



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 approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission announces export transparency mechanism for vaccines

Medicines, Medical Devices, and Personal Protective Equipment

- AstraZeneca vaccine in final stages of approval by European Medicines Agency, but the European Commission announces a supply problem

Cybersecurity, Privacy & Data Protection

- European Medicines Agency pursues investigation of cyberattack

COMPETITION & STATE AID

State Aid

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:

- €1.9 billion Polish scheme to support companies in various sectors whose revenue or income suffered a drop of at least 40% due to the coronavirus outbreak
- Modifications to Portuguese schemes increasing their budget to €1.2 billion to support micro, small and medium businesses in the context of the coronavirus outbreak
- €425 million budget increase and prolongation of Danish scheme to compensate for damages caused by cancellation of public events due to the coronavirus outbreak
- €12 billion German umbrella scheme to compensate companies for damages suffered during the lockdown periods imposed by the German government in response to the coronavirus outbreak
- €642 million German umbrella scheme to compensate companies active in trade fairs and the congress sector for damages suffered due to the coronavirus outbreak
- €200 million French scheme to support companies welcoming the public (hotels, tourism, restaurants, event organization) impacted by the coronavirus pandemic
- €120 million French scheme to sports clubs and organizers of sporting events impacted by the coronavirus outbreak
- €4 million Danish tax deferral scheme to support SMEs affected by the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Commission announces export transparency mechanism for vaccines (see [here](#))

On 25 January 2021, European Commissioner for Health and Food Safety, Stella Kyriakides, announced that an export transparency mechanism for vaccines would be established as soon as possible.

Such mechanism aims at gaining full transparency on transactions for the export of vaccines from the EU, such that all companies producing vaccines against COVID-19 in the EU would be required to provide early notification when seeking to export vaccines to third countries.

The export transparency mechanism responds to AstraZeneca's recent and unexpected announcement to the Commission and the EU Member States that it intended to supply considerably fewer doses of its vaccine against COVID-

19 in the coming weeks than agreed and announced (*for further details, see below section on Medicines*).

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

AstraZeneca vaccine in final stages of approval by European Medicines Agency, but the European Commission announces a supply problem (see [here](#))

On 25 January 2021, European Commissioner for Health and Food Safety, Stella Kyriakides, announced that the AstraZeneca vaccine against COVID-19 is in the final stages of approval by the European Medicines Agency, which could recommend market authorization in the coming days.

To recall, on 14 August 2020, the Commission had finalized the first Advanced Purchase Agreement (APA) with AstraZeneca, enabling EU Member States to purchase 300 million vaccine doses, with the option of an additional 100 million doses (*see Jones Day COVID-19 Update No. 20 of 1 September 2020*).

However, Commissioner Kyriakides also announced a supply problem with AstraZeneca. The company now seeks to supply considerably fewer doses in the coming weeks than agreed, leading to the Commission's announced pursuit of an export transparency mechanism (*for further details, see above section on Trade/Export Controls*).

Rejecting the new delivery schedule announced by AstraZeneca, the Commission seeks delivery of the ordered and pre-financed doses as soon as possible.

As stated by Ursula von der Leyen, President of the European Commission Europe, on 26 January 2020 (see [here](#)): *“Europe invested billions to help develop the world’s first COVID-19 vaccines.... And now, the companies must deliver. They must honour their obligations. This is why we will set up a vaccine export transparency mechanism.”*

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Medicines Agency pursues investigation of cyberattack (see [here](#))

On 26 January 2021, the European Medicines Agency (EMA) provided its latest update on the cyberattack experienced by EMA on 9 December 2020, affecting BioNTech and Pfizer COVID-19 documents.

EMA's ongoing investigation further reveals that some of the unlawfully accessed documents, including email correspondence, were disseminated by media outlets once they were made available on the Internet.

However, an in-depth analysis of the leaked documents showed that the documents were not all published in their full, original form and some may have been taken out of context.

In addition, it appears that although the email correspondence is authentic, data relating to different users were selected and aggregated. The perpetrators also created screenshots from multiple folders and mailboxes such that trust in vaccines could be undermined.

EMA also reiterated that it *“continues to fully support the criminal investigation led by law enforcement authorities, in cooperation with other entities”*.

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