

COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 20 | 1 September 2020

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

· No noteworthy developments for this issue

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission approves funding for training of healthcare professionals for employment in intensive care units
- European Commission concludes exploratory talks with four COVID-19 vaccine manufacturers
- European Commission finalizes the first agreement with vaccine manufacturers for the purchase of large amounts of COVID-19 vaccine doses

Cybersecurity, Privacy & Data Protection

• No noteworthy developments for this issue

COMPETITION & STATE AID

State Aid

EU approves new and amended Member State measures to support the economy (see 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 million Romanian public support to compensate Timisoara Airport for damage caused by the coronavirus outbreak
- €6 billion German scheme to compensate public transport companies for damages suffered due to the coronavirus outbreak
- €38 million Czech scheme to support health SPA facilities affected by the coronavirus outbreak
- €2 billion Italian guarantee scheme to support trade credit insurance market in the context of the coronavirus outbreak
- €133 million Portuguese liquidity support to SATA airline;
- €67.5 million Maltese scheme to support SMEs affected by coronavirus outbreak
- €95 million Polish scheme to support companies active in the primary agricultural sector affected by the coronavirus outbreak
- €114,000 Latvian scheme to support cooperatives active in the forestry sector affected by the coronavirus outbreak
- €10 billion Spanish fund to provide debt and capital support to companies affected by the coronavirus outbreak
- €6 billion Italian schemes to support SMEs affected by the coronavirus outbreak
- €300 million Italian direct grants scheme to support internationally active companies affected by the coronavirus outbreak
- Modification to €2 billion Greek repayable advance scheme to support companies affected by the coronavirus outbreak
- €51 million Latvian scheme to support companies with exporting activities affected by the coronavirus outbreak
- €40 billion budget increase and amendments to previously approved Spanish guarantee schemes in context of the coronavirus outbreak
- €11 million Belgian scheme to support certain companies affected by the coronavirus outbreak
- €665 million Austrian scheme to support non-profit organizations and their related entities affected by the coronavirus outbreak
- €25 million Slovak scheme to support innovative companies with limited access to credit facilities in the context of the coronavirus outbreak

- €143 million Hungarian scheme to support research and development and production of coronavirus-relevant products
- €30 million Estonian measure to support Nordica in the context of the coronavirus outbreak
- German aid scheme to support airports affected by the coronavirus outbreak
- Modification to €100 million Hungarian scheme to support companies affected by the coronavirus outbreak
- €100 million Slovenian scheme to support companies affected by the coronavirus outbreak, as well as research, development and production of coronavirus-relevant products
- Irish loan guarantee scheme mobilising €2 billion support for companies affected by the coronavirus outbreak
- €26 million Irish scheme to support companies in the tourism and hospitality sectors affected by the coronavirus outbreak
- €4.4 million Bulgarian support measure to Burgas and Varna airports in the context of the coronavirus outbreak
- €1 billion Danish and Swedish measure to recapitalise SAS
- €1.6 million Italian scheme to support sport associations and entities affected by the coronavirus outbreak
- €34 million Czech scheme to support cultural events' operators affected by the coronavirus outbreak
- Bavarian fund to enable up to €46 billion of liquidity and capital support to enterprises in Bavaria in the context of the coronavirus
- €62 million Romanian loan guarantee to compensate Blue Air for damage suffered due to coronavirus outbreak and provide the airline with urgent liquidity support
- €290 million Belgian support to Brussels Airlines in the context of the coronavirus outbreak
- €460,000 Italian scheme to support companies in the municipality of Campione d'Italia in the context of the coronavirus outbreak
- UK subordinated loan scheme of up to approximately €16 million to support Scottish businesses affected by the coronavirus outbreak
- €50 million Irish scheme to support beef sector affected by the coronavirus outbreak
- €97 million Czech scheme to support companies affected by the coronavirus outbreak
- €500,000 Cypriot scheme to support pig sector in the context of the coronavirus outbreak
- €935 million Romanian scheme to support SMEs and certain large enterprises affected by the coronavirus outbreak

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European
Commission
approves funding
for training of
healthcare
professionals for
employment in
intensive care
units (see here)

On 18 August 2020, the European Commission approved €2.5 million in funding for a healthcare professionals training program, under the Emergency Support Instrument (ESI) for the use of economic resources in combating COVID-19.

The training program is dedicated to a multidisciplinary pool of healthcare professionals to assist intensive care units during the COVID-19 pandemic. It aims at providing intensive care medical skills to healthcare professionals who do not regularly work in such units. The program will run from August to December 2020 and will cover at least 1,000 hospitals and 10,000 doctors and nurses

European
Commission
concludes
exploratory talks
with four COVID19 vaccine
manufacturers
(see here, here,
here and here)

The Commission has concluded exploratory talks with several marketing authorization holders (MAHs) of COVID-19 vaccines.

These discussions will result in executing agreements for the purchase of potential vaccines under the advance purchase agreements scheme (APAs, see Jones Day COVID-19 Update No. 13 of 19 July 2020). This contractual framework will enable the purchase of specific amounts of doses, once one or more vaccines will be authorized on the EU market, including with:

- Sanofi-GSK on 31 July 2020 under a draft agreement for the purchase of 300 million doses. The vaccine candidate is expected to obtain a marketing authorization (MA) in June 2021;
- Johnson & Johnson on 13 August 2020 under a draft agreement to enable EU Member States to purchase the vaccine, as well as to donate to lower and middle income countries or re-direct to EEA countries. The initial purchase would concern 200 million doses, with the option of up to an additional 200 million doses;
- <u>CureVac</u> on 18 August 2020 on a draft agreement to provide a regulatory framework for the initial purchase of 225 million doses on behalf of all EU Member States; and
- Moderna on 24 August 2020 on a draft agreement to enable the purchase 80 million doses, with the option of the same additional amount.

European
Commission
finalizes the first
agreement with
vaccine
manufacturers for
the purchase of
large amounts of
COVID-19 vaccine
doses (see here)

On 14 August 2020, the Commission finalized the first APA with AstraZeneca (Agreement).

The Agreement will enable EU Member States to purchase 300 million vaccine doses, with the option of an additional 100 million doses. AstraZeneca's vaccine candidate (based on a non-replicative recombinant chimpanzee adenovirus-based vaccine ChAdOx1) is currently undergoing large-scale Phase II/III clinical trials.

The Agreement will be financed under the Emergency Support Instrument (ESI), which includes funds specifically dedicated to creating a portfolio of potential vaccines with different profiles and marketed by different MAHs.

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