



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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COMPETITION & STATE AID

European Commission adopts Communication on Energy Prices to tackle exceptional rise in energy prices (see [here](#))

On 13 October 2021, the Commission adopted a Communication on Tackling Rising Energy Prices: a Toolbox for Action and Support.

The Communication seeks to respond to the sharp rise global energy prices, anticipated to continue throughout the winter. The price surge is principally attributed to increased global demand for energy, as economic recovery accelerates as the COVID-19 pandemic subsides.

The Communication includes a “toolbox” that the EU and its Member States can use with the aim of addressing the immediate impact of current prices increases and further strengthening resilience against future shocks.

Presenting the Toolbox, Energy Commissioner Kadri Simson explained: *“Rising global energy prices are a serious concern for the EU. As we emerge from the pandemic and begin our economic recovery, it is important to protect vulnerable consumers and support European companies.”*

Immediate measures to shield consumers and businesses include, among others:

- Providing aid to companies or industries, in line with EU State aid rules and international subsidy rules.
- Facilitating broader access to renewables power purchase agreements beyond large business, including SMEs, for instance by aggregating end-user demand in line with competition rules.
- Investigating possible anti-competitive behavior in the energy market and requesting the European Securities and Markets Authority (ESMA) to further enhance monitoring of developments in the carbon market.

Medium-term measures for a sustainable and resilient energy system include, among others:

- Boosting investments in renewables and energy efficiency and speeding up renewables auctions and permitting processes;
- Considering revising the security of supply regulation to ensure a better use and functioning of gas storage in Europe.
- Exploring the potential benefits of voluntary joint procurement of gas stocks by Member States.

Commissioner Simson is presenting the Communication and Toolbox to Members of the European Parliament and to Energy Ministers. The European Council on 21-22 October will also discuss energy prices. The Communication is the Commission's contribution to the continued debate among EU policymakers.

Anticipated limited extension of State aid Temporary Framework and new support tools (see [here](#))

Margrethe Vestager, Executive Vice-President and Commissioner for Competition provided remarks to the media on 19 October 2021 on the contemplated extension of the State aid Temporary Framework. She indicated that this was hopefully the last version of the Temporary Framework.

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.

The European Commission is currently consulting 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 (*see Jones Day Update No. 63 of 11 October 2021*).

For some sectors still in difficulty, Commissioner Vestager also remarked that certain tools would be used to support recovery, particularly in view of incentivizing private investment.

As the Commission previously announced on 30 September 2021, for a limited period beyond 30 June 2022, it proposes to allow Member States to grant:

- Investment support measures to help Member States address the investment gap resulting from the crisis; 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 facilitating access to equity financing.

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.

Update on Recovery and Resilience Plans and initial disbursements (see [here](#) and [here](#))

On 18 October 2021, [Bulgaria](#) submitted its official recovery and resilience plan to the Commission, requesting a total of €6.6 billion in grants.

The Commission will continue to closely engage with [The Netherlands](#) to deliver a robust national recovery plan. While Member States were invited to notify their plans before 30 April 2021, The Netherlands may do so until mid-2022.

To recall, the Member State plans set out the reforms and public investment projects foreseen for implementation with the support of the Recovery and Resilience Facility (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 Commission will now assess Bulgaria's plan based on the criteria set out in the Regulation establishing the RRF (Regulation (EU) 2021/241 of 12 February 2021).

Commission assessment of plans. In evaluating the Member State plans under 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.

The Commission has thus far adopted positive assessments for 22 Member State plans. Commission approval remains pending for 3 plans: Hungary (€7.2 billion); Poland (€23.9 billion); and Sweden (€3.2 billion) (see [here](#)).

As a rule, the Council will have four weeks to adopt the Commission proposals for Council Implementing Decisions for the approval of national Recovery and Resilience plans. The Decisions, in particular, open the way to disbursements of pre-financing payments of up to 13% of the country’s total financial allocation under the RRF.

On 13 October 2021, Slovakia became the latest Member State to receive pre-financing disbursements from the Commission (€822.7 million) under the RRF (see [here](#)). Additionally, Malta awaits pre-financing disbursement of some €41.1 million, following the adoption of a Council Implementing Decision on 5 October 2021 of its €316.4 million plan (see [here](#)). The Council also recently approved the plan for Ireland (€989 million), which has not requested to receive pre-financing disbursement of part of its allocated funds (see [here](#)).

The Commission’s earlier pre-financing disbursements to 16 Member States include: Austria (€450 million); Belgium (€770 million); Croatia (€818 million); Cyprus (€157 million); Czechia (€915 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 the 17 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); €6.3 billion (Slovakia); €1.8 billion (Slovenia); and €69.5 billion (Spain).

Following recent approvals by the Commission, the Council will assess Member State plans for Estonia (€982.5 million); Finland (€2.1 billion), and Romania (€29.2 billion).

With the objective of rapidly responding to the pandemic crisis, a larger part of the EU’s financial support should reach Member States by the end of 2022.

European Commission approves new and amended Member State measures to support the

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.

- €7 million Italian scheme to support open top bus operators in the context of the coronavirus outbreak.

economy (see [here](#) and [here](#))

- €45 million Belgian scheme to support companies in the context of the coronavirus outbreak.
- €31.9 billion Italian scheme to support companies in the context of the coronavirus outbreak.
- €700 million French scheme to support certain retail businesses and services in the context of the coronavirus outbreak.
- €110 million Belgian scheme to support hotels, restaurants and cafés in the context of the coronavirus outbreak.
- €2 million Italian scheme to support the pyrotechnics sector in the context of the coronavirus outbreak.

TRADE / EXPORT CONTROLS

European Commission launches consultation platform on EU-US Trade and Technology Council (see [here](#) and [here](#))

On 18 October 2021, the Commission launched the “Futurium” consultation platform to collect input from all interested parties on initiatives under the EU-US Trade and Technology Council (TTC).

To recall, the TTC’s formation was announced in June 2021 at the first European Union – United States Summit in seven years. The TTC seeks 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.

The TTC comprises an initial 10 Working Groups led by relevant government services to set out deliverables and coordinate technical work. The Commission’s Futurium platform will allow stakeholders to join any of these 10 Working Groups addressing areas such as Technology Standards; Climate and Clean Tech; and Access to and Use of Digital Tools.

In particular, [Working Group 3 – Secure Supply Chains](#) includes a specific focus on [semiconductors](#). As earlier stated by the Commission, 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 (see also [Jones Day COVID-19 Update No. 62 of 4 October 2021](#)).

The Futurium platform will also enable participants to receive information and updates on progress of the Working Groups.

G20 Ministerial Statement on Trade and Investment (see [here](#))

On 12 October 2021, the G20 Trade and Investment Ministers issued a Statement, following its meeting under the 2021 G20 Italian Presidency*, which reiterated the goal of building a resilient, sustainable economic recovery and mitigating COVID-19’s impact on international trade and investment through a coordinated global response.

This G20 Trade and Investment Ministerial Meeting sought to provide a springboard for a successful outcome of the 12th WTO Ministerial Conference (30 November to 3 December 2021), which is anticipated as a key moment in revitalizing the multilateral trading system.

The Statement notes that despite the upheaval to the world economy caused

by the COVID-19 outbreak, the multilateral trading system provided a source of stability and played a key role in easing the pandemic's effects.

In particular, the Statement recognized the importance of supporting:

- Resilience across the entire global supply chain related to health emergencies, including raw materials to produce vaccines; production and accessibility of medicines and medical equipment; as well as non-pharmaceutical goods.
- Targeted, proportionate, transparent, temporary emergency trade measures designed to tackle COVID-19, if deemed necessary, which do not create unnecessary barriers to trade or disruptions to global supply chains. The Statement praised WTO members for rolling back over half of COVID-19 trade restrictive measures and encouraged members to continue in this way.
- Enhanced capacity of the multilateral trading system to increase pandemic and disaster preparedness and resilience by adopting a multi-pronged response focused on, e.g., trade-related aspects of intellectual property rights; expansion of production and delivery of vaccines, therapeutics, and essential medical goods; and diversification of manufacturing locations.

** The G20 members: Argentina, Australia, Brazil, Canada, China, France, Germany, Japan, India, Indonesia, Italy, Mexico, Russia, South Africa, Saudi Arabia, South Korea, Turkey, the United Kingdom, the United States, and the European Union. Spain is also invited as a permanent guest.*

MEDICINES AND MEDICAL DEVICES

European Commission proposes extended transitional provisions for certain in vitro diagnostic medical devices (see [here](#) and [here](#))

On 14 October 2021, the Commission issued a Proposal to amend the In Vitro Diagnostic Medical Devices Regulation (IVDR) (Regulation (EU) 2017/764)) in view of postponing the entry into force of certain provisions.

The Proposal seeks to remediate the lack of Notified Body capacity, due to the COVID-19 pandemic, which diverted resources from Member States, health institutions and businesses. Under the IVDR, Notified Bodies (i.e. conformity assessment bodies) will play a greater role: they will independently monitor whether devices comply with safety and performance requirements before reaching the EU market.

The shortage of Notified Bodies thereby impedes the capacity of manufacturers to timely comply with the changes introduced by the IVDR.

Given such difficulties, while maintaining the IVDR's general date of application as of 26 May 2022, the Proposal plans to extend the timeline of certain transitional provisions. In this respect, the length of the proposed transition periods would depend on the type of device:

- Higher risk devices (such as HIV or hepatitis tests (class D) and certain influenza tests (class C)), would have a transition period until May 2025 and 2026.
- Lower risk devices (such as class B and A sterile devices) would have a longer transition period until May 2027.

The Proposal does not affect (i) CE-marked devices that do not require Notified Body involvement under the IVDR; and (ii) devices that are “new”, i.e. those without either a Notified Body certificate or a Declaration of Conformity under the current In Vitro Medical Devices Directive 98/79/EC (IVDD).

Furthermore, the Proposal would also postpone application of requirements for “in-house devices”, i.e., those manufactured by, and used within the same health institution.

The Proposal will now go to the European Parliament and Council for adoption. A Q&A provides further information on the Proposal (see [here](#)).

Update on EMA evaluations of medicines and vaccines for treating or preventing COVID-19

The European Medicines Agency (EMA) has issued various recent announcements on the evaluation of potential COVID-19 treatments and vaccines:

- On 11 October 2021, the European Medicines Agency (EMA) announced the start of evaluating the application for a marketing authorization (MAA) submitted by Roche Registration GmbH for [Ronapreve](#) (co-developed by Regeneron Pharmaceuticals Inc. (see [here](#))). A monoclonal antibody combination, Ronapreve is intended for adults and adolescents aged 12 years and older for:

- (i) treating COVID-19 for those not requiring supplemental oxygen therapy and who are at increased risk of progressing to severe COVID 19; and

- (ii) preventing COVID-19.

Benefitting from a rolling review (i.e., a regulatory tool enabling the EMA to review clinical data as soon as they become available), the EMA will assess the MAA under a reduced timeline and could issue an opinion within two months.

- On 12 October 2021, CureVac AG informed the EMA of the withdrawal of the MAA for the [CVnCoV](#) COVID-19 vaccine (see [here](#)). The withdrawal is due to CureVac’s decision to focus on a second-generation COVID-19 vaccine program.
- On 14 October 2021, the EMA announced the start of the rolling review of [Evusheld](#) (see [here](#)), a combination of two monoclonal antibodies intended to treat COVID-19 in adults. The decision to commence the rolling review is based on preliminary results from clinical studies and will continue until sufficient evidence is available for the manufacturer to submit a formal MAA.
- On 18 October 2021, the EMA announced the start of evaluating the application for an extension of the marketing authorization of [Comirnaty](#) (BioNTech/Pfizer’s COVID-19 vaccine) for use in children aged 5-11 (see [here](#)). The vaccine is currently authorized for use in people aged 12 and older. EMA’s final decision is expected by the end of the year.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission adopts Report on

On 18 October 2021, the European Commission adopted a Report on the EU Digital COVID Certificate and its implementation across the EU (see [also Jones Day COVID-19 Update No. 54 of 5 July 2021](#)).

EU Digital COVID Certificate (see [here](#))

The Report details the success of the EU Digital COVID Certificate in Europe's response to the pandemic, particularly as it facilitates safe travel for citizens and supports Europe's tourism industry. The Commission also considers the EU Digital COVID Certificate a worldwide success that has set a global standard and is the only system currently operating at international level.

43 countries are connected to the EU system (27 EU Member States, 3 European Economic Area (EEA) countries, Switzerland, and 12 other countries and territories). Technical discussions are also ongoing with 28 third countries interested in joining the EU system.

According to Commissioner for Health, Stella Kyriakides: *"The EU Digital COVID Certificate is a symbol of an open and safe Europe. The quick roll-out of the system, not just in the EU but internationally, is an example of the EU cooperating and delivering in extraordinary circumstances."*

Furthermore, to recall, any processing of personal data must comply with the General Data Protection Regulation. In particular, COVID-19 Certificates should contain only the personal data strictly necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic, and personal data will not be retained.

The Commission will continue to monitor the validity of vaccination and recovery certificates, as well as the use of antibody and rapid antigen tests for recovery certificates, and will reconsider options in light of new scientific guidance.

By 31 March 2022, the Commission plans to submit another report on the application of the EU Digital COVID Certificate Regulation (see [here](#)), possibly accompanied by a legislative proposal extending the period of application of the Regulation.

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