to support the economy and companies affected by coronavirus outbreak include: • €60 million French scheme to support companies in the beef cattle sector affected by the coronavirus outbreak. • €20 million Dutch scheme to support the agricultural and horticultural sectors affected by the coronavirus outbreak. • €8 million Portuguese scheme to support micro, small and medium-sized companies in the region of the Azores affected by the coronavirus outbreak. • €8 million Greek scheme to support companies active in the audio-visual distribution sector affected by the coronavirus outbreak. • Modification to two Italian schemes to further support companies affected by the coronavirus outbreak, including an extension of the eligible period until 31 December 2021 and an increase of the maximum maturity of the guaranteed loans from six to eight years. • €20 million Greek scheme to support breeders of pigs and producers of honey affected by the coronavirus outbreak. • €297 million Swedish scheme to support organizers of events affected by the coronavirus outbreak. • €39.7 million of Italian aid measure to compensate Alitalia for further damages suffered due to the coronavirus outbreak. • Austrian scheme to support organizers of events affected by the coronavirus outbreak, should events be cancelled or significantly restricted as a result of restrictive measures implemented by the Austrian government, with damage compensation limited to a maximum of 80% of the actual net costs of cancelled events.
TRADE / EXPORT CONTROLS	
European Commission prolongs COVID-19 export authorization mechanism until 30 September 2021 (see here)	On 29 June 2021, the Commission extended the EU's export transparency and authorization requirement for COVID-19 vaccines until 30 September 2021, adopting Implementing Regulation (EU) 2021/1071 (see here). To recall, this export authorization mechanism was first introduced on 30 January 2021 (see *COVID-19 Update No. 34 of 3 February 2021*) as an emergency measure, initially set to last for a period of six weeks. Under its terms, COVID-19 vaccines, as well as the active substances used for the manufacture of such vaccines, are subject to an authorization for export outside the EU to ensure respect of contractual agreements and supply chain security. On 12 March 2021, the Commission extended the measure's application until 30 June 2021 (see *Jones Day COVID-19 Update No. 40 of 17 March 2021*).

European Commission 2020 Annual Burden Survey includes proposed Single Window customs initiative (see here)

On 29 June 2021, the Commission published the 2020 Annual Burden Survey, which outlines the EU's efforts in the past year to simplify legislation in areas ranging from customs and taxation to financial services, transport, and the environment.

In the field of customs, the Survey includes the proposed "EU Single Window Environment for Customs," announced by the Commission on 28 October 2020 (see *Jones Day Update No. 26 of 3 November 2020*). To recall, this initiative is part of the Commission's efforts to improve and streamline the management of EU customs and to reinforce responsiveness to crises like the COVID-19 pandemic.

Most notably, the Single Window will enable businesses to complete all border formalities in one electronic step in an individual Member State. This is expected to lead to faster clearance of essential medical products, including expedited verification that goods comply with EU requirements and prevention against the entry of counterfeit or unsafe medical goods.

MEDICINES AND MEDICAL DEVICES

European Commission identifies five promising candidate therapeutics for treating COVID-19 and associated conditions (see here)

On 29 June 2021, the European Commission announced the first portfolio of five therapeutics that may soon be available to treat patients in combating COVID-19.

The identification of such potential treatments builds upon the EU COVID-19 Therapeutics Strategy (*see also Jones Day COVID-19 Update No. 47 of 12 May 2021*), which mandated the Commission with establishing, on the ground of scientific criteria agreed with Member States, a list of five promising candidates by June 2021 and another five candidates by October 2021. The goal is to authorize at least three new therapeutics by October 2021 and possibly an additional two by end-2021.

Four of the currently identified therapeutics are monoclonal antibodies that are currently under rolling review by the European Medicines Agency ("EMA"), a regulatory procedure allowing to speed up the assessment of promising medicinal products based on promising preliminary results from clinical studies. The fifth product is an immunosuppressant already granted with a marketing authorization, which may be extended to include the treatment of COVID-19 patients.

The Commission is also preparing a framework for a broader portfolio of therapeutics with the assistance of the HERA expert group on variants. HERA (EU Health Emergency Preparedness and Response Authority) is one component of the EU's response to the COVID-19 pandemic and the pursuit of a robust European Health Union, seeking to improve Europe's ability to respond to cross-border health threats and emergencies (*see also Jones Day COVID-19 Update No. 43 of 7 April 2021)*.

Additionally, the Commission is evaluating the possibility to launch new joint procurement procedures for the purchase of COVID-19 therapeutics similar to those carried out in the last 12 months.

CYBERSECURITY, PRIVACY & DATA PROTECTION

EU Digital COVID Certificate enters into application in EU (here)

On 1 July 2021, the European Commission announced the entry into force of the EU Digital COVID Certificate Regulation (*see also Jones Day COVID-19 Update No. 41 of 24 March 2021*).

In practice, this means that EU citizens and residents can now have their Digital COVID Certificates ("Certificates") issued and verified across the EU.

Certificates have already been issued by 21 Member States, as well as Norway, Iceland and Liechtenstein, and five additional EU countries started issuing Digital COVID Certificates on 1 July 2021.

European Commission President Ursula von der Leyen welcomed the entry into application of the Certificates, stating: "*The European Digital COVID Certificate is a symbol of an open and safe Europe that is opening cautiously putting the protection of the health of our citizens first*."

To recall, the Certificate is available in either digital or paper format and is issued by national authorities free of charge.

The Certificate will certify whether a person has been vaccinated against COVID-19, has a recent negative test result, or has recovered from the infection. In practice, these will be three distinct certificates (i.e., proof of vaccination, testing, or recovery).

In addition, any processing of personal data must comply with the General Data Protection Regulation. Certificates will be verified offline, and personal data will not be retained (*see also Jones Day COVID-19 Update No. 51 of 15 June 2021).*

European Commission revises EU rules on product safety and consumer credit, including response to digitalization accelerated by the pandemic (here)

On June 30 2021, the Commission proposed to revise two sets of EU rules to enhance consumer rights in the current environment of digitalization and the COVID-19 pandemic, publishing a Proposal for a General Product Safety Regulation (see here) and a revision of the Consumer Credit Directive (see here).

The revisions aim to reinforce EU consumer safety by ensuring that certain products are recalled from the market and that credit offers are presented to consumers in a clear way, such as easy readability on digital devices.

Didier Reynders, Commissioner for Justice, emphasized: "*The COVID-19 crisis has impacted consumers in multiple ways and many have faced financial difficulties. The digitalisation that has been accelerated by the pandemic, leads to a surge of online shopping and is profoundly changing the financial sector. It is our duty to safeguard consumers, in particular, the most vulnerable ones* […]".

Online sales have significantly increased in the past twenty years, often concerning new technology "gadgets" such as smart air purifiers and gaming consoles. Thus, the proposed General Product Safety Regulation will address risks related to these new technology products, including cybersecurity risks.

The proposed new rules will seek to ensure the safety of products reaching EU consumers, regardless of whether they originate from within the EU or from outside the EU.

	The Council and Parliament will now discuss the proposals of the Commission.
European Commission publishes reports by online platforms on combating coronavirus disinformation (see here)	On 29 June 2021, the Commission announced the publication of reports by various online platforms, as signatories of the Code of Practice on Disinformation (see here), regarding measures taken in May 2021 against coronavirus disinformation. According to the Vice-President for Values and Transparency, Věra Jourová, "*this monitoring programme remains a test case for the platform that will inform the strengthening of the Code of Practice on Disinformation*." For instance, one of the online platforms implemented a search feature that presents users seeking information on COVID-19 vaccines with a list of authorized vaccines and related information and statistics. To reduce the spread of misinformation on COVID and vaccines, another online platform updated its notifications to users to a "strike"-based system, such that user tweets are labelled or removed, with gradual account suspension. However, the Commission also stressed that more granular data is necessary in view of attaining a better understanding of the impact of measures taken by online platforms to fight coronavirus related disinformation.

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