



# 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 endorses last national recovery and resilience plan, subject to rule of law milestones
- European Commission approves further schemes under COVID Temporary Crisis Framework
- European Commission approves further schemes under Ukraine Temporary Crisis Framework

### Trade / Export Controls

- Launch of new Digital Partnership between EU and Republic of Korea
- European Commission proposes Regulation establishing a market correction mechanism to protect against excessively high gas prices
- Council of the European Union expands sanctions against Iran and Russia

### Medicines and Medical Devices

- European Commission adopts EU Global Health Strategy
- European Commission adopts EU4Health Work Programme for 2023

### Cybersecurity, Privacy & Data Protection

- Council of the European Union adopts NIS2 Directive for high common level of cybersecurity across the Union
- European Commission establishes European Centre for Algorithmic Transparency

## COMPETITION & STATE AID

### State Aid

#### European Commission endorses last national recovery and resilience plan (subject to meeting rule of law milestones) (see [here](#) and [here](#))

On 30 November 2022, the Commission endorsed Hungary's recovery plan under the Recovery and Resilience Facility (RRF)\*, to be financed by €5.8 billion in grants. With this approval, the Commission has now endorsed all 27 Member State recovery plans.

However, the Commission's endorsement of Hungary's recovery plan is conditioned on Hungary's full and effective implementation of 27 milestones on the rule of law, judicial independence, anti-corruption, and protecting the EU's budget. These reforms must be fulfilled before any payment to Hungary is possible. Later reversals or watering-down of these milestones would block any subsequent payments under the RRF.

Of the 27 milestones, 17 of these respond to the Commission's launch against Hungary of a "conditionality mechanism of the rule of law procedure" in April 2022. This procedure against Hungary is the first one under the Conditionality Regulation, adopted in December 2020 to protect the EU budget (see [here](#) and [Jones Day COVID-19 Update No. 87 of 23 September 2022](#)).

The remaining milestones in Hungary's recovery plan concern other rule of law reforms related to judicial independence and audit and control measures.

Despite certain reforms underway by Hungary, the Commission considered that Hungary had failed to timely and adequately implement central aspects of the necessary 17 remedial measures agreed under the conditionality mechanism. The Commission thereby also announced on 30 November 2022 that it maintained its proposal to the Council (see [here](#)) for budget protection measures under the Conditionality Regulation against Hungary's breaches of the rule of law, including:

- a suspension of 65% of the commitments for three operational programs under cohesion policy, amounting to €7.5 billion; and
- a prohibition to enter into legal commitments with the public interest trusts for programs implemented in direct and indirect management.

The [European Parliament](#) also earlier adopted a Resolution on 24 November 2022 on Hungary's compliance with the rule of law and Hungary's recovery plan (see [here](#)). The Resolution asserted the ongoing risk of misuse of EU funds in Hungary and, in this respect, deplored that because of the Hungarian government's actions, EU recovery funds have not yet reached its people. The Resolution also emphasized that final beneficiaries of EU funds should not be deprived of support due to Hungary's lack of cooperation and called on the Commission to find ways to distribute EU funds via local governments and NGOs.

Next steps: Regarding the Commission proposal to protect the EU budget against Hungary's breaches of principles of the rule of law, the Council has until 19 December 2022 to take a decision, by qualified majority.

Concerning the RRF, the Council now has, in principle, four weeks to adopt the proposed Council Implementing Decision to endorse the Commission's

positive assessment of Hungary's recovery and resilience plan.

*\* The RRF is the key component of NextGenerationEU, the EU's historic recovery fund for rebounding from the COVID-19 crisis (and now also the energy crisis). Member State recovery plans have set out the reforms and public investment projects foreseen for implementation with the RRF, which makes available €723.8 billion (in current prices) (i.e., grants totaling €338 billion and €385.8 billion in loans). These national recovery plans must comply with State aid rules.*

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

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 adopted in March 2020.

With certain exceptions, the Temporary Framework applied until 30 June 2022.\* Among the latest schemes (until 30 November 2022):

- €557 million German support to compensate Deutsche Bahn for damages suffered by its subsidiary DB Fernverkehr due to the coronavirus pandemic.
- €100 million Cypriot scheme to support companies and self-employed persons affected by the coronavirus pandemic.
- 12.6 million Dutch scheme to support zoos in the context of the coronavirus pandemic.

*\* Exceptions notably include the possibility for Member States to (i) create direct incentives for private investments (until 31 December 2022) and (ii) provide solvency support measures (until 31 December 2023) aimed at easing access to equity finance for smaller companies*

**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.

The Commission recently prolonged (until 31 December 2023 (instead of 31 December 2022)) and expanded the Crisis Framework (see [Jones Day COVID-19 Update No. 90 of 28 October 2022](#)).

Among the latest schemes under the Crisis Framework (until 30 November 2022):

- €50 million Latvian scheme to support the manufacturing industry in the context of Russia's war against Ukraine.
- €50 million Italian scheme to support companies in the region of Marche in the context of Russia's war against Ukraine.
- Amendments to Italian scheme, including €50 million budget

increase, to support the agricultural, forestry, fisheries and aquaculture sectors in Friuli Venezia Giulia in the context of Russia's war against Ukraine.

- €1.22 billion Irish scheme to support companies across sectors in the context of Russia's war against Ukraine.
- €34.4 million Italian scheme to support companies in the context of Russia's war against Ukraine.
- Amendments to existing German umbrella schemes, including their prolongation and an up to €45 billion overall budget increase, to support companies in the context of Russia's war against Ukraine.
- €50 million Slovak scheme to support the agricultural, fishery and aquaculture sectors in the context of the Russia's war against Ukraine.
- €7.75 million Cypriot scheme to support some agricultural producers in the context of Russia's war against Ukraine.
- €45 billion budget increase, to support companies in 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

### **Launch of new Digital Partnership between EU and Republic of Korea (see [here](#))**

On 28 November 2022, a new Digital Partnership between the EU and the Republic of Korea was announced by European Commission President Ursula von der Leyen and President of the Republic of Korea (ROK) Yoon Suk Yeol.

The Partnership aims at strengthening cooperation between trusted and technologically advanced partners in the digital area, which is crucial for trade and investment ties between the EU and Korea, as well as the sustainable advancement of their economies.

The Partnership will enhance joint work on semiconductors, next generation mobile networks, quantum and High-Performance Computing, cybersecurity, artificial intelligence, platforms, data-related law and systems, and digital skills.

In the priority areas of enhanced digital cooperation, the Partnership sets out shared objectives and initial joint actions, such as:

- Strengthening the transparency and resilience of the global semiconductor supply chain and reinforcing cooperation to advance research and innovation for the next generation of semiconductors. This includes, for example, identifying gaps and potential disruptions to the global supply chain including through early warning systems;
- Building a cooperative relationship regarding digital trade facilitation, to be reflected in a set of digital trade principles covering issues such as, *inter alia*, paperless trading, electronic invoicing, electronic transactions framework and digital identities, and online consumer protection. Both sides aim at a collaborative approach to digital protectionist measures and trends worldwide that negatively impact trade and investment flows; and
- Enhancing international cybersecurity cooperation, particularly given the increased importance of cooperation in cybersecurity as a lesson learned from the pandemic and current international developments. This includes, for instance, increased sharing of information on cybersecurity threats and in other areas where exchanges are considered valuable.

Next steps: The EU and ROK intend to comprehensively discuss various economic and societal issues driven by digital transformation and intend to hold an annual Digital Partnership Council at ministerial level.

The Partnership further notes that regular stakeholder participation is key to its success, and the organization of exchanges is anticipated as part of existing cooperation mechanisms and through joint Digital Partnership dialogues with stakeholders.

**European Commission proposes Regulation establishing a market correction mechanism to protect against excessively high gas prices (see [here](#))**

On 22 November 2022, the European Commission announced a proposed Regulation establishing a Market Correction Mechanism to protect against excessively high gas prices.

The proposed Mechanism seeks to reduce volatility on European gas markets while safeguarding the security of gas supply. It builds upon the Commission's proposed Regulation of 18 October 2022 to enhance solidarity through better coordination of gas purchases, exchanges of gas across borders and reliable price benchmarks (Articles 23 and 24 on a potential market correction mechanism to limit episodes of excessive gas prices) (see also [Jones Day COVID-19 Update No. 90 of 28 October 2022](#)).

More specifically, the proposed Mechanism would limit excessively high prices spikes on the main European gas exchange, the Dutch Title Transfer Facility (TTF)\*. As the most commonly used European price benchmark, many gas contracts in Europe are currently indexed to the TTF.

The proposed Mechanism consists of a safety price ceiling of €275, applicable solely to the month-ahead TTF derivatives,\*\* which play a key role as a reference price in the European wholesale gas market. Such price ceiling would be triggered automatically (foreseen as of 1 January 2023) only when certain conditions are met such that TTF prices reach levels that are deemed exceptional as compared with LNG (Liquified Natural Gas) prices at other trading exchanges.

Suspension / automatic deactivation. To enable responding to potential unintended negative consequences of the price ceiling, the proposed Regulation foresees that the Mechanism can be suspended at any time, either by automatic deactivation (i.e. conditions for price ceiling no longer met) or by a Commission decision (i.e. in the event of unintended market disturbances or manifest risks that negatively impact security of supply, intra-EU gas flows or financial stability).

Next steps. The proposed Regulation, which is a temporary and emergency measure, requires adoption by a qualified majority of Member States. If adopted, the market correction mechanism can only be activated as of 1 January 2023. The Regulation would be in force for one year, subject to review and possible extension.

*\* The TTF is a “hub” or a “virtual trading point” of a so-called entry / exit system, where market players can transfer gas between each other. In addition to the Dutch TTF, other main gas hubs in Europe include, e.g., German Trading Hub Europe (THE); French Gas exchange point - North (PEG); Belgian Zeebrugge (Beach).*

*\*\* Derivatives markets, notably with contracts concerning the future delivery of gas (e.g. month-ahead or longer) are essential for gas companies to hedge their financial risks when purchasing gas in volatile markets.*

**Council of the European Union expands sanctions against Iran and Russia (see [here](#) and [here](#))**

The EU relies on restrictive measures (sanctions) as one of its tools to advance its Common Foreign and Security Policy (CFSP) objectives, such as safeguarding EU's values, fundamental interests, and security; preserving peace; and supporting democracy and the rule of law.

Sanctions include measures such as travel bans (prohibition on entering or transiting through EU territories); asset freezes; prohibition on EU citizens and companies from making funds available to the listed individuals and entities; ban on exports (e.g., no exports to Iran of equipment that might be used for internal repression and of equipment for monitoring telecommunications).

Among the most recent additions to EU sanctions:

- Iran: On 14 November 2022, the Council added an additional 29 individuals and a further three entities to the list of those subject to EU restrictive measures in the context of the existing Iran human rights sanctions regime. This is in view of their role in the death of Mahsa Amini and the violent response to the recent demonstrations in Iran.

The sanctions list now comprises a total of 126 individuals and 11 entities.

- Russia: On 6 October 2022, in light of the escalating war and illegal annexation in Ukraine the Council has adopted new sanctions which include, amongst other: a price cap related to the maritime transport of Russian oil for third countries; additions to the list of restricted items which may contribute to Russia's military and technological enhancement; additional restrictions on trade and services with Russia; and an additional 30 individuals and 7 entities.

Altogether, EU restrictive measures now apply to a total of 1236 individuals and 115 entities.



Provision of humanitarian aid: The Commission has also provided guidance on the provision of humanitarian aid in compliance with EU sanctions. The Commission most recently published a Guidance Note in June 2022 (see [here](#)). The Commission notes the importance of the Guidance Note in clarifying humanitarian exceptions to EU sanctions imposed in response to Russia's invasion of Ukraine, although the Guidance Note seeks to provide clarifications for all EU sanctions regimes.

This Guidance Note notably builds on previous guidance of August 2021 on the provision of humanitarian aid to fight the COVID-19 pandemic (clarification on COVID-19 vaccines and therapeutics, EU counter-terrorism sanctions and Iran, Nicaragua, Syria, Venezuela sanctions regimes) (see [here](#) and [Jones Day COVID-19 Update No. 59 of 21 August 2022](#)).

In particular, the Guidance Note provides a series of hypothetical cases on the application of sanctions. These include various accompanying references to the August 2021 COVID-19 guidance as a source of clarification (e.g., If a designated (sanctioned) person intervenes in a humanitarian transaction, this does not automatically mean that the transaction must be abandoned. Insofar as no funds or economic resources are made available to a designated person, the Iran Regulations do not prohibit liaising with the former).

## MEDICINES AND MEDICAL DEVICES

### **European Commission adopts EU Global Health Strategy (see [here](#))**

On 30 November 2022, the European Commission adopted the Communication from the Commission on the EU Global Health Strategy: Better Health for All in a Changing World.

The Strategy emphasizes that the COVID-19 pandemic starkly spotlighted that health has no borders, and that global health is a geopolitically critical sector and fundamental to the EU's open strategic autonomy.

The Strategy offers a framework for EU health policies leading up to 2030. It sets policy priorities and guiding principles to shape global health, with concrete lines of action identified for both the Commission and Member States. The Strategy's efforts focus on three interrelated priorities:

- (1) Delivering better health and well-being across all ages, in particular, by improving equitable access to essential health services and tackling addressing the root causes of ill-health arising from economic, social and environmental conditions;
- (2) Strengthening health systems and advance universal health coverage, such as by improving primary healthcare with built-in surge capacity, as the pandemic demonstrated the importance of having proper available medical capacity to evaluate and care for a markedly increased volume of patients — one that challenges or exceeds normal operating of health systems. Additionally, the EU should take a leading role fostering digital action for global health and strengthening global health research to develop the technologies and countermeasures necessary to improve health; and
- (3) Preventing and combating health threats, including pandemics, including strengthening capacities for prevention, preparedness and response and early detection of health threats globally, as well as continuing to tackle the ongoing COVID-19 pandemic and its aftermath and, building on lessons from

the past three years, assemble a comprehensive approach to ensuring global health security.

The Strategy contains a non-exhaustive list of key projects to carry out at different levels (global, regional and national) to support the lines of action, referring to an indicative timeframe (2021-2027). Among the projects expected to be carried out in 2023-2024:

Global projects:

- Setting up a coordination system with EU Member States to ensure a forceful EU voice and leadership in global health;
- Expanding the existing European Antimicrobial Resistance Surveillance Network into an integrated surveillance mechanism covering all pathogens;
- Leveraging the potential of health data worldwide.

Regional projects:

- Undertaking an initiative on digital health for health system strengthening and universal health coverage to support strong and digitally enabled health systems in Africa; and
- Supporting research and development of vaccines against emerging infectious diseases, including through the Coalition for Epidemics Preparedness Innovations (CEPI) initiative for Africa-based public health capacity through support to public health institutes in Africa, at national and regional levels and through partnerships between African Union and EU public health institutes.

The accompanying Q&A to the EU Global Health Strategy provides further details (see [here](#)).

**European Commission adopts EU4Health Work Programme for 2023 (see [here](#))**

On 21 November 2022, the European Commission adopted Implementing Decision of 21 November 2022 on financing of the EU4Health Programme (Programme for Union's action in the field of health) and adopting the 2023 EU4Health Work Programme.

To recall, the EU4Health Programme is the EU's €5.3 billion Programme for action in the field of health for the period 2021-2027 (see [here](#)). Established in 2021, the Programme aims at prioritizing financial resources to enable healthcare systems to cope with unforeseeable events, such as the COVID-19 pandemic, to foster innovation, and to modernize the public and private healthcare sectors in the long-term (see also [Jones Day COVID-19 Update No. 10 of 29 May 2020](#)).

The 2023 EU4Health Work Programme, with a budget of €735.8 million, intends to enable rapid progress on priority actions related to continued development of the European Health Union (see also [Jones Day COVID-19 Update No. 90 of 28 October 2022](#)).

These actions include strengthening the EU's resilience to cross-border health threats, the implementation of initiatives such as the Pharmaceutical Strategy for Europe; Europe's Beating Cancer Plan; and the European Health Data Space (EHDS) (see also [Jones Day COVID-19 Update No. 84 of 17 May 2022](#)).



In addition, the 2023 Work Programme will also support health-related urgencies resulting from the war in Ukraine, following the agreement signed between the Commission and the Ukrainian government associating Ukraine to the EU4Health Programme, and consequently opening access for Ukraine to EU funding in the area of health (see [here](#)).

The actions proposed for funding under the annual Work Programmes can be implemented in direct (in the form of grants and procurement) and indirect management either by the Commission or by the Health and Digital Executive Agency (HaDEA) depending on the specific actions. Among the main areas of the 2023 Work Programme:

- Action grants (e.g., supporting access to medical devices for cross-border health threats; supporting orphan medical devices; supporting preparatory actions for reuse of data in the proposed European Health Data Space.);
- Procurement under direct management (e.g., supporting the development, access and uptake of innovative technologies and critical medicines; supporting the Commission on identifying priority threats and medical countermeasures; purchasing medical countermeasures in emergency situations; capacity building for secondary uses of health data for the EHDS); and
- IT support: (e.g., supporting and updating the European Medicinal Products database; supporting the creation of a European database on medical devices (EUDAMED); ensuring the development and completion of the IT platform for HTA (Regulation on Health Technology Assessment); and supporting the digital passenger locator form (EUdPLF) platform).

## CYBERSECURITY, PRIVACY & DATA PROTECTION

**Council of the European Union adopts NIS2 Directive for high common level of cybersecurity across the Union (see [here](#))**

On 28 November 2022, the Council adopted the Directive on measures for a high common level of cybersecurity across the Union (NIS2 Directive), following the European Parliament's approval on 10 November 2022 (see [here](#)). This repeals Directive 2016/1148 on measures for a high common level of security of network and information systems across the Union (NIS Directive) (see also [Jones Day COVID-19 Update No. 84 of 17 May 2022](#) and [Jones Day Alert, EU Adopts Enhanced Legal Framework to Provide for High Common Level of Cybersecurity, Dec. 2022](#)).

To recall, during the COVID-19 pandemic, growing security threats emerged, demonstrating the vulnerability of increasingly interdependent societies (e.g., interdependencies mean that any disruption, even if initially confined to one entity or one sector, can have broader cascading effects, potentially resulting in far-reaching and long-lasting negative impacts in the delivery of services across the EU).

On its objectives and scope, in particular, the NIS2 Directive:

- Aims at further harmonizing cybersecurity requirements and their implementation across the EU. In this respect, the NIS2 Directive intends to strengthen the resilience and incident response capacities

of public and private entities, competent authorities, and the EU as a whole.

- Broadens the scope of both the sectors and entities covered by the rules to include:
  - (i) medium-sized and large "essential and important" entities operating in new sectors, including public electronic communications networks or services, social networking services platforms and data centers, space, public administration, and manufacture of critical products, such as pharmaceuticals, medical devices, food, or chemicals; and
  - (ii) certain critical "essential and important" entities, irrespective of their size.
- Introduces clarifications on entities that are excluded from its scope (e.g., entities carrying out activities in areas such as defence or national security, public security, and law enforcement).

The NIS2 Directive also provides reinforced risk and incident management and cooperation, and in particular:

- More stringent reporting obligations, the most important of which is a three-stage incident reporting;
- Requires responsible entities to implement cybersecurity risk management measures and sets minimum measures to be adopted internally and in the supply chain;
- Administrative fines, applicable to specific breaches, of up to 10 million EUR or 2% of the total worldwide annual turnover, whichever is higher (for essential entities), and up to 7 million EUR or 1.4 % (for important entities).

The NIS2 Directive also formally establishes the European Cyber Crises Liaison Organisation Network (EU-CyCLONe) which will support the coordinated management of large-scale cybersecurity incidents and introduce mechanisms for effective cooperation among Member States authorities.

The NIS 2 Directive will enter into force on the 20th day following its publication in the Official Journal of the EU. From this date, Member States will have 21 months to transpose the NIS2 Directive into national law.

**European Commission establishes European Centre for Algorithmic Transparency (see [here](#))**

On 22 November 2022, the European Commission's Joint Research Centre (JRC) announced the establishment of a new European Centre for Algorithmic Transparency (ECAT).

The ECAT will support the enforcement of the Digital Services Act (DSA, see also [Jones Day COVID-19 Update No. 90 of 28 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).

The ECAT, which will gather top-level technical and scientific expertise, is intended to serve as a hub for international research in the field and the analysis of data provided under the DSA. In particular, ECAT will support the Commission in assessing whether the functioning of algorithms used by the platforms and search engines falling within the DSA's scope are in line with the DSA's risk management obligations.

The JRC is currently recruiting experts for the ECAT team until 9 January 2023, and the Commission is also recruiting for the DSA team in the Directorate General for Communications Networks, Content and Technology (DG CONNECT).

It is expected that the ECAT will be fully operational in Q1 2023.

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