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
- Executive Vice-President and Competition Commissioner Vestager speech on the future of State Aid rules for the recovery from the current coronavirus outbreak

Trade / Export Controls

- *No noteworthy developments for this issue*

Medicines, Medical Devices, and Personal Protective Equipment

- European Medicines Agency (EMA) to hold a public meeting on COVID-19 vaccines approval
- EMA publishes guidance for COVID-19 vaccine developers
- European Commission adopts the Pharmaceutical Strategy for Europe
- European Commission signs Advanced Purchase Agreement with Moderna for purchase of COVID-19 vaccine

Cybersecurity, Privacy & Data Protection

- ENISA issues Report on Telecom Security During a Pandemic

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:

- €22.2 million Cypriot six-year term loan to Hermes Airports Limited to deal with the effects caused by the coronavirus outbreak
- €100 million Lithuanian scheme to support businesses affected by public emergency measures to limit the spread of COVID-19
- €10 million Irish scheme to support companies operating in the coach tourism sector affected by the coronavirus outbreak
- €7 million Irish scheme to support commercial venues, promoters, and producers of live performances affected by the coronavirus outbreak
- €434 million Belgian scheme to provide grants to cover for social-security contributions due by employers in the hospitality, culture, sports and tourism sectors between July and September affected by the coronavirus outbreak
- €30 billion German scheme to cover the fixed costs of businesses suffering from a turnover decline between March 2020 and June 2021 of at least 30% due to the coronavirus outbreak
- Austrian scheme that in addition to the scheme approved in May 2020 amounts to up to €12 billion to support uncovered fixed costs of companies affected by the coronavirus outbreak
- €1.34 billion Danish scheme to recapitalize large enterprises affected by the coronavirus outbreak
- €12.4 million Romanian scheme to support wine producers affected by the coronavirus pandemic
- €4.4 million Romanian scheme to compensate regional airport operators for damages suffered due to the coronavirus outbreak
- €120 million Luxembourgish scheme to support uncovered fixed costs of companies affected by the coronavirus outbreak
- €5.5 million Estonian scheme to support companies active in the tourism sector affected by the coronavirus outbreak
- €75 million German scheme to compensate accommodation providers for child and youth education for the loss of revenue caused by the coronavirus outbreak
- €107 million Danish scheme to support businesses affected by local COVID-19 restrictions to preserve employment

	• €750 million Portuguese scheme to support companies in sectors particularly affected by the coronavirus outbreak • €6 million Danish scheme to support the Danish aviation sector in the context of the coronavirus outbreak
European Commission Executive Vice-President Margrethe Vestager speech on the future of State Aid rules for the recovery from the current coronavirus outbreak (see here)	On 16 November 2020, Executive VP and Competition Commissioner Vestager spoke at the State Aid High Level Forum of the Member States, focusing on new State aid rules to respond to the current economic crisis caused by the pandemic. In addition to the Temporary Framework for State Aid, which is extended until mid-2021, Commission Vestager emphasized the importance of the recently introduced Recovery and Resilience Facility (see here) under the European Recovery Plan (NextGenerationEU). This unprecedented measure will allow the EU to borrow and deploy resources from a budget of up to €670 billion, in view of achieving both economic recovery and the EU's environmental and digital goals. In the coming weeks, the European Commission plans to publish a set of templates providing State aid guidance in support of the Recovery and Resilience Facility. The templates will assist Member States in designing investments in line with the Union's key priorities, in view of either avoiding notification or obtaining quick approval. Commissioner Vestager further noted the Commission's recently launched call for contributions seeking input on how State aid rules for energy and environmental protection can best support the EU's Green Deal. The next step is a concrete legislative proposal, expected in 2021.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Medicines Agency (EMA) to hold a public meeting on COVID-19 vaccines approval (see here)	On 11 December 2020, the European Medicines Agency (EMA) will hold a public meeting on the EU regulatory processes for the approval of COVID-19 vaccines and the EMA's role in the development, evaluation, approval and safety monitoring of such medicines. The meeting will provide a platform for the public and stakeholders to communicate their concerns, which EMA and the European medicines regulatory network will take into consideration in the decision-making process. The full agenda is here.
EMA publishes guidance for COVID-19 vaccine developers (see here)	On 27 November 2020, the EMA published two sets of guidelines for COVID-19 vaccines developers. Under the first set of guidelines, in particular, the EMA made available a selection of European Pharmacopoeia quality standards and related guidance on antivirals on the website of the European Directorate for the Quality of Medicines & Healthcare (EDQM). The EDQM also released guidance on: (i) analytical strategy options for developing COVID-19 viral vector-based vaccines, which aims to fill a gap in available guidance on quality in relation to these new technologies; and (ii) recombinant viral vectored vaccines for human use. The second set of guidance published by the EMA addresses packaging and labelling flexibilities on COVID-19 vaccines.

	In particular, this guidance includes practical advice on certain exemptions and provides further details on the European Commission's memorandum of Understanding with Member States on regulatory flexibility for COVID-19 vaccines.
European Commission adopts the Pharmaceutical Strategy for Europe (see here)	On 25 November 2020, the European Commission published the long-awaited Pharmaceutical Strategy for Europe. The Strategy outlines the EU's approach to promoting a strong, competitive and green industry that is responsive to patients and that draws on the potential of the digital transformation era. The Strategy is built on four pillars: – Ensuring patients with accessible and affordable medicines; – Supporting a competitive, innovative and sustainable European pharmaceutical industry; – Enhancing EU resilience and strategic autonomy in crisis preparedness and supply chain security; – Creating a strong EU voice on the global stage. The Strategy aims at, *inter alia*, addressing anti-microbial resistance and rare diseases; fostering more equitable and prompt access to medicines throughout the EU; establishing HTA (health technology assessment) policies for medicines pricing; and repatriating manufacturing of raw materials and finished pharmaceutical products to the EU. An accompanying Q&A document on key topics and the Commission goals is provided here. The Strategy will undergo immediate implementation.
European Commission signs Advanced Purchase Agreement with Moderna for purchase of COVID-19 vaccine (see here)	On 25 November 2020, the Commission signed an Advanced Purchase Agreement (APA) for the purchase of 80 million doses of Moderna's potential COVID-19 vaccine. This is the sixth agreement entered into between the Commission and COVID-19 vaccine developers. Under this APA, the Commission also has option to purchase an additional 80 million doses. The rolling review of Moderna's vaccine already commenced on 16 November 2020, as communicated by the EMA (here).

CYBERSECURITY, PRIVACY & DATA PROTECTION

ENISA issues Report on Telecom Security During a Pandemic (see here)	On 26 November 26, 2020, the European Union Agency for Cybersecurity (ENISA) issued a report on Telecom Security During a Pandemic (Report). The Report highlights that the COVID-19 pandemic led to far greater reliance on electronic communication networks and services due to remote working, schooling, and a heightened demand for online service offerings. The need for secure and robust electronic communication networks and services is more critical than ever. The Report focuses on the telecom sector's role in responding to these needs. It examines modifications in usage, traffic patterns, and network performance during the COVID-19 pandemic and provides an overview of

initiatives and good practices in the telecom sector to mitigate the impact of the pandemic. The Report also highlights the current strength and resilience of the telecom sector, despite the COVID-19 pandemic.

Among the many illustrations of coordinated responses to the pandemic, in Denmark, the competent authority (Centre for Cyber Security (CFCS)) handled the lockdown in close collaboration with the most essential communications providers. These providers regularly reported on operating status, special challenges and problems, risks related in particular to COVID-19, and any unusual cyber-related incidents. Emergency legislation was also enacted to enable the police to prevent access to malicious websites.

However, the Report makes it clear that increased cooperation between the public and private sectors is needed to ensure the strength of telecom security.

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