

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

- EU General Court fully dismisses Ryanair challenge to Croatia Airlines COVID-19 aid
- European Commission approves further schemes under Ukraine Temporary Crisis Framework

Trade / Export Controls

- European Commission presents Communication on ensuring availability and affordability of fertilisers
- Latest meeting of EU-US Task Force on Energy Security

Medicines and Medical Devices

 HERA signs Joint Procurement Framework Contract of up to 2 million doses of monkeypox vaccine

Cybersecurity, Privacy & Data Protection

- Digital Services Act: Entry into force and Q&As published
- Digital Markets Act: Entry into force and Q&As published

COMPETITION & STATE AID

State Aid

EU General Court fully dismisses Ryanair challenge to Croatia Airlines COVID-19 aid (see here) On 9 November 2022, the General Court (GC) fully dismissed Ryanair's challenge, launched on 19 February 2021, of a Commission Decision approving a Croatian State aid measure to compensate Croatia Airlines in the context of alleged damages suffered following the COVID-19 outbreak (T-111/21 Ryanair v. Commission).

The contested Decision (SA.55373 (2020/N) of 30 November 2020) had approved Croatia's EUR 11.7 million direct grant to state-owned Croatia Airlines as compatible with State aid rules.

The GC, in particular, dismissed Ryanair's claims that the Commission breached its procedural rights:

Ryanair <u>alleged that the Commission carried out an insufficient examination during the preliminary examination stage</u> and <u>should have initiated a formal investigation</u>. Ryanair contended that the Commission had failed to do so and therefore deprived it of the opportunity to submit its comments on Croatia's notified measure and to provide the Commission with, in particular, factual information.

In dismissing this claim, the GC ruled in particular that Ryanair had not demonstrated the existence of serious difficulties in appraising the alleged damage suffered by Croatia Airlines that would have triggered a formal investigation (e.g., the GC held that Ryanair erroneously deemed that domestic flights in Croatia were not affected by the restrictions imposed by the Croatian authorities, and thus claimed that the Commission had overestimated the damage. The GC, however, found that the contested Decision had set out that the Croatia's restrictive measures had affected both Croatia Airlines' international and domestic flights).

Ryanair further <u>contended that the Commission failed to fulfil its</u>
 <u>obligation to state reasons</u>, e.g. by failing to justify the fact that Croatia
 Airlines was distinguished from other airlines as the only one to receive
 aid in the form of compensation, whereas other airlines, including
 Ryanair, also suffered damage from the COVID-19 pandemic.

In dismissing this claim, the GC ruled in particular that by definition, individual aid benefits only one company, to the exclusion of all other companies, including those in a comparable situation. Consequently, the nature of such individual aid results in difference in treatment, or even discrimination, which is nevertheless inherent in the individual character of that measure. It also noted that Member States are not required to grant aid to all victims of damage caused by an exceptional occurrence referred to in State aid rules under Article 107(2)(b) TFEU. Thus, the contested Decision was not required to explain why it considered it lawful to grant the aid at issue solely to Croatia Airlines.

The GC thus rejected Ryanair's grounds alleging procedural errors and dismissed the action in its entirety.

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 <u>Jones Day</u> COVID-19 Update No. 90 of 28 October 2022).

Among the latest schemes under the Crisis Framework (until 18 November 2022):

- €500 million Romanian scheme to support companies in the context of Russia's war against Ukraine.
- €1.23 billion Czech scheme to support the economy in the context of Russia's war against Ukraine.
- — €2.1 million Latvian scheme to support some producers active in the agriculture sector in the context of the Russia's war against Ukraine.
- €30 million scheme to support companies in the context of Russia's war against Ukraine.
- €60 million Irish scheme to support the agricultural sector, in particular producers of fodder, in the context of the Russia's war against Ukraine.
- Approved modification of Luxembourg scheme, including a budget increase of €150 million, aimed at supporting companies in the context of the war led by Russia 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

European
Commission
presents
Communication
on ensuring
availability and
affordability of
fertilizers (see
here)

On 9 November 2022, the Commission released a Communication on ensuring availability and affordability of fertilizers.

The Communication addresses the global mineral fertilizer crisis, which is the most severe since the 1970s. The COVID-19 pandemic's supply chain disruptions and the energy crisis triggered by Russia's invasion of Ukraine have resulted in record high fertilizer prices, which are impacting food security and food prices. The Communication notes that the global scarcity of fertilizers is primarily caused by the high price of natural gas, which is necessary to produce mineral nitrogen fertilizers.

In this context, the Communication seeks to ensure the availability and affordability of fertilizers, such as by:

- Confirming fertilizers as a critical sector: Member States may prioritize
 the continued and uninterrupted access to natural gas for fertilizer
 producers in their national emergency plans in the event of gas rationing;
- <u>Enhancing market transparency</u>: The Commission will establish a market observatory for fertilizers in 2023 to share data on production, use, prices and trade;
- <u>Promoting organic fertilizers</u>: Where possible, mineral fertilizers should be substituted by organic fertilizers to reduce EU's dependence on gas, as well as the sector's carbon footprint;
- Trade-related measures, such as:
 - Trade diversification:
 - The Commission is seeking <u>alternative suppliers of fertilizers</u> to compensate for previous supplies from Belarus and Russia.
 Oman, Turkmenistan, and Qatar were identified as alternative sources of nitrogen fertilizers. Imports from Egypt and Algeria have risen substantially, with Egypt anticipated to replace Russia as the EU's main source of imports in 2022.
 - The Commission proposed a Regulation to suspend trade tariffs on inputs used for the production of nitrogen fertilizers until end-2024 (see here). The EU heavily depends on imports of these inputs from third countries, including Russia as the second largest supplier. In addition to lowering costs for EU producers and farmers, the proposal would promote stability and diversification of supply by fostering imports from a wider range of third countries, while excluding Russia and Belarus from the tariff suspensions.
 - Avoiding export restrictions on fertilizer trade in the WTO, in view of meeting commitments under the Declaration on Food Insecurity agreed at the 12th WTO Ministerial Conference held in June 2022 (see here).
 - On <u>sanctions against Russia</u>, the Commission notes that the EU has essentially exempted the agri-food sector and fertilizers from its restrictive measures against Russia. In this respect, EU sanctions

contain specific provisions to ensure that transactions for Russian agricultural products, including fertilizers, are able to proceed smoothly.

European Commission President, Ursula von der Leyen, also recently announced work "at full speed on a ninth sanctions package" against Russia and the anticipated approval of "a global price cap on Russian oil with the G7 and other major partners." (see

The accompanying Annexes provide further details on the Communication (see here).

Latest meeting of EU-US Task Force on Energy Security (see here)

On 3 November 2022, the EU-US Task Force on Energy Security held its latest meeting to discuss implementation of the EU and US Joint Statement of 25 March 2022 announcing a Task Force aimed at diversifying the EU's natural gas supplies and reducing natural gas demand and consumption (see here). The meeting was co-chaired by Björn Seibert, Head of Cabinet of the European Commission President, and Amos Hochstein, US Special Presidential Coordinator.

To recall, the Task Force's efforts are centered upon two main prongs: (i) Diversifying liquefied natural gas (LNG) supplies in line with climate objectives, in particular with the US working with international partners towards ensuring expanded LNG volumes for the EU market; and (ii) Reducing demand for natural gas in the U.S. and EU by accelerating market deployment of clean energy measures. (see also <u>Jones Day COVID-19</u> <u>Update No. 83 of 29 April 2022</u> and <u>Jones Day Newsletter</u>, <u>U.S. and EU Create Joint Task Force</u>, <u>May 2022</u>).

The Task Force meeting assessed joint work to date, including multiple meetings with EU Member States and EU and US industry representatives to address policy approaches, as well as best practices with respect to energy savings, deployment of clean energy technologies, and reducing dependence on Russian energy. In particular, the meeting discussed:

- The <u>successful expansion of LNG supplies from the US to Europe</u>:
 - This expansion surpassed the Joint Statement's commitment to increase LNG supplies to Europe by 15 bcm (billions of cubic meters) in 2022 as compared to 2021. In 2022 (between January to October), approximately 48 bcm of LNG was exported from the US to the EU, which is 26 bcm more than for 2021. The meeting participants committed to work on keeping a high level of LNG supplies to Europe in 2023, with an additional approximately 50 bcm as compared to 2021.
 - The effort to increase LNG supplies will be further supported with the EU Energy Platform as an instrument for demand aggregation and joint purchase of gas. To recall, the EU Energy Platform is a voluntary coordination mechanism to secure the supply of gas, LNG, and hydrogen. As stated in the REPowerEU Plan adopted on 18 May 2022 (see here), the Commission seeks to develop a "joint purchasing mechanism" to negotiate and contract gas purchases on behalf of participating Member States. The Commission describes such joint purchasing mechanism as replicating the ambition of the common COVID vaccine purchasing program (see also Jones Day COVID-19 Update No. 85 of 1 June 2022).

- Russia's weaponization of energy, which reinforces the need to accelerate the energy transition and implement more ambitious policies to reduce dependence on gas and other fossil fuels. In this respect, the participants committed to pursue a series of targeted sub-dialogues to pursue closer cooperation on incentivizing utilities and consumers to, e.g., implement energy efficiency solutions for lowering electricity and gas use, as well as digital solutions to help reduce consumers' bills.
- In light of the <u>environmental impact of LNG production and consumption</u>, the EU and US also committed to expand efforts to reduce methane emissions both in bilateral trade and at the global level, by supporting domestic and international measures for reinforced monitoring, reporting and verification, as well as transparency, for methane emissions data in the fossil energy sector.

MEDICINES AND MEDICAL DEVICES

HERA signs
Joint
Procurement
Framework
Contract of up to
2 million doses
of monkeypox
vaccine (see
here)

On 17 November 2022, the European Health Preparedness and Response Authority (HERA)* signed a Joint Procurement Framework Contract (JFC) with vaccines company Bavarian Nordic for the supply of up to 2 million doses of the monkeypox vaccine in 2023 and 2024.

The Commission has emphasized the importance of recalling the lessons learned from the COVID-19 pandemic, including during the ongoing work on the monkeypox outbreak (see here).

In announcing the JFC, European Commissioner for Health and Food Safety, Stella Kyriakides stated: "Through a united and decisive response, the EU and its Member States worked together to successfully bring the monkeypox outbreak under control. However, it is still important to remain vigilant, and to be prepared should cases rise again in the future."

The JFC with Bavarian Nordic enables the 14 participating Member States to purchase monkeypox vaccine doses to address their medium- and long-term needs and build stockpiles. To recall, the EU's joint procurement mechanism is provided under the EU's Joint Procurement Agreement of 2014 (see here), as signed by 36 countries. The mechanism allows to jointly procure medical countermeasures (as an alternative or complement to procurement at national level) when at least 4 of the 36 participating countries are interested in jointly procuring a medical countermeasure.

This JFC complements previous measures taken by HERA aimed at covering immediate needs of Member States, such as procuring over 334,000 vaccine doses and securing over 10,000 antiviral treatment courses to treat monkeypox (see Jones Day COVID-19 Update No. 88 of 3 October 2022).

The first deliveries of the monkeypox vaccine doses under the JFC will commence in Q2 2023.

^{*} HERA was launched as a new European Commission Directorate-General on 16 September 2021 in the aftermath of the COVID-19 pandemic (see <u>Jones Day COVID-19 Update No. 37 of 24 February 2021</u>). It works 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.

CYBERSECURITY, PRIVACY & DATA PROTECTION

Digital Services Act: Entry into force and Q&As published (see here) The Digital Services Act ("DSA", see here) entered into force on 16 November 2022, and certain provisions also became applicable on the same day (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). Most DSA provisions will be applicable as of 17 February 2024 (see also Jones Day COVID-19 Update No. 89 of 14 October 2022 and Jones Day COVID-19 Update No. 90 of 28 October 2022).

The DSA, proposed by the Commission on 15 December 2020, is one of the measures taken as part of the EU Recovery Plan to lead Europe out of the COVID-19 pandemic (see <u>Jones Day COVID-19 Update No. 10 of 29 May 2020</u>).

To recall, the DSA introduces a <u>uniform framework</u> across the EU of 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 DSA complements other existing rules, and in particular, the GDPR.

The European Commission also published Q&As on the DSA on 14 November 2022. The Q&A notes, in particular, that the <u>DSA's most far-reaching rules focus on very large online platforms</u> (reaching at least 45 million users in the EU (representing 10% of the population)). Similarly, <u>very large online search engines</u> (with over 10% of the 450 million consumers in the EU) will bear greater responsibility in curbing illegal content online.

The Q&A further notes that the DSA introduces, for instance:

- New rules to trace sellers on online marketplaces, to enhance trust and more easily pursue scammers;
- Bans on targeted advertising on online platforms by profiling children or based on special categories of personal data such as ethnicity, political views or sexual orientation;
- A ban on using so-called "dark patterns" on the interface of online platforms, referring to misleading tricks that manipulate users into choices they do not intend to make;
- New provisions to allow certain researchers to access data of key platforms, in order to scrutinize how platforms work and how online risks evolve.

The Q&A also provides clarification on the DSA's <u>enforcement mechanisms</u>, consisting of national and EU-level cooperation. In particular:

- Each Member State must appoint, by 17 February 2024, a <u>Digital Services Coordinator</u>, an independent authority responsible for all matters relating to supervision and enforcement of the DSA in that Member State. These Coordinators will cooperate within an independent advisory group, called the European Board for Digital Services, which will provide supporting analysis, reports and recommendations; and
- The <u>European Commission</u> will have direct supervision and enforcement powers in relation to obligations of providers of very large online platforms and very large online search engines.

Furthermore, <u>users will have new rights</u>, including a right to complain to the platform, seek out-of-court settlements, complain to their national authority in their own language, or seek compensation for breaches of the rules. Representative organizations will also be able to defend user rights for large scale breaches of the law.

Digital Services Coordinators and the European Commission will have the power to impose <u>penalties</u>, <u>including financial fines</u> (in the case of very large online platforms and very large online search engines, fines of up to 6% of the global turnover of a service provider can be imposed in the most serious cases), and the power to require immediate actions where necessary to address very serious harms.

Digital Markets Act: Entry into force and Q&As published (see here)

The Digital Markets Act (DMA, see here) entered into force on 1 November 2022 and will be applicable as of 2 May 2023. The European Commission also published Q&As on the DMA on 31 October 2022.

To recall, the Joint Declaration on EU Legislative Priorities for 2022 (see <u>Jones Day Alert No. 72 of 10 January 2022</u>), which aimed to guide the EU's recovery from the COVID-19 pandemic, listed the DMA as a priority initiative.

The DMA aims to prevent the imposition of unfair conditions on businesses and end users by those designated as "gatekeepers" (i.e., large digital platforms deemed as significantly impacting the internal market, serving as an important gateway for business users to reach their end users, and which enjoy, or will foreseeably enjoy, an entrenched and durable position) that provide a "core platform service" (e.g., online search engines; online social networking services, web browsers, virtual assistants).

Among other things, gatekeepers shall not:

- Use the data of business users when gatekeepers compete with them on their own platform;
- Combine personal data from the relevant core platform service with personal data from any further core platform services;
- Rank the gatekeeper's own products or services in a more favorable manner compared to those of third parties; and
- Require app developers to use certain of the gatekeeper's services (such as payment systems or identity providers) in order to appear in the gatekeeper's app stores.

Additionally, gatekeepers shall:

- Allow end users to easily un-install pre-installed apps or modify default settings on operating systems, virtual assistants or web browsers that steer them to the products and services of the gatekeeper;
- Provide business users with access to the data generated by their activities on their platform; and
- Provide end users and third parties authorized by end users with effective data portability, at their request and free of charge.

With respect to <u>data protection</u>, in particular, where consent for collecting, processing, cross-using and sharing of personal data is required to ensure compliance with the DMA, a gatekeeper shall take the necessary steps either to enable business users to directly obtain the required consent to their processing, where such consent is required under the GDPR or ePrivacy Directive 2002/58/EC, or to comply with EU data protection and privacy rules and principles in other ways, including by providing business users with duly anonymized data where appropriate.

The <u>Commission will be the sole enforcer</u> of the DMA rules. <u>If a gatekeeper fails to comply with the DMA</u>, the Commission can impose fines of up to 10% of the company's total worldwide annual turnover or 20% in the event of repeated infringements (i.e., at least three violations in eight years) and periodic penalty payments of up to 5% of the company's total worldwide daily turnover.

The DMA, as a Regulation containing precise obligations and prohibitions for gatekeepers, can be enforced directly in national courts. This will facilitate <u>direct actions for damages</u> by businesses and individual users harmed by the conduct of non-complying gatekeepers.

Once the DMA is applicable (as of 2 May 2023), potential gatekeepers that meet the DMA's quantitative thresholds must notify their core platform services to the Commission within two months. The Commission will designate gatekeepers at the latest by 6 September 2023. Following their designation, gatekeepers must comply with DMA requirements at the latest by 6 March 2024.

For further details, see Jones Day White Paper "<u>Digital Markets Act:</u>
<u>European Union Adopts New "Competition" Regulations for Certain Digital Platforms</u>", August 2022.

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