

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 approves further schemes under State aid Temporary Crisis Framework in context of Russia's invasion of Ukraine
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission and Bulgaria create first regional taskforce under EU Energy Purchase Platform
- Meeting of EU-US Task Force on European Energy Security
- EU and India announce Trade and Technology Council

Medicines and Medical Devices

- European Commission launches EU FAB network
- Commission publishes Communication on COVID-19: Sustaining EU preparedness and Response: Looking ahead

Cybersecurity, Privacy & Data Protection

- European Parliament endorses proposal to modify and prolong application of EU Digital COVID-19 Certificate Regulation
- EU General Court dismisses MEP challenge against required presentation of EU Digital COVID-19 Certificate to access European Parliament buildings

COMPETITION & STATE AID

State Aid

European
Commission
approves further
schemes under
State aid
Temporary Crisis
Framework in
context of
Russia's invasion
of Ukraine (see
here)

On 19 April 2022, the Commission approved additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine.

These are among the first schemes approved under this Crisis Framework, adopted by the Commission on 23 March 2022, which sets out the criteria for Member States to support businesses in the context of Russia's invasion of Ukraine and its serious disruption to the EU economy (see <u>Jones Day COVID-19 Update No. 80 of 25 March 2022</u>).

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 also disrupted supply chains for both EU imports from Ukraine (in particular, cereals and vegetable oils) and EU exports to Ukraine.

The latest schemes under the Crisis Framework include:

- — €836 million (PLN 3.9 billion) Polish scheme to support the
 agricultural sector, open to farmers active in Poland affected by the
 increase of fertilizers costs caused by the current geopolitical crisis
 and related sanctions.
- €20 billion German scheme to support companies active in all sectors (except the financial sector) affected by the current geopolitical crisis and related sanctions.
- €50 million Italian scheme to support companies in Friuli Venezia Giulia active in the agricultural (including primary production, processing and marketing of agricultural products), forestry, fisheries and aquaculture sectors affected by the current crisis and the related sanctions.
- €18 million Irish scheme to support the road haulage sector affected by the fuel prices increase caused by the current geopolitical crisis and the related sanctions.
- €169 million Spanish scheme to support the milk producers sector, open to the producers of cow's, sheep's and goat's milk active in Spain affected by the price increase of electricity, animal feed and fuel caused by the current geopolitical crisis and the related sanctions.

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 (see <u>Jones Day COVID-19 Update No. 68 of 22 November 2021</u>), provided that their respective cumulation rules are respected.

The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2022. 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.

European
Commission
approves new and
amended Member
State measures to
support the
economy (see here
and here)

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.

The Temporary Framework, adopted in March 2020, is currently applicable until 30 June 2022.

- €700 million French scheme to support research, development and innovation projects across all sectors in the context of recovery from the coronavirus pandemic.
- Re-introduction of Swedish guarantee scheme for companies in the context of the coronavirus pandemic, prolonging until 30 June 2022 the possibility to extend the maximum term of guarantees granted under the guarantee programme up to five years.
- €80 million Maltese scheme to support small and medium-sized enterprises in the context of the coronavirus pandemic.
- €30 million Spanish scheme to support companies affected by the coronavirus pandemic.
- €91 million Romanian scheme to support bovine, pigs and poultry producers in the context of the coronavirus pandemic.
- €45 million Belgian scheme to support companies affected by the coronavirus pandemic.
- Amendment to Polish scheme, including €695,000 budget increase, to support tour operators affected by the coronavirus pandemic.
- €800,000 Luxembourg scheme to support pigmeat producers in the context of the coronavirus pandemic.
- Re-introduction of Finnish scheme, including €10 million budget increase, to support uncovered fixed costs of companies affected by the coronavirus pandemic.
- €2 million Lithuanian scheme to support broiler producers in the context of the coronavirus pandemic.
- €7 billion French scheme to support investment towards a sustainable recovery under the State aid temporary framework.

TRADE / EXPORT CONTROLS

European
Commission and
Bulgaria create
first regional
taskforce under
EU Energy

On 28 April 2022, the Commission and Bulgaria agreed to establish the first regional taskforce as part of the EU's Energy Purchase Platform, a voluntary coordination mechanism to secure the supply of gas, LNG (Liquefied Natural Gas), and hydrogen.

To recall, the Platform followed the European Council's conclusions of 24 - 25

Purchase Platform (see here)

March 2022 that Member States and the Commission shall "urgently" work together on voluntary common energy purchases. As earlier stated by the Commission, such collective purchases would be inspired by experience from the COVID-19 pandemic, where EU wide action was viewed as crucial to ensuring adequate supplies of vaccines (see also <u>Jones Day COVID-19</u> <u>Update No. 80 of 25 March 2022</u>).

This first regional taskforce, based in Sofia, will assess gas and electricity needs, prices, and infrastructure aspects, in view of supporting efforts to reduce dependency on Russian fossil fuels,* fill storage ahead of next winter, and further accelerate decarbonization of the energy sector.

The first ministerial meeting of this taskforce was planned on 5 May 2022, with Bulgaria bringing together neighboring Member States and other countries.

* Following Russia's invasion of Ukraine, European energy companies notably face unprecedented uncertainty, and the potential reduction or cessation of Russian gas imports would invariably impact all market segments in Continental Europe. For a discussion on such impact on European gas markets and potential legal arguments in response to continued contractual performance if imports are reduced or stopped, see the Jones Day White Paper on The War in Ukraine: Downstream Ripple Effects on the European Gas Market, May 2022. See also the below summary on the Meeting of the EU-US Task Force on European Energy Security.

Meeting of EU-US Task Force on European Energy Security (see here)

On 28 April 2022, the EU-US Task Force on Energy Security discussed implementation of the goal of decreasing Europe's dependence on Russian fossil fuels and increasing European energy security. US President Biden and European Commission President von der Leyen announced the Task Force's launch on 25 March 2022 (see here).

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.

The Task Force meeting discussed, in particular, progress on diversifying natural gas supplies to Europe and lessening Europe's demand for natural gas.

Also discussed was the EU Energy Purchase Platform and plans to create a framework to accelerate diversification of gas supply, including additional LNG supplies.

The Task Force plans to reconvene in June 2022 to assess progress on work plans.

For further details on the impact of efforts to reduce dependency on Russian fossil fuels, see above summary on Bulgaria creating the first regional taskforce under EU Energy Purchase Platform, including commentary on <a href="https://doi.org/10.1081/jha.2081/jha.

EU and India announce Trade and Technology

On 25 April 2022, Ursula von der Leyen, President of the European Commission and Narendra Modi, Prime Minister of India, announced the launch of the EU-India Trade and Technology Council (TTC).

Council (see here)

The EU is India's third largest trading partner, accounting for €88 billion worth of trade in goods in 2021 or 10.8% of total Indian trade. India is the EU's 10th largest trading partner, accounting for 2.1% of EU total trade in goods in 2021.

The EU-India TTC aims to reinforce cooperation in trade, technology and security, in view of tackling current challenges in these areas and responding to rapidly shifting geopolitical circumstances, including through reporting at the political level to ensure implementation and follow-up in areas of key importance to the sustainable advancement of the EU and Indian economies.

This will be India's first TTC with its partners and the EU's second, following its first TTC with the US. Initiated in June 2021, the EU-US TTC focused, in particular, on ensuring resilient and diversified supply chains for vital goods such as semiconductors, which suffered from shortages during the COVID-19 crisis (see <u>Jones Day COVID-19 Update No. 64 of 18 October 2021</u>).

The EU-India TTC reinforces other initiatives such as the EU-India Strategic Partnership for strengthening the EU-India trade and investment relationship. This includes promoting inclusive and sustainable economic growth and recovery from the COVID-19 pandemic by establishing, for instance, a joint working group on resilient supply chains (see <u>Jones Day COVID-19 Update No. 47 of 12 May 2021</u>).

MEDICINES AND MEDICAL DEVICES

European Commission launches EU FAB network (see here and here)

On 27 April 2022, the European Commission launched the EU FAB, a procurement procedure aimed at building a network of vaccine producers in the EU and EEA in view of ensuring that agile and adequate manufacturing capacities for different vaccine types remain operational and can be readily activated in times of crisis.

In initiating the EU FAB, the Commission notes that the COVID-19 pandemic revealed that although effective vaccines could be developed and authorized relatively swiftly, manufacturing capacities fell short of meeting European and global demand. Consequently, this lack of supply led to a slow start in distributing and administering vaccines.

To better respond to future public health emergencies, the EU FAB seeks to reserve manufacturing capacities and obtain a priority right for manufacturing of vaccines for a minimum of 450 million doses and an annual budget of €160 million.

The EU FAB will operate within the framework of (i) a <u>preparedness phase</u> (manufacturing capacity is reserved); (ii) a <u>public health emergency phase</u> (decision to activate EU FAB facilitates); and a <u>crisis phase</u> (launch of manufacturing).

On the same day, the Commission launched the <u>EU FAB Call for Tender</u>, open to pharmaceutical companies and contract manufacturing organizations (CMOs) that provide manufacturing services to other companies in the pharmaceutical industry. The Call covers manufacturing capacities for mRNA-, vector-, and protein-based vaccines.

Tendering entities must be based in the EU or EEA countries, with manufacturing sites in the EU or EEA, as well as a sufficient manufacturing capacity to guarantee the number of doses reserved/to be manufactured (i.e. a capacity that allows for manufacturing at least 50 million doses when a "crisis phase" is activated).

Following the Call's first step of soliciting requests to participate (until 3 June 2022), selected candidates may proceed to the second step of submission of tenders, negotiations and evaluation.

Commission publishes
Communication on COVID-19:
Sustaining EU preparedness and Response:
Looking ahead (see here)

On 26 April 2022, the Commission published a Communication on COVID-19: Sustaining EU Preparedness and Response: Looking ahead.

Expecting that the coming summer months will ease pressure from the COVID-19 pandemic, the Communication urges to use this window to prepare for the autumn/winter period and for possible future pandemic surges.

The Communication puts forward a coordinated, EU-wide approach to managing the pandemic in the coming months, moving from emergency to a more sustainable mode.

Member States are asked to take actions before the autumn to strengthen their surveillance, healthcare systems, and overall pandemic preparedness, such as by:

- <u>Elevating the uptake of COVID-19 vaccines</u>, focusing on increasing the roll-out of booster doses, especially for the most vulnerable groups;
- Promoting surveillance and intelligence gathering through testing and sequencing, e.g. by establishing integrated year-round surveillance systems for acute respiratory illnesses (integrating surveillance of COVID-19, influenza and other respiratory viruses);
- Supporting targeted testing and whole-genome sequencing, e.g.
 through sufficient testing and contact-tracing capacities and plans for
 scaling up national testing strategies when needed, as well as
 continued capacity building for laboratory sequencing and virus
 characterization services.
- Addressing mis- and dis-information, such as by preparing communication strategies for the possible approaching need for additional doses of COVID-19 vaccines with new or modified vaccines.

The Communication also urges researchers and vaccine manufacturers to prioritize the development of universal, variant-proof vaccines that offer longer term protection against infection, as well as the development of COVID-19 therapeutics, particularly targeted for immunocompromised patients. To support these goals, the Communication announces EU-level actions such as:

- <u>Promoting COVID-19 vaccines, therapeutics and clinical trials,</u> e.g. by:
 - Identifying promising candidates for the next generation of <u>COVID-19 vaccines</u> and mobilizing all available instruments to support their development. Regulatory flexibilities and simplifications needed for next generation and universal vaccines against COVID-19 will be addressed by the Commission and the European Medicines Agency ("EMA") by building on changes already made to the regulatory framework and on existing

guidance documents.

- Work with Member States to <u>identify priorities for further joint procurements for therapeutics</u> and strengthen the integration with established national and EU processes. To date, eight COVID-19 therapeutics of different categories have been authorized, addressing different stages and severity of the disease. New therapeutics should preferably be easier to store and administer.
- Strengthen national capacity in EU/EEA countries to undertake research and contribute to multi-country clinical trials during a crisis, prioritizing the timely implementation of European multi-state trials. The COVID-19 pandemic demonstrated a need for a faster and more robust procedure for a coordinated approval of multi-national clinical trials by Member States to avoid fragmentation when small, mono-national trials are competing for the same resources and patient populations.
- Ensure resilient supply chains throughout the pandemic and its aftermath, e.g. by launching EU FAB, a network of ever-warm single and/or multi-technology production facilities in Europe for the production of vaccines (see above summary on EU Fab) and the continuous supply chain monitoring for critical medical countermeasures and their input materials, notably in collaboration with global partners, including through the Joint EU-U.S. Taskforce on COVID Manufacturing and Supply Chains.

In addition, the Communication sets out measures to be taken in the medium and long term, such as increasing the focus on healthcare system resilience adaptability in terms of financial and human resources and speeding up digitalization in health.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European
Parliament
endorses
proposal to
modify and
prolong
application of EU
Digital COVID-19
Certificate
Regulation (see
here)

On 28 April 2022, the Civil Liberties Committee of the European Parliament endorsed the Commission proposal to modify and prolong the application of the EU Digital COVID-19 Certificate Regulation (Regulation (EU) 2021/953).

To recall, the EU Digital COVID-19 Certificate, which seeks to facilitate the free movement of citizens within the EU Member States during the pandemic, serves as proof that a person: (i) is vaccinated against COVID-19; (ii) received a negative test result; or (iii) recovered from COVID-19.

The Regulation is currently applicable until 30 June 2022. The Commission proposed to extend the validity of the EU Digital COVID-19 Certificate scheme until 30 June 2023 and to make certain modifications to the Regulation, such as to enable Member States to grant test certificates based on new types of antigen assay tests (see <u>Jones Day COVID-19 Update No. 76 of 9 February 2022</u>).

Members of the European Parliament ("MEPs") amended the Commission proposal, emphasizing that Member States should avoid additional restrictions on the freedom of movement for EU Digital COVID-19 Certificate holders, unless absolutely necessary. If restrictions are needed, these should be limited and proportionate.

Furthermore, the MEPs requested the Commission to assess whether the EU Digital COVID-19 Certificate scheme is necessary and proportionate six months after the extension.

The proposal will now need endorsement by the Council.

EU General Court dismisses MEP challenge against required presentation of EU Digital COVID-19 Certificate to access European Parliament buildings (see here and here)

On 27 April 2022, the General Court dismissed actions to annul the Bureau of the European Parliament's decision to make access to the Parliament's buildings conditional upon presenting an EU Digital COVID-19 Certificate for an initial period until 31 January 2022 (*Joined Cases T-710/21 Roos and others v Parliament, T-722/21 D'Amato and others v Parliament and T-723/21 Rooken and others v Parliament*).

For the first time, the General Court examined the legality of certain restrictions imposed by the EU institutions in view of protecting the health of their staff in the context of the COVID 19 pandemic.

The General Court held that the Parliament may require anyone who wishes to access the buildings to present a valid EU Digital COVID-19 Certificate. In particular, it found that the Parliament did not need express authorization from the EU legislature in order to adopt the contested decision, which fell within the Parliament's power to adopt rules for its own internal organization and only applied on its premises.

Furthermore, the General Court did not consider the Parliament's processing of personal data to be unlawful or unfair. In this respect, it found that the processing pursued an EU general public interest, i.e., the protection of public health. The General Court also concluded that the processing was fair and transparent, as the Parliament informed the concerned individuals of the further processing of their personal data for another purpose beyond why such data were initially obtained.

The General Court's ruling may be appealed before the Court of Justice within two months and ten days of the date of its publication.

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