



COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 90 | 28 October 2022

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 issues FAQs on leniency policy and practice
- European Commission publishes State aid brief on use of COVID Temporary Framework
- European Commission prolongs investment support measures and approves further schemes under COVID Temporary Crisis Framework
- European Commission amends Ukraine Temporary Crisis Framework
- European Commission approves further schemes under Ukraine Temporary Crisis Framework

Trade / Export Controls

- Council adopts EU Single Window for Customs
- European Commission proposes new emergency Regulation to address high gas prices and supply security

Medicines and Medical Devices

- Council of the European Union adopts three Regulations as part of European Health Union
- HERA and Coalition for Epidemic Preparedness Innovations (CEPI) agree on stronger cooperation in development of medical countermeasures
- European Commission adopts Work Programme for 2023

Cybersecurity, Privacy & Data Protection

- Digital Services Act published in EU Official Journal
- European Commission adopts Work Programme for 2023

COMPETITION & STATE AID

Competition

European Commission issues FAQs on leniency policy and practice (see [here](#))

On 24 October 2022, the Commission published FAQs to provide guidance on its leniency policy and practice. The Commission has operated a leniency program since 1996 and introduced the currently applicable Leniency Notice in 2006 (see [here](#)).

In view of a more complex leniency landscape, the Commission indicated that the FAQs seek to facilitate leniency applications, in particular, by:

- Providing clarifications on application of the Leniency Notice and details on the legal protections and benefits offered by the leniency program;
- Setting out new practical arrangements, such as Leniency Officers who are the first point of contact in the Cartels Directorate of DG Competition for any potential leniency applicant. Companies or their legal representatives can contact Leniency Officers for informal advice on leniency or guidance on submitting a potential leniency application on a “no-name” basis;
- Indicating the Commission's intention to discuss potential leniency applications on a “no-name” basis, without the need to disclose the sector, the parties involved or any other details identifying the potential cartel. This will allow potential applicants to ascertain whether the conduct at stake is likely to be viewed as a secret cartel and whether reporting it to the Commission would entitle them to benefit from the leniency program.

The FAQs also explain the Commission's eLeniency platform, which allows applicants to submit their leniency applications, including marker applications and supporting documents, directly online on the Commission's secure server. During the COVID-19 lockdown period, the Commission earlier noted that the eLeniency tool ensured the smooth running of its leniency program

As of October 2022, to recall, the new version of eLeniency now allows the Commission to securely grant access to corporate statements and other leniency material to parties involved in cartel and antitrust proceedings, which would otherwise only be accessible at the Commission's physical premises. Additionally, the upgraded eLeniency tool enables the Commission to notify online letters, decisions and other documents in the context of the leniency procedure (e.g. letters granting a marker, no-action letters, etc.) (see also [Jones Day COVID-19 Update No. 88 of 3 October 2022](#)).

Since its introduction in 2019, the FAQs note that eLeniency has become the primary and preferred procedure for leniency submissions (applications and corporate statements).

State Aid

European Commission publishes State aid brief on use of COVID Temporary Framework (see [here](#))

On 17 Oct 2022, the Commission issued a State aid Brief, "*Looking back at the State aid COVID Temporary Framework: the take-up of measures in the EU.*"

To recall, the COVID Temporary Framework, adopted on 19 March 2020 and amended six times, sought to enable Member States to put in place unprecedented levels of support to keep otherwise profitable companies afloat during the COVID crisis. The Commission decided not to extend the State aid COVID Temporary Framework beyond the expiry date of 30 June 2022, with some exceptions (see *below*).

The State aid Brief reports that the Commission took some 1185 decisions approving over 865 national measures notified by all Member States for an overall budget of over €3.1 trillion in aid approved between the crisis' emergence in mid-March 2020 and end-2021. Of this €3.1 trillion in aid, around 30% (€940 billion) was actually granted to businesses.

The gap between the amounts committed and the amounts actually deployed shows that Member States had not yet exhausted their support capacity six months before the expiry of the Temporary Framework on 30 June 2022 (with certain exceptions, see *below*).

In absolute terms, according to preliminary Member State data, Germany granted the most COVID aid (€226 billion), followed by France (€223 billion). In relative terms, Italy provided the highest share of aid as compared to its own GDP (6%), followed by Spain (5.3%), Hungary (5%), France (4.7%), and Greece (4%).

Despite signs that the European economy is emerging from the pandemic crisis, the State aid Brief indicates that Russia's war against Ukraine, followed by restrictive measures against Russia and countermeasures, has created a serious disturbance in the European economy. EU companies are facing difficulties such as blockages in the supply of energy and raw materials and surging energy and food prices. In response, in March 2022, the Commission adopted the Ukraine Temporary Crisis Framework (see *below for more details*).

The State aid Brief indicates that the Commission continuously monitors the actual implementation of COVID-19 State aid measures in the Member States, in order to continuously adapt its State aid strategy to the evolution of the internal market situation.

DG Competition's main statistical data on COVID-19 State aid is available [here](#).

European Commission prolongs investment support measures and approves further schemes under COVID Temporary Crisis

The Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the State aid COVID Temporary Crisis Framework.

The COVID Temporary Framework (adopted in March 2020) applied until 30 June 2022, with certain exceptions:

- On 28 October 2022, the Commission decided to prolong the possibility for Member States to grant investment support measures under the Temporary Framework until 31 December 2023 (instead of

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

31 December 2022).

- Member States may provide solvency support measures aimed at easing access to equity finance for smaller companies until 31 December 2023.

Additionally, the Temporary Framework already provides for a flexible transition, under clear safeguards, in particular for conversion and restructuring of debt instruments (e.g. loans and guarantees) into other forms of aid, such as direct grants, until 30 June 2023.

Among the latest schemes (until 27 October 2022) under the COVID Temporary Framework:

- €24.3 million Austrian measure to support rail freight operators affected by the coronavirus pandemic. This measure prolongs an existing aid scheme for the provision of rail freight services that was initially approved by the Commission in July 2012 (SA.33993) and subsequently prolonged and amended, most recently in May 2022 (SA.102132).

European Commission adopts second amendment of Ukraine Temporary Crisis Framework (see [here](#))

On 28 October 2022, the Commission decided to prolong and amend the Ukraine State aid Temporary Crisis Framework in view of addressing the evolving needs of Member States to support the economy in the context of Russia's war against Ukraine (see *below for further details*).

The Temporary Crisis Framework was adopted on 23 March 2022 and first amended on 20 July 2022 (see [Jones Day COVID-19 Update No. 86 of 8 September 2022](#)). The second amendment, in particular:

- Extends all measures set out in the Temporary Crisis Framework until 31 December 2023;
- Raises ceilings for limited amounts of aid for companies active in the agriculture sector (up to €250,000) and the fisheries and aquaculture sectors (up to €300,000), and up to €2 million for companies active in all other sectors.
- Introduces greater flexibility for liquidity support to energy utilities for their trading activities. In exceptional cases and subject to strict safeguards, Member States may provide public guarantees exceeding 90% coverage, where provided as financial collateral to central counterparties or clearing members.
- Increases flexibility and support possibilities for companies impacted by rising energy costs, subject to safeguards. Member States may calculate support based on either past or present consumption, taking into account the need to maintain market incentives to diminish energy consumption and to ensure the continuity of economic activities; and
- Introduces new measures seeking to support electricity demand reduction, in line with Regulation (EU) 2022/1854 of 6 October 2022 on an emergency intervention to address high energy prices.

In announcing the amendment, Executive Vice-President and Competition Commissioner Margrethe Vestager stated: "*Today's changes have been discussed intensely with Member States in three rounds of consultations, involving a survey on Member States' needs and two subsequent*

consultations on specific drafting proposals. We will continue to work closely with Member States and coordinate our action to make sure our Framework serves all European consumers and continues to support the Commission's policy initiatives in the field of energy."

European Commission approves further schemes under Ukraine Temporary Crisis Framework (see [here](#))

The Commission continues to approve additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine.

To recall, in adopting this Crisis Framework, the Commission noted that the conflict had significantly impacted the energy market, and steep rises in energy prices had affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The conflict has also disrupted supply chains for both EU imports from Ukraine (in particular, cereals and vegetable oils) and EU exports to Ukraine.

Among the latest schemes under the Crisis Framework (until 27 Oct 2022):

- €1.25 billion Hungarian scheme to support companies in context of Russia's war against Ukraine
- €58 million Italian scheme to support manufacturing companies in the context of Russia's war against Ukraine
- €1.25 billion Hungarian scheme to support companies in context of Russia's war against Ukraine
- €35 million Italian aid measure to support commercial bus transport operators in the context of Russia's war against Ukraine

Notably, the Crisis Framework complements the various possibilities for Member States to design measures in line with existing EU State aid rules. For instance, State aid measures under the Crisis Framework may be cumulated with aid granted under the COVID-19 Temporary Framework, provided that their respective cumulation rules are respected.

The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2023. During its period of application, the Commission will keep the Framework under review in light of developments regarding the energy markets, other input markets, and the general economic situation. Prior to the Crisis Framework's end date, and in view of maintaining legal certainty, the Commission will assess whether it should be prolonged.

TRADE / EXPORT CONTROLS

Council adopts EU Single Window for Customs (see [here](#))

On 24 October 2022, the Council of the European Union adopted the Regulation establishing the EU Single Window for Customs, which amends Regulation (EU) No 952/2013 on the Union Customs Code.

To recall, the Single Window initiative is part of the Commission's efforts to improve and streamline the management of EU customs and to reinforce responsiveness to crises like the COVID-19 pandemic (see [Jones Day](#)

[COVID-19 Update No. 54 of 5 July 2021](#)).

The Single Window sets out the conditions for digital collaboration between customs and partner authorities. Once the Single Window is fully implemented, businesses will no longer face the burden of submitting documents to multiple authorities through different portals.

The Single Window will enable Member State authorities involved in goods clearance at the EU's external borders to access and exchange electronic information submitted by traders. The Single Window environment will also support the automated verification of non-customs formalities (e.g. in areas such as health, safety, and the environment) for goods entering or leaving the EU. This will eliminate the need for manual documentary controls to verify certain non-customs formalities.

The new streamlined approach is anticipated to facilitate, for example, the prevention from entry of counterfeit or unsafe medical goods and faster clearance of essential medical equipment into the EU.

The Regulation will be signed at the European Parliament's plenary session on 9-10 November 2022 and enter into force on the third day following its publication in the Official Journal of the European Union.

European Commission proposes new emergency Regulation to address high gas prices and supply security (see [here](#))

On 18 October 2022, the European Commission proposed a new emergency Regulation to address high gas prices in the EU and ensure security of supply (*Proposal for a Council Regulation enhancing solidarity through better coordination of gas purchases, exchanges of gas across borders and reliable price benchmarks*).

The draft Regulation, according to the Commission, seeks to tackle excessive energy price levels through measures aimed at preventing price spikes and manipulation, bolstering transparency and stability to the market, and ensuring gas flows in a crisis situation.

In announcing the draft Regulation, the Commission noted the considerable worsening of the energy market situation since Russia's invasion of Ukraine, which aggravated an already constricted supply situation after the COVID-19 pandemic.

The draft Regulation's main features include, in particular, joint gas purchasing, whereby the Commission would contract a service provider to organize demand aggregation at EU level, group together gas import needs, and seek offers on the market to match the demand. This mechanism is intended to facilitate negotiating better prices, reduce the risk of Member States outbidding each other on the market, and safeguard security of supply across the EU.

The Commission notes that while experience with joint purchasing in the field of natural gas is rather limited, the experience with joint purchasing for COVID-19 vaccines proved to be a useful tool. However, the Commission cautions that while Member States purchased vaccines, gas shall be purchased by private undertakings, which raises specific challenges. Under the current draft Regulation, private undertakings (not the EU or the Commission) will remain parties to the contracts for gas supply established under the joint purchasing.

Among the draft Regulation's other measures:

- Default solidarity rules, in case of supply shortages, would apply between Member States in the absence of bilateral solidarity agreements. For instance, the proposed Regulation broadens the obligation to provide solidarity by extending this requirement to Member States with LNG facilities (even if without direct pipeline connection), provided that the gas can be transported to the Member State where it is needed.
- Targeted intervention in market gas prices, such as by developing a new complementary price benchmark with ACER (European Agency for the Cooperation of Energy Regulators) with the intended aim of providing stable and predictable pricing, as many gas contracts in Europe are currently indexed to the main European gas exchange, the TTF (Title Transfer Facility). According to the Commission, the TTF no longer accurately reflects the price of LNG transactions in the EU.

The proposed Council Regulation requires a qualified majority vote in the Council to be approved, and its adoption will depend on the Council's internal procedures. The Commission stated that it stands ready to have the proposed measures in place as soon as possible.

MEDICINES AND MEDICAL DEVICES

Council of the European Union adopts three Regulations as part of European Health Union (see [here](#) and [here](#))

On 24 October 2022, the Council adopted three Regulations as further building blocks of the European Health Union, aimed at continuing to address COVID-19 and improve Europe's ability to respond to cross-border health threats and emergencies (see also [Jones Day COVID-19 Update No. 27 of 18 November 2020](#)).

The adopted Regulations notably add to the Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (see also [Jones Day COVID-19 Update No. 75 of 1 February 2022](#)).

The three adopted Regulations, in particular, concern:

- The Regulation on Serious cross-border threats to health and repealing Decision No 1082/2013/EU (see [here](#)), which will strengthen the EU and Member States' ability to react rapidly and to trigger the implementation of preparedness and response measures to cross-border threats to health across the EU (see also [Jones Day COVID-19 Update No. 86 of 8 September 2022](#)). The Regulation provides, among other measures:
 - The Commission may formally recognize a public health emergency at EU level in view of triggering stronger intra-EU cooperation and enabling the timely development, stockpiling and joint procurement of medical countermeasures;
 - The Commission shall establish an EU health crisis and pandemic plan to promote an effective and coordinated response to cross-border threats to health at Union level, including the sharing of best practices and effective exchange of information in times of crisis, such as concerning capacities

for specialized treatment and intensive care across neighboring regions; and

- The Commission shall inform the European Parliament of any joint procurement measures and make the contracts accessible to the Members of the Parliament.
- The Regulation amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC) (see [here](#)) reinforces the ECDC's role (see also [Jones Day COVID-19 Update No. 89 of 14 October 2022](#)). The ECDC's broader roles include, in particular:
 - Coordinating the standardization of data collection procedures, data validation, analysis and dissemination of data at EU level;
 - Developing risk assessments and digital platforms for epidemiological surveillance and work towards harmonized approaches to data collection and modelling in order to produce comparable EU-wide data;
 - Monitoring the uptake of vaccination against major communicable diseases across the EU; and
 - Creating an EU Health Task Force to assist local responses to the outbreak of diseases.
- The Regulation on the Emergency framework regarding medical countermeasures (see [here](#)) to facilitate the timely supply of medical countermeasures (see also [Jones Day COVID-19 Update No. 72 of 10 January 2022](#)). The Regulation, among other measures, provides for:
 - The establishment of a Health Crisis Board; setting up a system to monitor relevant information concerning the supply and demand of crisis-relevant medical countermeasures and raw materials within and outside the EU;
 - Joint procurement and purchase of crisis-relevant medical countermeasures and crisis-relevant raw materials, emergency funding and financing; and
 - The establishment an inventory of crisis-relevant production and production facilities, raw materials, consumables, equipment and infrastructure, including measures aiming at increasing their production in the EU.

The adopted Regulations are directly applicable in all Member States and will enter into force on the 20th day following their publication in the Official Journal of the EU.

HERA and Coalition for Epidemic Preparedness Innovations (CEPI) agree on

On 24 October 2022, a Letter of Intent was issued on Cooperation between the Coalition for Epidemic Preparedness Innovations (CEPI)* and the Health Emergency Preparedness and Response Authority of the European Commission (HERA)**.

In announcing the Letter of Intent, European Commissioner for Health and

stronger cooperation in development of medical countermeasures (see [here](#) and [here](#))

Food Safety, Stella Kyriakides, stated: *“The COVID-19 pandemic showed how important it is for all key players to come together to work towards the common goal of protecting the public health of everyone, globally. Our cooperation with CEPI will ensure that HERA can continue to improve preparedness and response to serious cross border health threats by also tapping into the considerable expertise CEPI have on emerging diseases, and innovative approaches to vaccine development.”*

The Letter of Intent provides, in particular, that HERA and CEPI shall strengthen cooperation in developing medical countermeasures, which will notably enable efficient coordination on end-to-end vaccine research & development, manufacturing capacity and capability building both within the EU and globally.

Towards maximizing the impact of their respective activities and eliminating unnecessary overlaps, HERA and CEPI agree, in particular, to exchange information on related research, development, manufacturing and other priorities relevant for medical countermeasures in order to ensure cooperation on the overall priorities.

The Letter of Intent indicates that HERA and CEPI intend to meet twice a year at senior level to discuss topics of mutual interest and review progress on the cooperation.

** CEPI is a global partnership between public, private, philanthropic, and civil society organizations for promoting public-private collaboration to develop, manufacture and stockpile medical countermeasures necessary to respond to pandemic threats to ensure their accessibility.*

*** HERA is a Directorate-General of the European Commission, working to improve preparedness and response to serious cross-border threats in the area of medical countermeasures, in particular by strengthening health security cooperation within the Union during preparedness and crisis times and by enabling the development, rapid availability, access and distribution of needed countermeasures and bolstering pandemic architecture for the EU.*

European Commission adopts Work Programme for 2023 (see [here](#))

On 18 October 2022, the Commission adopted its Work Programme for 2023 of key initiatives for the coming year and how these will be concretely pursued, particularly towards addressing the crises brought on by Russia’s war against Ukraine, promoting the ongoing green and digital transformations, and further steering the EU towards recovery from the pandemic. (See also *previous Work Programme 2022*, [Jones Day COVID-19 Update No. 65 of 25 October 2021](#)).

The Work Programme highlights the necessity of not letting up the response to the COVID-19 pandemic, which persists across the EU.

In the priority area, “Promoting our European way of life”, the Work Programme notes the Commission’s plans, among others, regarding:

- Advocating the swift adoption of a [European Health Data Space](#) under the proposed Regulation of 3 May 2022 to strengthen the quality and continuity of healthcare and ensure citizens’ rights concerning their health data (see also [Jones Day COVID-19 Update No. 84 of 17 May 2022](#)); and
- Developing a [comprehensive approach to mental health](#), a major societal issue brought into sharp focus during the pandemic, in

response to a proposal from the Conference on the Future of Europe (see *Conference Final Report of May 2022* ([here](#))).*

* *The Conference on the Future of Europe (under the authority of the Presidents of the European Parliament, the Council, and the European Commission) offers the opportunity for European citizens to debate on Europe's challenges and priorities.*

For further details on the Work Programme for 2023, please see below Section on Cybersecurity.

CYBERSECURITY, PRIVACY & DATA PROTECTION

Digital Services Act published in EU Official Journal (see [here](#))

On 27 October 2022, the Digital Services Act (Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act (DSA)) was published in the EU Official Journal (see also [Jones Day COVID-19 Update No. 89 of 14 October 2022](#)).

To recall, the DSA is one of the measures taken as part of the EU Recovery Plan to lead the EU out of the COVID-19 pandemic (see also [Jones Day COVID-19 Update No. 10 of 29 May 2020](#)).

The DSA introduces rules and obligations on digital services that act as intermediaries in their role of connecting consumers with goods, services and content (e.g., online marketplaces, internet service providers, cloud services, messaging, social networks). It aims to strengthen the protection of users and fundamental rights online, establish a strong transparency and accountability framework for online platforms, and provide a uniform framework across the EU. The DSA complements other existing rules, and in particular, the GDPR.

Among other things, the DSA:

- Sets out requirements for online marketplaces in view of combating the online sale of illegal products and services;
- Introduces measures to counter illegal content online and obligations for platforms to react swiftly, while preserving fundamental rights;
- Protects minors online by prohibiting platforms from using targeted advertising based on the use of minors' personal data;
- Limits the presentation of advertising and on use of sensitive personal data for targeted advertising, including in relation to gender, race and religion; and
- Places transparency reporting obligations on online platforms.

In addition, the DSA imposes stricter rules on very large online platforms and search engines (i.e., online platforms which reach a number of average monthly users in the EU equal to or higher than 45 million), which must:

- Assess and mitigate the systemic risks they generate (e.g., risks concerning illegal content dissemination, detrimental effects on fundamental rights, electoral processes and gender-based violence or mental health);
- Offer users a system for recommending content that is not based on

profiling; and

- Provide detailed information on online advertisement, such as the information necessary to allow users to understand when and on whose behalf the advertisement is presented.

The DSA will enter into force on 16 November 2022. While most DSA provisions will become applicable on 17 February 2024, some become applicable on 16 November 2022 (e.g., certain transparency obligations for online platforms, the Commission's obligation to designate very large online platforms/search engines and to charge these an annual supervisory fee, and enforcement provisions concerning such very large online platforms/search engines).

European Commission adopts Work Programme for 2023 (see [here](#))

On 18 October 2022, the Commission adopted its Work Programme for 2023 of key initiatives for the coming year and how these will be concretely pursued, particularly towards addressing the crises brought on by Russia's war against Ukraine, promoting the ongoing green and digital transformations, and further steering the EU towards recovery from the pandemic. (See also *previous Work Programme 2022*, [Jones Day COVID-19 Update No. 65 of 25 October 2021](#)).

The Work Programme contains 43 new policy initiatives across the six headline ambitions for 2019-24 set out by Commission President Ursula von der Leyen (see [here](#)), and building on her 2022 State of the Union speech (see [here](#)).

The Work Programme highlights the necessity of not letting up the response to the COVID-19 pandemic, which persists across the EU.

In the priority area, "A Europe fit for the digital age," the Work Programme sets out the Commission's plans, among others, to:

- Propose tools on developing open human-centric virtual worlds, such as metaverses;
- Propose a Recommendation on piracy of live content offering a toolbox to fight the illegal streaming of live events;
- Propose a common European mobility data space to boost the digitalization of the mobility sector;
- Finalize the proposal on expanding and upgrading the use of digital tools and processes in company law enhance transparency around companies in the single market, simplify administrative and judicial procedures, and facilitate the cross-border expansion of companies.

In the area of data protection, The Work Programme also indicates that the Commission will propose to harmonize some national procedural aspects of national data protection authorities' procedures, in order to improve their cooperation in enforcing the General Data Protection Regulation.

For further details on the Work Programme for 2023, please see above Section on Medicines.

LAWYER CONTACTS

Kaarli H. Eichhorn

Partner, Antitrust & Competition Law;
Government Regulation; Technology
Brussels

keichhorn@jonesday.com

+32.2.645.14.41

Dr. Jörg Hladjk

Partner, Cybersecurity, Privacy & Data
Protection; Government Regulation;
Technology
Brussels

jhladjk@jonesday.com

+32.2.645.15.30

Nadiya Nychay

Partner, Government Regulation; Antitrust &
Competition Law
Brussels

nnychay@jonesday.com

+32.2.645.14.46

Cristiana Spontoni

Partner, Health Care & Life Sciences;
Government Regulation
Brussels

cspontoni@jonesday.com

+32.2.645.14.48

Rick van 't Hullenaar

Partner, Government Regulation;
Investigations & White Collar Defense
Amsterdam

rvanthullenaar@jonesday.com

+31.20.305.4223

Lucie Fournier (Associate), Cecelia Kye (Consultant), and Justine Naessens (Associate) in the Brussels Office contributed to this Update.