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 approves new synthetic securitization product to support SMEs affected by the pandemic
- European Commission distributes additional pre-financing under Recovery and Resilience Plans to 4 Member States
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission issues expanded Guidance Note on providing COVID-19-related humanitarian aid in sanctioned environments
- Latest Eurostat data – A rise in exports, imports, and intra-euro area trade as compared to June 2020

Medicines and Medical Devices

- European Commission approves latest Advanced Purchase Agreement with Novavax for potential COVID-19 vaccine
- EMA commences evaluating use of RoActemra in hospitalized adults with severe COVID-19

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

COMPETITION & STATE AID

State Aid

European Commission approves new synthetic securitization product to support SMEs affected by the pandemic (see here)

On 16 August 2021, the Commission approved, in line with EU State aid rules, a new synthetic securitization product (specifically, guarantees on synthetic securitization tranches) under the European Guarantee Fund ("Fund"). The Fund, established as a part of the overall EU response to the COVID-19 crisis, seeks to assist companies affected by the pandemic in the 22 Member States participating in the Fund.* The European Investment Bank Group (composed of the European Investment Bank ("EIB") and European Investment Fund ("EIF")) oversees the Fund.

The newly approved synthetic securitization product, with a planned budget of €1.4 billion, is anticipated to mobilize some €13 billion in new lending by financial intermediaries to small and medium-size enterprises ("SMEs") affected by the outbreak.

As explained by the Commission, synthetic securitization is a financial technique whereby an originating entity (e.g., a bank):

- identifies a pool of existing assets (e.g., a portfolio of loans) that it holds on its balance sheet;
- creates tranches with different risk/reward profiles against that pool; and subsequently
- transfers a part of the risk stemming from the pool by buying protection on a specific tranche (e.g., by getting a guarantee on the relevant risk tranche) from a protection seller.

In return, the originating entity pays a premium to the protection seller.

Under the new synthetic securitization product, the EIB Group will serve as a protection seller, providing financial intermediaries with protection in the form of a guarantee on a specific risk tranche for certain qualifying portfolios of existing assets. In exchange for providing the guarantee, the EIB Group will charge the financial intermediary with a subsidized guarantee fee.

The financial intermediary must pass on the financial advantage stemming from the transaction, to the fullest extent possible, to the ultimate beneficiaries of the new instrument, i.e., to SMEs receiving new loans.

The intended purpose of the new securitization product is to help originate new, riskier lending by financial intermediaries to SMEs. The aim is to free up lending capacity of financial intermediaries and prevent a shifting of their resources towards lower-risk assets, instead of loans to SMEs.

The Fund was launched following the Commission's approval under State aid rules, in December 2020, of the Fund's establishment, contributions to the Fund by participating Member States, and downstream interventions in the form of guarantees on debt instruments (such as loans).

Thus far, the EIB and EIF have approved a total of €17.8 billion in projects under the Fund, which are anticipated to lead to some €143.2 billion in total mobilized investments. The Fund's intended goal is to mobilize up to €200

	billion of additional financing in the participating 22 Member States. * *All Member States may participate in the Fund. Thus far, the following 22 Member States decided to participate and jointly guarantee the Fund's operations: Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain and Sweden.*
European Commission distributes pre-financing under Recovery and Resilience Plans to an additional 4 Member States (see here and here)	As of 17 August 2021, an additional 4 Member States received pre-financing disbursements from the Commission (Greece (€4 billion), Italy (€24.9 billion), Lithuania (€289 million), and Spain (€9 billion)) under the Recovery and Resilience Facility (RRF) towards boosting their economies and recovering from the COVID-19 fallout. This follows the preceding first set of disbursements to 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 initial Member States receiving pre-financing are €5.9 billion (Belgium); €30.5 billion (Greece); €191.5 billion (Italy); €2.2 billion (Lithuania); €93.4 million (Luxembourg); €16.6 billion (Portugal); and Spain (€69.5 billion). The 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 16 Member States (Austria, Belgium, Croatia, Cyprus, Denmark, France, Germany, Greece, Italy, Latvia, Lithuania, Luxembourg, Portugal, Slovakia, Slovenia and Spain), who received the first green lights for use of EU recovery and resilience funds in July 2021 (see here). Council approval remains pending for 2 Member State Recovery and Resilience plans, as approved by the Commission: Czechia (€7 billion) and Ireland (€989 million). 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 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. • €430 million Italian scheme to compensate ski lift operators for damages suffered in the context of the coronavirus outbreak. • €19.7 million Danish scheme to support cultural institutions affected by the coronavirus outbreak. • €15 million Irish scheme to support commercial bus operators in the context of the coronavirus outbreak. • €10 million Slovak scheme to support professional sport clubs affected by the coronavirus outbreak. • €550 million German support to compensate the railway company Deutsche Bahn for damages suffered by its subsidiary DB Fernverkehr in the context of the coronavirus outbreak. • €3.7 million Slovenian scheme to support operators of cableway installations in the context of the coronavirus outbreak. • €450 million Italian scheme to support large companies affected by the coronavirus outbreak.
TRADE / EXPORT CONTROLS	
European Commission issues expanded Guidance Note on providing COVID-19-related humanitarian aid in sanctioned environments (see here)	On 13 August 2021, the Commission published an expanded Guidance Note on the provision of humanitarian aid to fight the COVID-19 pandemic in certain environments subject to EU sanctions. A new chapter on counter-terrorism sanctions sets out practical guidance on how to comply with EU sanctions when providing humanitarian aid, in particular medical assistance and equipment, to fight the COVID-19 pandemic. These sanctions address, for example, persons and entities associated with Al-Qaida and the Islamic State in Iraq and the Levant ("ISIL (Da'esh)") who may be active in several countries or in cross-border areas (e.g., Afghanistan/Pakistan border area, northern Afghanistan and Central Asia). The additional guidance on counter-terrorism sanctions builds on the existing chapters on Syria, Iran, Venezuela and Nicaragua. Those chapters remain unchanged, as set out in the previous Commission Guidance Note adopted on 16 November 2020 (*see also Jones Day Update No. 27 of 18 November 2020).* The EU has some 40 different sanctions regimes currently in place. These

	sanctions seek to support key EU objectives such as maintaining peace, bolstering international security, and supporting democracy, international law and human rights. The sanctions target those who threaten these values, aiming to limit, to the extent possible, adverse consequences on the civilian population.
Latest Eurostat data – A rise in exports, imports, and intra-euro area trade as compared to June 2020 (see here)	On 13 August 2021, the European Commission published the latest Eurostat data on international trade. The first estimate for euro area* exports of goods to the rest of the world in June 2021 was €209.9 billion, an increase of 23.8% compared with June 2020 (€169.6 billion). These statistics of last June were significantly impacted by the Member States' COVID-19 containment measures. Imports from the rest of the world amounted to €191.8 billion, a rise of 28.2% compared with June 2020 (€149.6 billion). Thus, the euro area recorded a €18.1 billion surplus in trade in goods with the rest of the world in June 2021, compared with +€20.0 billion in June 2020. Intra-euro area trade rose to 188.0 billion in June 2021, up 24.6% compared with June 2020. Extra-EU** exports rose to €188.3 billion in June 2021 (up 22.3% compared with June 2020). The highest increases were registered in Malta (+65.4%), Greece (+47.3%) and Cyprus (+45.7%). Extra-EU imports stood at €173.5 billion (up by 29.6% compared with June 2020). The highest increases were observed in Latvia (+88.7%), Slovakia (+72.1%) and Estonia (+62.4%). The EU thus recorded a €14.8 billion surplus in trade in goods with the rest of the world in June 2021, compared with +€20.0 billion in June 2020. Intra-EU trade rose to €294.4 billion in June 2021 (up 24.6% compared with June 2020). ** The euro area (EA19) includes Belgium, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Austria, Portugal, Slovenia, Slovakia and Finland.* *** The EU (European Union) includes Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland and Sweden.*
MEDICINES AND MEDICAL DEVICES	
European Commission approves latest Advanced Purchase Agreement with Novavax for potential COVID-19 vaccine (see here)	On 4 August 2021, the Commission approved its seventh Advanced Purchase Agreement (APA) with pharmaceutical company, Novavax, to ensure access to a potential vaccine against COVID-19 as from Q4 2021. This latest APA will enable Member States to purchase up to 100 million doses of the Novavax vaccine with an option for 100 million additional doses during the course of 2021, 2022, and 2023, once reviewed and approved by the European Medicines Agency ("EMA") as safe and effective. The Novavax agreement broadens the portfolio of vaccines to be produced in Europe, including contracts with AstraZeneca, BioNtech-Pfizer, CureVac,

	Janssen Pharmaceutica NV, Moderna, Sanofi-GSK, and the concluded exploratory talks with Valneva. Novavax is a biotechnology company developing next-generation vaccines for serious infectious diseases. Its COVID-19 vaccine is currently under rolling review by EMA in view of a potential market authorization. The Commission's decision to support this vaccine is based on scientific assessment, the technology used, the company's experience in vaccine development, and its production capacity to supply the whole of the EU. To recall, on 17 June 2020, the Commission adopted a Communication on EU Strategy for COVID-19 vaccines, in view of accelerating the development, manufacturing and deployment of effective and safe vaccines against COVID-19 *(see Jones Day Update No. 13 of 19 June 2020).* This includes the Commission's financing, through APAs, of part of the upfront costs of vaccines producers, in return for the right to buy a specified number of vaccine doses in a given timeframe. In light of the current and emerging SARS-CoV-2 variants, the Commission and the Member States are negotiating new agreements with companies already in the EU vaccine portfolio to enable the purchase of rapidly adapted vaccines in sufficient quantities to reinforce and prolong immunity.
EMA commences evaluating use of RoActemra in hospitalized adults with severe COVID-19 (see here)	On 16 August 2021, the European Medicines Agency ("EMA") announced the start of its evaluation of the anti-inflammatory medicine RoActemra (tocilizumab) to extend its use to include the treatment of certain hospitalized adult patients with severe COVID-19. RoActemra is viewed as a potential treatment for COVID-19, given its ability to block the action of interleukin-6, a substance produced by the body's immune system in response to inflammation, which plays an significant role in COVID-19. EMA's Committee for Medicinal Products for Human Use ("CHMP") will conduct an accelerated assessment of the data submitted in the application to decide whether to authorize the extension of indication. The CHMP's opinion, together with any requirements for further studies and additional safety monitoring, will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States. The results of EMA's evaluation are expected by mid-October 2021, unless supplementary information is needed.

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