



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 adopts Communication on revised Guidelines on Regional State Aid
- European Commission launches public consultation on proposed revised State aid Framework for research, development and innovation
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission presents new 5-year strategy to combat organized crime, including significantly rising imports of counterfeit medical products

Medicines and Medical Devices

- European Commission purchases additional 100 million doses of Pfizer's COVID-19 vaccine
- European Parliament to approve European Commission's proposed simplified authorization procedure for vaccines adapted to new COVID-19 variants

Cybersecurity, Privacy & Data Protection

- European Commission presents new 5-year strategy to combat organized crime, including surging cybercriminality following the COVID-19 pandemic

COMPETITION & STATE AID

State Aid

European Commission adopts Communication on revised Guidelines on Regional State Aid (see [here](#))

On 19 April 2021, the Commission adopted a Communication on revised Guidelines on Regional State Aid, setting out the rules for Member States in granting State aid to companies to promote the economic growth of disadvantaged areas in the EU.

The revised Guidelines on Regional Aid include various modifications towards simplification and building on experience gained from applying the previous rules. The revised Guidelines also seek to reflect new policy priorities under the EU's green and digital strategies.

The revised Guidelines set out key elements such as:

- increasing overall regional aid coverage to 48% of the EU population (previously 47%);
- increasing maximum aid intensities to support the European Green Deal and Digital Strategy objectives by enabling additional incentives for investments in disadvantaged areas of the EU;
- a general simplification of the structure of the Guidelines; and
- validity of regional aid maps for the period 2022-2027.

As concerns regional aid maps, the Communication further notes that the effects of the COVID-19 crisis may persist longer in certain areas. It considers, however, that it is premature to predict the pandemic's impact in the mid- to long- term and to identify the areas that will be particularly affected. Given this, the Commission plans a mid-term review of the regional aid maps in 2023, which will take into account the latest available statistics.

The revised Guidelines shall enter into force on 1 January 2022.

European Commission launches public consultation on proposed revised State aid Framework for research, development and innovation (see [here](#) and [here](#))

On 8 April 2021, the Commission launched a public consultation on a proposed revision of the State aid Framework for research, development and innovation ("RDI Framework").

The RDI Framework aims at facilitating or incentivizing research, development and innovation, providing support for certain economic activities that would not develop in the absence of aid.

Recovery of the EU economy from the COVID-19 pandemic, in the Commission's view, will be supported under the RDI Framework. Executive Vice-President and Competition Commissioner Margrethe Vestager explained that revising the RFI Framework aims to: *"... further simplify our existing State aid Framework to make it easier for Member States to support research, development and innovation, including by small and medium sized enterprises, while ensuring that possible competition distortions are kept to the minimum.... All this is to provide the right incentives to tackle the challenges we are facing and enable Europe's green and digital transition."*

The proposed revision focuses on:

- Improving and updating the existing definitions of research and innovation activities eligible for support under the RDI Framework;

- Introducing new provisions to enable public support for technology infrastructures, particularly in view of bringing innovative solutions to urgent challenges like climate change and the shift towards digitalization; and
- Simplifying certain rules to strengthen the practical application of the RDI Framework, towards alleviating administrative burdens for companies and managing authorities.

The consultation will run until 3 June 2021, with the Commission also holding discussions with Member States. Adoption of the new RDI Framework is foreseen for the second half of 2021.

EU approves new and amended Member State measures to support the economy (see [here](#) and [here](#))

Since the onset of the coronavirus outbreak, the European 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 most recent measures adopted to support the economy and companies affected by coronavirus outbreak include:

- €268 million Czech scheme to support operators offering accommodation services affected by the coronavirus outbreak
- Approximately €1.74 billion (DKK 13 billion) Danish scheme to compensate mink farmers and mink-related businesses for measures taken in the context of the coronavirus outbreak
- €14.6 million for hotels and other accommodation providers in Wallonia affected by the coronavirus crisis
- €120 million Lithuanian scheme to support companies affected by the coronavirus outbreak
- Extension and changes of Belgium's program to support airports in the Wallonia region affected by the coronavirus pandemic, including a budget increase of €17.5 million for 2021
- €8 million Cypriot scheme to support tour operators affected by the coronavirus outbreak
- €500 million Romanian scheme to support companies active in tourism, accommodation and food services as well as travel agencies affected by the coronavirus outbreak
- €10 million Italian scheme to support companies operating small ships in the tourist transport sector in the context of the coronavirus outbreak
- €150 million Portuguese scheme to support companies in Azores region affected by the coronavirus outbreak
- €50 million Hungarian 'umbrella' scheme to support companies affected by the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Commission presents new 5-year strategy to

On 14 April 2021, the Commission presented its Communication on the EU Strategy to tackle Organised Crime 2021-2025. This new 5-year Strategy tackles organized crime groups, which have rapidly adapted to the COVID-19 pandemic, including sharply increasing counterfeit medical products. The

combat organized crime, including significantly rising imports of counterfeit medical products (see [here](#))

Strategy sets out the tools and measures to counter the business models and structures of criminal organizations across jurisdictions, both online and offline.

As concerns counterfeit products, the Communication reports that such products represent 6.8% of EU imports and are a significant source of income for organized crime groups. The COVID-19 crisis triggered a significant rise in counterfeit medical and sanitary products, including the production and supply of counterfeit protective equipment, test kits and pharmaceuticals. Attempted fraudulent sales of over 1 billion vaccine doses for a total price of over €15.4 billion have targeted individuals and public authorities.

Law enforcement authorities together with Europol and the European Anti-Fraud Office have undertaken large-scale operations, leading to numerous arrests and seizures of counterfeit products. The new 5-year Strategy will boost such efforts through, in particular, an “EU Toolbox against counterfeiting,” which outlines principles for joint action, cooperation and data sharing among law enforcement authorities, right holders, and intermediaries.

For further details on the 5-year Strategy, see below Section on Cybersecurity.

MEDICINES AND MEDICAL DEVICES

European Commission purchases additional 100 million doses of Pfizer’s COVID-19 vaccine (see [here](#))

On 19 April 2021, Pfizer announced that the Commission had exercised the option under its expanded Advanced Purchase Agreement to purchase an additional 100 million doses of Pfizer’s COVID-19 vaccine (COMIRNATY).

This brings the total number of COMIRNATY doses to be delivered to the EU to 600 million.

Pfizer intends to deliver 250 million doses to the EU in Q2, a four-fold increase on Q1’s agreed quantity. All additional COMIRNATY doses are expected to be delivered to Member States in 2021.

European Parliament to approve European Commission’s proposed simplified authorization procedure for vaccines adapted to new COVID-19 variants (see [here](#))

On 16 April 2021, the European Parliament’s Environment, Public Health and Food Safety (ENVI) Committee voted to recommend the Commission’s proposed Delegated Regulation amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human and veterinary medicinal products (“Proposal”).

The Proposal, adopted on 23 March 2021, builds on the earlier announced HERA Incubator initiative of February 2021 (see *Jones Day COVID-19 Update No. 37 of 24 February 2021*).

The Proposal provides for a simplified procedure for approving adaptations to market authorizations (MAs) for COVID-19 vaccines aimed at preventing new COVID-19 variants. It sets out derogations from certain provisions of Regulation 1234/2008, such that the Commission could exceptionally and temporarily accept a modification to the terms of an MA for coronavirus or human influenza vaccines, even “*where certain pharmaceutical, nonclinical or clinical data are missing*” (see [here](#)).

Following the ENVI's favorable vote on the Proposal, it will now be put forth for approval by the plenary session of the European Parliament.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission presents new 5-year strategy to combat organized crime, including surging cybercriminality following the COVID-19 pandemic (see [here](#))

On 14 April 2021, the Commission presented its Communication on the EU Strategy to tackle Organised Crime 2021-2025. This new 5-year Strategy tackles organized crime groups, including addressing surging cybercriminality with the COVID-19 pandemic. *For further details on the 5-year Strategy, see above Section on Trade / Export Controls.*

The Communication observes that the rapid drive towards digitalization, in tandem with the pandemic, has opened new vulnerabilities for exploitation by cybercriminals. Over the past year, the volume and degree of sophistication of cyberattacks has flourished, including the use of malware, hacking of sensitive personal or industry data, or denial of service attacks.

The Communication further notes that evidence-gathering instruments and measures designed for physical evidence are not yet fully adapted to the digital world. With an estimated 80% of crimes having a digital component, law enforcement and the courts require swift access to digital leads and evidence. They also need modern technology and the tools and skills to keep pace with criminal operations.

Under the 5-year Strategy, the Commission will address lawful and targeted access to encrypted information in the context of criminal investigations and prosecutions. It will also analyze and outline possible approaches to data retention.

Data retention measures, in particular, raise important questions in relation to their interference with fundamental rights, including the right to privacy and protection of personal data. The Commission will assess potential approaches and solutions, in line with the European Court of Justice's recent rulings, which appropriately respond to the needs of law enforcement and the judiciary. Towards developing the way forward, the Commission will consult Member States before end-June 2021.

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