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 distributes first pre-financing under Recovery and Resilience Plans to 3 Member States
- European Commission amends decision approving €7 billion in support to Air France in the context of the COVID-19 crisis
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- *No noteworthy developments for this issue*

Medicines and Medical Devices

- European Commission confirms that on 31 January 2022, the Clinical Trials Regulation and becomes officially applicable and Clinical Trials Information System goes live
- European Commission launches interactive map on COVID-19 vaccine production capabilities

Cybersecurity, Privacy & Data Protection

- European Commission adopts equivalence decisions for Vatican and San Marino digital COVID certificates
- European Commission publishes reports by online platforms regarding COVID-19 disinformation

COMPETITION & STATE AID	
State Aid	
European Commission distributes first pre-financing under Recovery and Resilience Plans to 3 Member States (see here and here)	On 3 August 2021, the first three Member States received pre-financing disbursements from the Commission under the Recovery and Resilience Facility (RRF) towards boosting their economies and recovering from the COVID-19 fallout (Belgium (€770 million); Luxembourg (€12.1 million); and Portugal (€2.2 billion)). These sums are equivalent to approximately 13% of the respective countries' financial allocations. The Commission will subsequently authorize additional disbursements based on satisfactorily fulfilling the milestones and targets, as set out in each of the Council Implementing Decisions, concerning investments and reforms covered in each Member State's Recovery and Resilience plan. The total amounts foreseen for these first Member States receiving pre-financing are €5.9 billion (Belgium); €93.4 million (Luxembourg); and €16.6 billion (Portugal). These first disbursements follow the adoption of the initial set of Council Implementing Decisions, allowing up to 13% pre-financing, for the approval of national Recovery and Resilience plans for 12 Member States (Austria, Belgium, Denmark, France, Germany, Greece, Italy, Latvia, Luxembourg, Portugal, Slovakia and Spain), who received the first green lights for use of EU recovery and resilience funds on 13 July 2021 (see here). On 26 July 2021, EU economic and finance ministers and the European Commission conducted a positive exchange of views on the assessment of a second set of Member State national recovery and resilience plans (Croatia (€6.3 billion); Cyprus (€1.2 billion); Lithuania (€2.2 billion); and Slovenia (€2.5 billion) (see here). The Council will soon adopt its implementing decisions on the approval of these plans. Additionally, 11 Member State Recovery and Resilience plans, as approved by the Commission, are pending Council approval: Austria (€3.5 billion); Czechia (€7 billion); Denmark (€1.5 billion); France (€39.4 billion); Germany (€25.6 billion); Greece (€30.5 billion); Ireland (€989 million); Italy (€191.5 billion); Latvia (€1.8 billion); Slovakia (€6.3 billion); and Spain (€69.5 billion). To recall, the Member State plans set out the reforms and public investment projects foreseen for implementation with the support of 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).. 7 Member State plans also remain pending Commission approval (see here), with the following total amounts requested under the RRF: Estonia (€982.5 million); Finland (€2.1 billion); Hungary (€7.2 billion); Malta (€316.4 million); 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. Member State plans pending submission. The Commission will continue to closely engage with the 2 remaining Member States (i.e. Bulgaria and 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 amends decision approving €7 billion in support to Air France in the context of the COVID-19 crisis (see here)	On 27 July 2021, the Commission adopted an amending act in view of modifying certain aspects of its Decision of 4 May 2020, which approved a French aid measure of €7 billion for Air France (part of the Air France–KLM Group) aimed at providing urgent cash support in the context of the coronavirus pandemic. The Commission's amending act now adds further elements to the initial decision, in view of seeking to confirm that Air France is in fact the only beneficiary of the French aid measure. The Commission undertook these changes following the General Court's ("GC") judgment of 19 May 2021, which annulled the Commission Decision approving a Dutch aid measure in favor of KLM (the other member of the Air France–KLM Group) for insufficient reasons on assessing the beneficiary of the aid. In the GC's view, in particular, the Commission had not adequately set out the elements necessary for assessing a complex situation, featuring the parallel grant of two State aid measures to two subsidiaries of the same holding company (Air France had already received the above-referred €7 billion in State aid in May 2020). According to the GC, the Commission had simply concluded that KLM was the beneficiary of the contested aid measure and that the Dutch authorities had confirmed that the financing granted to KLM would not be used by Air France (*see also Jones Day COVID-19 Update No. 49 of 2 June 2021)*. The Commission indicated that the amending act to the original Decision did not alter its view that the measure is necessary, appropriate and proportionate to remedy a serious disturbance in the economy of a Member State, in accordance with Article 107(3)b of the TFEU and under the conditions set out in the Temporary Framework for State aid.
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. • €525.3 million German scheme aid in favor of airline Condor in the context of the coronavirus outbreak. • €800 million Italian scheme to compensate airports and ground-handling operators for the damage suffered in the context of the coronavirus outbreak. • Modification to a Dutch scheme to further support companies affected by the coronavirus outbreak, including a €1.8 billion budget increase. • Modification to a Swedish scheme to further compensate companies

	for damages suffered in the context of the coronavirus outbreak, including a €224 million budget increase. • €8.4 billion French wage subsidy scheme to support small and medium-sized enterprises in the context of the coronavirus outbreak. • €130 million Greek scheme to support micro and small enterprises in the context of the coronavirus outbreak. • €20 million Greek scheme to support newspapers, magazines, regional media service providers and radio stations in the context of the coronavirus outbreak. • €1.8 million Estonian scheme for liquidity support to fish processors in the context of the coronavirus outbreak. • €1.4 million Slovenian scheme to support farmers in the context of the coronavirus outbreak. • €275,000 Portuguese scheme to support the sugarcane-processing sector affected by the coronavirus outbreak. • €3 million Slovenian scheme to support companies active in the MICE (Meetings, Incentives, Conferences, Exhibitions) sector in the context of the coronavirus outbreak. • €2.5 billion German scheme to support rail freight and passenger operators in the context of the coronavirus outbreak. • €868 million Italian scheme to reduce labor costs borne by private employers operating in the tourism, spas, commerce, cultural or recreational sectors in the context of the coronavirus outbreak. • €80 million Belgian scheme to support micro, small and medium-sized enterprises, including the self-employed, which supply the restaurant and café sectors in the context of the coronavirus outbreak. • €31 million Czech scheme to compensate rail passenger transport operators for damages suffered in the context of the coronavirus outbreak. • €3.9 million Czech scheme to support the self-employed affected by the coronavirus outbreak. • €22.8 million Slovenian scheme to support companies active in various sectors, such as accommodation, food service and recreation, affected by the coronavirus outbreak. • €26 million Danish scheme to support providers of rail transport of public passenger in the context of the coronavirus outbreak. • €13 million Danish scheme to support large events suppliers in the context of the coronavirus outbreak.
	MEDICINES AND MEDICAL DEVICES
European Commission confirms that on 31 January 2022,	On 31 July 2021, the Commission published the Decision launching the Clinical Trials Information System ("CTIS") (Commission Decision (EU) 2021/1240 on the compliance of the EU Portal and the EU Database for clinical trials of medicinal products for human use with the requirements

the Clinical Trials Regulation becomes officially applicable and Clinical Trials Information System goes live (see here)	referred to in Article 82(2) of Regulation (EU) No 536/2014). The Decision recognizes the complete functionality of the CTIS, an IT system tool designed to apply the Clinical Trials Regulation ("CTR"). CTIS will provide a single entry point for submitting clinical trial information in the EU. The European Medicines Agency ("EMA") will make information stored in CTIS publicly available subject to transparency rules. The CTR will officially become fully applicable as of 31 January 2022. As stated by Stella Kyriakides, Commissioner for Health and Food Safety: "*The pandemic has clearly shown the importance of efficient clinical trials that do not compromise on rigorous safety and efficacy standards. With the Clinical Trials Regulation, we will be able to guarantee higher safety protection for participants of clinical trials, support EU-wide clinical trials, and deliver faster access to the most promising safe and effective medical products to citizens, for the COVID-19 crisis and beyond*." Until 31 January 2023, sponsors are granted the possibility to submit a clinical trial application under either the current Directive 2001/20/EC ("Clinical Trials Directive") or according to the CTR. While clinical trials can continue to be governed by the Clinical Trials Directive until 31 January 2025, as of this date, the CTR will become the sole applicable legislative framework.
European Commission launches interactive map on COVID-19 vaccine production capabilities (see here)	On 27 July 2021, the Commission published an interactive map that shows available COVID-19 vaccine production capacities within the EU (e.g., locations of supply, production, packaging, storing and shipment sites). The tool is based on data gathered by the European Medicines Agency's ("EMA") Task Force for Industrial Scale-up of COVID-19 vaccine production, information compiled by the Member States, as well as information gathered from the "matchmaking" event hosted by the Commission in March 2021 (*see also Jones Day COVID-19 Update No. 42 of 31 March 2021)*. The map can be accessed here and will be complemented as soon as further information becomes available.
CYBERSECURITY, PRIVACY & DATA PROTECTION	
European Commission adopts equivalence decisions for Vatican and San Marino digital COVID certificates (here)	On 2 August 2021, the Commission adopted decisions to ensure that COVID-19 certificates issued by the Vatican City State and San Marino are considered equivalent to the EU Digital COVID Certificate. In practice, this means that Vatican City State and San Marino will be connected to the EU's system and that COVID certificates issued by both countries will be accepted in the EU under the same conditions as the EU Digital COVID Certificate. In return, the Vatican and San Marino will accept EU Digital COVID Certificates for travel to their countries. European Commissioner for Justice, Didier Reynders, stated: "*I am pleased to see that more countries are implementing a system based on the EU Digital COVID Certificate. We are taking active steps to recognise certificates issued by other third countries. However, they must be interoperable with the EU framework and allow for the verification of their authenticity, validity and integrity*."

	Switzerland was the first country from outside the 30 countries of EU and EEA area to be connected to the EU's system. On 8 July 2021, the Commission adopted a Decision establishing the equivalence of COVID-19 certificates issued by Switzerland to the EU Digital COVID Certificate *(see also Jones Day COVID-19 Update No. 55 of 12 July 2021)*. The Commission plans to connect with additional third countries. To do so, the Commission must assess whether the third country certificates are interoperable with the EU Digital COVID Certificate, allowing for the verification of their authenticity, validity and integrity.
European Commission publishes reports by online platforms regarding COVID-19 disinformation (here)	On 29 July 2021, the Commission published reports by online platforms such as Facebook and Twitter, as signatories of the Code of Practice on Disinformation (see here), regarding measures taken in June 2021 to fight coronavirus disinformation. The last reports covered measures taken in May 2021 *(see Jones Day COVID-19 Update No. 54 of 6 July 2021).* Věra Jourová, Vice-President for Values and Transparency, stated: "*The COVID-19 disinformation monitoring programme has allowed to keep track of important actions put in place by online platforms. With new variants of the virus spreading and vaccinations continuing at full speed, it is crucial to deliver on the commitments. We look forward to the strengthening of the Code of Practice.*" For instance, the vaccination campaign supported by TikTok in collaboration with the Irish government, gained over one million views and over 20,000 likes. Google continued work with public health authorities to provide information on vaccination locations in Google Search and Maps for users located in France, Poland, Italy, Ireland, and Switzerland. The Commission expressed the importance of sustaining these joint efforts to combat the persisting and complex challenges that online disinformation still presents. In this respect: – The Commission and current signatories are calling on new companies to join the Code of Practice on disinformation, as this will improve its effectiveness and expand its impact. – The COVID-19 disinformation monitoring program has been extended until end-2021, and reports will now be published every two months. The next reports are expected to be published in September 2021.

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