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

- €25 billion Pan-European Guarantee Fund deployed for the first time
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- *No noteworthy items for this issue*

Medicines, Medical Devices, and Personal Protective Equipment

- European Medicines Agency starts evaluation of AstraZeneca COVID-19 vaccine
- Commission concludes exploratory talks with Valneva to secure an additional COVID-19 vaccine
- Commission issues Notice in relation to medical devices, including temporary measures for remote audits for assessing quality management systems
- European Commission grants conditional marketing authorization for Moderna COVID-19 vaccine

Cybersecurity, Privacy & Data Protection

- European Medicines Agency pursues investigation of cyberattack

COMPETITION & STATE AID

State Aid

€25 billion Pan-European Guarantee Fund deployed for the first time (see here)

For the first time, the €25 billion Pan-European Guarantee Fund has been deployed, following an agreement between the European Investment Bank (EIB) and Spanish bank Banca March to support economic recovery in Spain.

The EIB (the EU's long-term lending institution owned by the Member States), in particular, will provide Banca March with a guarantee of up to €100 million. This will enable the Spanish bank to activate more than €267 million of financing for Spanish companies of all sizes, in view of providing loans to promote investments and working capital that are in line with the EIB's long-term mission, such as projects related to innovation and the environment. The EIB will also assume up to 75% of the risk for loans that Banca March grants to mid-caps (between 250 and 3000 employees) and large corporates (over 3000 employees), thereby promoting the provision of new financing and indirectly reinforcing the full ecosystem of small suppliers of the companies receiving such financing.

To recall, the Pan-European Guarantee Fund was approved on 23 April 2020 as part of the package of EU measures aimed at responding to the economic impact caused by COVID-19 pandemic. The Fund is operative since October 2020 under the EIB and can deploy up to an estimated €200 billion of additional financing. The Fund's primary focus is to support small and medium-sized enterprises across Europe.

Furthermore, two additional agreements between the EIB and Banca March will raise the total sum of guarantees and loans to €270 million, thus allowing the Spanish bank to mobilize over €600 million of financing to support Spain's economic recovery.

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:

- €1.25 billion German measure to support TUI for losses related to the coronavirus outbreak
- €202 million Croatian scheme to support companies in the tourism and sports sectors in the context of the coronavirus outbreak
- €87 million Cypriot guarantee scheme to support companies in the tourism sector in the context of the coronavirus outbreak

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Medicines Agency starts evaluation of AstraZeneca

On 12 January 2020, AstraZeneca submitted an application for a conditional marketing authorization before the European Medicines Agency (EMA) for the COVID-19 vaccine developed in collaboration with Oxford University.

COVID-19 vaccine (see here)	The EMA announced that it could issue an opinion on approval of the vaccine by 29 January, provided that the quality, safety and efficacy data are sufficiently robust and complete and that the company promptly submits any eventual additional information required to complete the assessment.
Commission concludes exploratory talks with Valneva to secure an additional COVID-19 vaccine (see here)	On 12 January 2020, the European Commission concluded exploratory talks with Valneva for the purchase of its potential COVID-19 vaccine. The draft contract provides for the possibility for all Member States to purchase 30 million doses of the vaccine, once approved, with the option to buy an additional 30 million doses.
Commission issues Notice in relation to medical devices, including temporary measures for remote audits for assessing quality management systems (see here)	On 11 January 2020, the Commission issued a Notice in relation to the Medical Devices and In-Vitro Medical Devices Regulations, which lay down the requirements related to a quality management system (QMS) for devices. Manufacturers must adhere to such QMS for devices, prior to placing on the market or putting into service. A manufacturer's QMS must undergo the review of third-party bodies (Notified Bodies), In light of travel and quarantine restrictions due to the pandemic, the Commission recognizes that these have affected Notified Bodies' ability to conduct on-site audits on the premises of manufacturers and their subcontractors. The Commission therefore calls for the possibility for Notified Bodies to conduct remote audits. However, the Commission indicates that the necessity of performing remote audits should be identified and justified on a case-by-case basis and should not go beyond what is required to ensure the continuous availability of safe and performant devices. The Commission further states that on-site audits should take place as soon as possible.
European Commission grants conditional marketing authorization for Moderna COVID-19 vaccine (see here)	On 6 January 2020, the Commission granted a conditional marketing authorization for the COVID-19 vaccine developed by Moderna (COVID-19 mRNA Vaccine (nucleoside modified)). The vaccine is recommended to prevent infection by the novel coronavirus in individuals 18 years of age and older and is administered as two injections, 28 days apart (here). The trial showed a 94.1% reduction in the number of symptomatic COVID-19 cases in persons who received the vaccine compared with those who received dummy injections.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Medicines Agency pursues investigation of cyberattack (see here)	On 12 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, in cooperation with law enforcement and other relevant entities, revealed that unlawfully accessed documents related to COVID-19 medicines and vaccines have been unlawfully published on the Internet.

The EMA continues to support the criminal investigation on the data breach and shall notify and communicate any additional entities and individuals affected by the data breach.

The EMA confirmed that it nevertheless remains fully functional and that the timelines related to the evaluation and approval of COVID-19 medicines and vaccines are not affected by the data breach.

The EMA will continue to provide information, to the extent possible, on the cyberattack.

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