COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 60 | 6 September 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 responds to concerns regarding pandemic-related State aid support
- 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 reports on effective use of EU trade defense instruments (TDIs) during COVID-19 pandemic

Medicines and Medical Devices

- European Commission and AstraZeneca resolve dispute over COVID-19 vaccine supply

Cybersecurity, Privacy & Data Protection

- European Commission adopts EU Digital COVID Certificate equivalence decisions for Turkey, North Macedonia, and Ukraine

COMPETITION & STATE AID	
State Aid	
European Commission responds to concerns regarding pandemic-related State aid support (see here and here)	On 20 August 2021, Commission Vice-President and Competition Commissioner Margrethe Vestager replied to a written question from June 2021 by Sara Skyttedal, a Member of the European Parliament ("MEP"), on potential distortions to the market arising from continued State aid support in a post-pandemic Europe. In particular, MEP Skyttedal, expressed her belief that since certain Member States and sectors already enjoy tremendous advantages through "*wealth or influence*", State aid would allow them to invest in particular industries and raise the risk of distorting the market. MEP Skyttedal indicated that hypothetically, State aid could result in monopolies that would sideline smaller Member States, research institutions, organizations, and SMEs and start-ups that lack similar weight. In response, Commissioner Vestager indicated the Commission's view that effective State aid control is key to a sustainable and rapid recovery, as this aims to ensure that aid complements private investments, instead of duplicating these or suppressing incentives to innovate. She also expressed the Commission's position that EU State aid rules apply in the same way to all Member States and that equal treatment is a key principle of State aid rules, including in relation to aid provided by Member States in the COVID-19 context. Commissioner Vestager further stated the Commission's view that it "*closely monitors*" the provision by Member States of COVID-19-related State aid relief and that "*to date, it has not observed Member States disproportionately outspending each other or compared to the economic damage of COVID-19*." She also cited safeguards under EU law in relation to dominant positions, as well as Commission initiatives that seek to promote SMEs. Furthermore, Commissioner Vestager noted that the Commission is preparing a strategy to phase out extraordinary crisis support, as soon as feasible under the economic situation.
European Commission distributes pre-financing under Recovery and Resilience Plans to an additional 3 Member States (see here, here and here)	As of 6 September 2021, an additional 3 Member States received pre-financing disbursements from the Commission (Denmark (€201 million); France (€5.1 billion), Germany (€2.25 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); Greece (€4 billion); Italy (€24.9 billion); Lithuania (€289 million); Luxembourg (€12.1 million); Portugal (€2.2 billion); 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 Member States receiving pre-financing are €5.9 billion (Belgium); €1.5 billion (Denmark); €39.4 billion (France); €25.6 billion (Germany); €30.5 billion (Greece); €191.5 billion (Italy); €2.2 billion

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<td>(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).

Following positive assessments on 6 September 2021, Council approvals are expected shortly for 2 additional Member State Recovery and Resilience plans, as earlier 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.</td>
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<td>European Commission approves new and amended Member State measures to support the economy (see here and here)</td>
<td>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.

• €1 billion Cypriot scheme to support enterprises and self-employed individuals in the context of the coronavirus outbreak.

• €1.3 million Slovenian scheme to compensate concession holder of Postojna and Predjama caves for damages suffered due to the coronavirus outbreak.

• €43 million Italian scheme to support the sports sector in the context</td>
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of the coronavirus outbreak.

- €10 million Italian scheme to support the theatre and live performance sector in the context of the coronavirus outbreak.
- €10 million Italian scheme to support companies active in historic centres of municipalities where religious sanctuaries are present in the context of the coronavirus outbreak.
- €108 million Danish aid measure to support coronavirus-related research and development activities of Bavarian Nordic.
- Modification to a French scheme to partially compensate sport clubs and sport event organizers for damages suffered in the context of the coronavirus outbreak, including a €140 million budget increase.
- €500 million Greek scheme to support uncovered fixed costs of companies affected by the coronavirus outbreak.
- €11.5 million Irish scheme to support companies active in the events sector in the context of the coronavirus outbreak.
- €520 million Italian scheme to compensate the trade fairs and congress sectors for damages suffered in the context of the coronavirus outbreak.
- €10 million Portuguese scheme to support farmers active in the outermost Region of the Azores affected by the coronavirus outbreak.
- €1.6 million Austrian scheme to support public companies active in the pool and wellness sector in the context of the coronavirus outbreak.

TRADE / EXPORT CONTROLS

European Commission reports on effective use of EU trade defense instruments (TDIs) during COVID-19 pandemic (see here)

On 30 August 2021, the Commission published its 39th Annual Report on the EU's anti-dumping, anti-subsidy and safeguard activities, as well as the trade defense activity of third countries against the EU in 2020.

The Report highlights that the COVID-19 pandemic raised practical difficulties for the Commission in applying TDIs in 2020, mainly since on-the-spot verifications were not possible. The Commission responded to these challenges by adapting its work practices; *inter alia* by setting up a system of remote cross-checking as well as easing deadlines for interested parties to submit data. As a result, the Commission managed to complete investigations within legal time limits and maintained the same levels of TDI activity as in previous years.

More specifically, according to the Report:

- 150 trade defense measures were in place in the EU at the end of 2020 – 10 more than at the end of 2019 – including 128 anti-dumping, 19 anti-subsidy, and 3 safeguard measures.
- The highest number of EU trade defense measures concern imports from China (99 measures), followed by Russia (9 measures), India (7 measures), and the United States (6 measures).
- In 2020, the Commission launched 15 investigations (compared to 16

in 2019), and imposed 17 provisional and definitive measures (compared to 15 in 2019).

Moreover, the Commission carried out the majority of its work in 2020 through remote cross-checks (83 in total), as compared to 26 on-the-spot verifications. Nevertheless, as this adapted system is quite burdensome, the Report stresses this is only a temporary solution until the Commission's normal practices can be resumed.

MEDICINES AND MEDICAL DEVICES

European Commission and AstraZeneca resolve dispute over COVID-19 vaccine supply (see here)

On 3 September 2021, the Commission and AstraZeneca reached a settlement agreement on supplying Member States with COVID-19 vaccine doses still outstanding under the terms of the Advance Purchase Agreement (APA), executed on 27 August 2020 for a total of 300 million doses.

The settlement also resolves the pending litigation initiated by the Commission before the Brussels Court of First Instance and provides for a new delivery schedule for the remaining 200 million doses. In this respect, AstraZeneca "*firmly commits*" to deliver the Member States with:

- 60 million doses by end-Q3 2021;
- 75 million doses by end-Q4 2021; and
- 65 million doses by end-Q1 2022.

Specific rebates on the cost of the doses will apply in case of delayed supplies, including up to 40% for three or more months of delay.

The deliveries of doses, however, are conditional upon certain assumptions, such as the absence of catastrophic events and the European Medicines Agency's approval of two new AstraZeneca manufacturing sites by end-October 2021.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission adopts EU Digital COVID Certificate equivalence decisions for Turkey (see here), North Macedonia (see here), and Ukraine (see here)

On 19 August 2021, the Commission adopted three decisions to ensure that COVID-19 certificates issued by Turkey, North Macedonia, and Ukraine are considered equivalent to the EU Digital COVID Certificate *(for other Commission equivalence decisions, see also Jones Day COVID-19 Updates No. 58 of 2 August 2021 and No. 55 of 12 July 2021)*.

In practice, this means that Turkey, North Macedonia, and Ukraine will be connected to the EU's system and that COVID certificates issued by these countries will be accepted in the EU under the same conditions as the EU Digital COVID Certificate.

In return, these three countries have accepted EU Digital COVID Certificates for travel to their countries.

European Commissioner for Justice, Didier Reynders, stated: "*I am pleased to see that the list of countries implementing a system based on the EU Digital COVID Certificate is growing steadily and we are setting standards internationally. This will help to facilitate safe travel, also beyond the borders of our Union.*"

The three decisions entered into force on 20 August 2021.

The European Commission continues cooperating with other third countries to connect them to the EU system.

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