COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 62 | 4 October 2021

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 consults Member States on future of State aid Temporary Framework
- European Commission distributes pre-financing under Recovery and Resilience Plans to an additional 3 Member States
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission extends COVID-19 export authorization mechanism to 31 December 2021
- EU-US Trade and Technology Council issues Inaugural Joint Statement
- European Commission publishes Memo on FAQs on the FDI Screening Regulation

Medicines and Medical Devices

- EMA evaluates booster dose of COVID-19 vaccine Spikevax

Cybersecurity, Privacy & Data Protection

- European Commission publishes reports by online platforms on combating disinformation

COMPETITION & STATE AID	
State Aid	
European Commission consults Member States on future of State aid Temporary Framework (see here)	On 30 September 2021, the Commission launched its consultation with Member States on a draft proposal to prolong the State aid Temporary Framework until 30 June 2022 and to extend its scope with the intended aim of further accelerating economic recovery. The Temporary Framework, to recall, was initially adopted on 19 March 2020 (and most recently amended on 28 January 2021) in view of supporting the economy following the COVID-19 outbreak through various aid measures which, in particular, could be rapidly approved upon notification to the Commission. In view of signs of economic recovery, the Commission is proposing a limited prolongation of the Temporary Framework with the objective of ensuring against suddenly discontinuing aid to businesses still impacted by the crisis, and instead enabling a coordinated phase-out of such support. In addition, for a limited period beyond 30 June 2022, the Commission proposes to allow Member States to grant: – Investment support measures towards a sustainable recovery, in order to help Member States address the investment gap resulting from the crisis while preserving competition; and – Solvency support measures to leverage private funds and investment in undertakings, in particular small and medium-sized enterprises (SMEs) and small mid-caps, by providing them with access to equity financing. Member States may now provide feedback on the Commission's draft proposal on amending the Temporary Framework, which the Commission will take into account in determining the way forward. The Commission, thus far, has taken more than 650 decisions in all Member States, including based on the Temporary Framework, to enable support worth over €3 trillion in total to companies affected by the pandemic.
European Commission distributes pre-financing under Recovery and Resilience Plans to an additional 3 Member States (see here, here, and here)	As of 4 October 2021, an additional 3 Member States received pre-financing disbursements from the Commission (Austria (€450 million); Croatia (€818 million); and Czechia (€915 million)) under the Recovery and Resilience Facility (RRF) towards boosting their economies and recovering from the COVID-19 fallout. This follows preceding disbursements to 13 Member States: Belgium (€770 million); Cyprus (€157 million); Denmark (€201 million); France (€5.1 billion); Germany (€2.25 billion); Greece (€4 billion); Italy (€24.9 billion); Latvia (€237 million); Lithuania (€289 million); Luxembourg (€12.1 million); Portugal (€2.2 billion); Slovenia (€231 million); and Spain (€9 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 initial 16 Member States receiving pre-financing are €3.5 billion (Austria); €5.9 billion (Belgium); €6.3 billion (Croatia); €1.2 billion (Cyprus); €7 billion (Czechia); €1.5 billion (Denmark); €39.4 billion (France); €25.6 billion (Germany); €30.5 billion (Greece); €191.5 billion (Italy); €1.8 billion (Latvia); €2.2 billion (Lithuania); €93.4 million (Luxembourg); €16.6 billion (Portugal); €1.8 billion (Slovenia); and €69.5 billion (Spain).

The disbursements follow the adoption of the Council Implementing Decisions, allowing up to 13% pre-financing, for the approval of national Recovery and Resilience plans for the above-mentioned Member States, which received the first green lights for use of EU recovery and resilience funds in July 2021 (see here), with Slovakia still awaiting its pre-financing disbursement.

Following a positive assessment on 6 September 2021, Council approval is anticipated for the Member State plan for Ireland (€989 million), as earlier approved by the Commission. In addition, the plans for Finland (€2.1 billion), Malta (€316.4 million), and Romania (€29.2 billion) will undergo Council assessment following recent approvals by the Commission.

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).

4 Member State plans remain pending Commission approval (see here), with the following total amounts requested under the RRF: Estonia (€982.5 million); Hungary (€7.2 billion); Poland (€23.9 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 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. • €10 million Belgian scheme to support social economy companies in the context of the coronavirus outbreak. • €16 million Dutch scheme to support the fireworks sector in the context of the coronavirus outbreak. • €61.19 million French scheme to support Brittany Ferries in the context of the coronavirus outbreak. • €900,000 Cypriot scheme to support wine producers in the context of the coronavirus outbreak. • €2.7 million Cypriot scheme to support companies active in agricultural production in the context of the coronavirus outbreak. • Modification to two Czech schemes to support companies in the context of the coronavirus outbreak, including increases in overall estimated budgets and prolongations until 31 December 2021 for both schemes and an increase of the maximum nominal amount of aid per company for the first scheme (SA.59899). • €1.2 million Romanian scheme to support airlines starting regular international flights at Maramureș International Airport in the context of the coronavirus outbreak.

TRADE / EXPORT CONTROLS

European Commission extends COVID-19 export authorization mechanism to 31 December 2021 (see here)	On 30 September 2021, the Commission announced the latest extension (until 31 December 2021) of the COVID-19 vaccines export transparency and authorization mechanism in its current form. The Commission does not intend to further prolong this mechanism after 31 December 2021. To recall, the export authorization mechanism, launched in January 2021, responded to vaccine supply problems and addressed the issue of transparency of vaccine exports outside the EU (*see Jones Day Update No. 34 of 3 February 2021*). The mechanism (covering COVID-19 vaccines and the active substances used to manufacture such vaccines) 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. The Commission reports that the authorization mechanism has greatly improved the transparency of vaccines production, deliveries and supply chains. It cautioned, however, of persisting uncertainties such as the emergence of new COVID-19 variants. There is therefore a continuing need for transparency of export deliveries and Union supplies. Following the expiry of the present export authorization mechanism, the Commission anticipates establishing a monitoring scheme as from 1 January 2022 to provide company-specific and timely vaccine export data. Such monitoring is expected to continue to afford the EU with transparency on vaccine exports, but without a compulsory export authorization mechanism.

EU-US Trade and Technology Council issues Inaugural Joint Statement (see [here](#))	On 29 September 2021, the EU-US Trade and Technology Council (TTC) issued its Inaugural Joint Statement. This inaugural TTC meeting was co-chaired by European Commission Executive Vice-President Margrethe Vestager, European Commission Executive Vice-President Valdis Dombrovskis, US Secretary of State Antony Blinken, US Secretary of Commerce Gina Raimondo, and US Trade Representative Katherine Tai. The EU and US reaffirmed the TTC's objectives to coordinate approaches to key global technology, economic, and trade issues, as well as to deepen transatlantic trade and economic relations. US-EU two-way trade in goods and services amounted to $1.1 trillion in 2019. <u>Semiconductors</u> are among the TTC's focus areas, recognizing that semiconductors are the material basis for integrated circuits that are essential to modern-day life and underpin every sector of the economy. The COVID-19 pandemic further amplified the importance of semiconductors, which enabled remote health care, medical research, working and studying from home, and electronic commerce. Shortages of certain semiconductors during the pandemic have highlighted the necessity of ensuring resilient and diversified supply chains for these vital goods. In the short-term, the TTC will focus on jointly identifying gaps and vulnerabilities, mapping capacity in the semiconductor value chain, and bolstering domestic semiconductor ecosystems, towards improving resilience through consultation with stakeholders and the right incentives. The TTC also stated its aim to avoid a subsidy race and the risk of shutting out valuable private investments. The EU and US also intend to work jointly such that any investment made on their territories is done in full respect of their respective security of supply. Semiconductors and other focus areas will be the subject of joint EU and US work over the coming months, with the goal of achieving concrete outcomes on these issues by the time of the TTC's next meeting. The TTC will meet periodically at political level to steer the cooperation.
European Commission publishes Memo on FAQs on FDI Screening Regulation (see [here](#))	On 17 September 2021, the Commission published a Memo on Frequently Asked Questions (FAQs) on the FDI Screening Regulation (Regulation (EU) 2019/452 of 19 March 2019 establishing a framework for the screening of foreign direct investments into the Union). The Regulation addressed concerns over foreign investors seeking to acquire control or influence in European firms implicating technologies, infrastructure, inputs, or sensitive information critical for more than one Member State or on a project of Union interest. It sets out a framework for identifying risks related to the acquisition or control of strategic assets that threatens security or public order. It also establishes a cooperation framework between Member States and the Commission, underpinning Member States' FDI assessments and facilitating a Member State's ultimate decision where the FDI is planned or completed. The FAQs note the role that FDI screening can play in dealing with the COVID-19 crisis, as the pandemic uncovered particular vulnerabilities, including the resilience of the EU's critical industries in areas such as healthcare and medical research. In this respect, the FAQs recall that in March 2020, the Commission issued

	Guidance addressing FDI screening in the context of the coronavirus pandemic. This Guidance, in particular, called upon Member States without such screening to set up a full-fledged mechanism to enable, for example, the review of transactions posing a risk to EU critical health infrastructures (see *Jones Day Alert, "New European Commission Guidance Calls for Increased Scrutiny of Investments Amid COVID-19 Crisis", March 2020, see* here). Following this Commission Guidance, various Member State measures were taken in response to the COVID-19 crisis (e.g., FDI screening provisions notified by Italy, Poland and Slovenia). The FAQs note that 18 Member States currently have a screening mechanism in place, notified pursuant to the FDI Screening Regulation, and calls upon the remaining Member States to set up a full-fledged screening mechanism.

MEDICINES AND MEDICAL DEVICES

EMA evaluates booster dose of COVID-19 vaccine Spikevax (see here)	On 27 September 2021, the Human Medicines Committee (CHMP) of the EMA started the evaluation of the application for use of a booster dose of Spikevax (Moderna's COVID-19 vaccine) to be given at least six months after the second dose in populations older than 12 years. The CHMP will carry out an accelerated assessment of data submitted by Moderna, which include results from an ongoing clinical trial. As result of the assessment, it may recommend to update the product information.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission publishes reports by online platforms on combating COVID-19 disinformation (see here)	On 1 October 2021, as part of the Fighting COVID-19 Disinformation Monitoring Programme, the Commission announced the publication of the latest reports by various online platforms (i.e. signatories of the Code of Practice on Disinformation (see here)), regarding their ongoing efforts taken in July and August 2021 to limit COVID-19 and vaccine disinformation (*See also Jones Day COVID-19 Update No. 54 of 6 July 2021*). For instance, social media platforms initiatives included: – introducing new features such as "Trends" and "TopView" to support governments in promoting vaccination campaigns. – launching educational videos to help users verify information to combat COVID-19 misinformation. – regularly updating vaccine trackers and official pages of credible platforms with authoritative information. – announcing collaboration agreements aiming at elevating reliable information on trending issues on COVID-19. The results of the COVID-19 Disinformation Monitoring Programme are also contributing to the revision of the Code of Practice on Disinformation, and in particular, the establishment of a monitoring framework for the strengthened Code. Drafting of a revised Code is anticipated by end-2021.

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