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
- DG COMP publishes overview of State aid rules in the aviation sector
- DG COMP invites comments on updated proposal on simplified rules for State aid combined with EU support

Trade / Export Controls

- Commission Guidance on provision of coronavirus-related humanitarian aid to Syria despite EU sanctions
- EU seeks to increase cooperation with the US to mitigate COVID-19's impact

Medicines, Medical Devices, and Personal Protective Equipment

- EMA recommendation on expansion of Remdesivir compassionate use

Cybersecurity, Privacy & Data Protection

- ENISA provides cybersecurity advice in healthcare sector during COVID-19 pandemic
- eHealth Network published Interoperability guidelines for approved contact tracing mobile applications in the EU

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 as of 15 May 2020 include:

- Danish guarantee scheme to stabilize trade credit insurance market in coronavirus outbreak
- French guarantee scheme for exporting small and midsize companies affected by the coronavirus outbreak.
- €450 million Polish scheme to support companies affected by the coronavirus outbreak.
- €500 million Greek scheme to support the self-employed affected by the coronavirus outbreak.
- €10.3 billion UK scheme to support self-employed individuals and members of partnerships during the coronavirus outbreak.
- €11.5 million Maltese scheme to support investments in the production of coronavirus-relevant products.
- €1.5 million Latvian scheme to support companies active in the agricultural sector affected by the coronavirus outbreak.
- €25 million Belgian aid scheme to support coronavirus related research and development activities in Wallonia.
- €322 million Croatian loan guarantees and subsidized loans scheme for micro, small and medium-sized companies affected by the coronavirus outbreak.
- €88 million Bulgarian scheme to support micro and small companies affected by the coronavirus outbreak.
- €500 million Belgian guarantee scheme to support internationally active companies affected by the coronavirus outbreak
- €40 million Maltese support scheme to grant interest rate subsidies to companies
- €18.5 billion Czech guarantee scheme for companies affected by coronavirus outbreak

DG COMP publishes overview of State aid rules in the

On 14 May 2020, DG COMP published a working document that provides an overview of the State aid rules and public service obligations rules applicable to the air transport sector during the COVID-19 outbreak.

aviation sector (see here)	The document provides guidance on the various support measures Member States may use, primarily with respect to airlines and airport operators, in line with EU State aid rules and Public Service Obligations rules in the exceptional context of the COVID-19 crisis. The document describes: (i) measures that do not constitute State aid within the meaning of Article 107(1) TFEU and, therefore, need not be notified to the Commission, (ii) measures that constitute State aid but may be exempted from notification to the Commission if they fulfil certain requirements, and (iii) measures that constitute State aid and must be notified to the Commission. The document does not address exit plans and post-crisis return to normal activities.
DG COMP invites comments on updated proposal on simplified rules for State aid combined with EU support (see here)	The European Commission is inviting Member States and other stakeholders to comment on its updated proposal to exempt aid from prior Commission scrutiny under EU State aid rules, where such aid is granted through national funds for projects supported under certain EU centrally managed programs. Member States were previously consulted on an earlier draft proposal. The Commission seeks to improve the interplay between EU funding rules and EU State aid rules. The proposal is therefore to streamline the State aid rules applicable to national funding of projects or financial products, which fall under the scope of certain EU programs. The Commission believes this will facilitate the combination of national and EU funds by exempting certain aid from prior notification and scrutiny under EU State aid rules. When launching this consultation, Executive Vice President Margrethe Vestager referred to the Commission's creation of specific temporary rules for aid to tackle the economic consequences of the coronavirus outbreak, but noted that it is a long term EU priority to enable funding that does not cause undue distortions of competition to quickly reach companies operating in the EU's Single Market.

TRADE / EXPORT CONTROL

Commission Guidance on provision of coronavirus-related humanitarian aid to Syria despite EU sanctions (see here)	On 11 May 2020, the Commission published a Guidance Note for competent authorities of EU Member States, as well as public and private operators involved in humanitarian activities, on how to comply with EU sanctions when providing humanitarian aid to fight the coronavirus pandemic. This Note covers EU sanctions placed on Syria and will be progressively updated to include further guidance on this and other sanctions regimes. Among other issues, the Guidance addresses whether exports to Syria of various products needed to fight against COVID-19 are allowed under the relevant Regulation (Council Regulation No 36/2012 of 18 January 2012 concerning restrictive measures in view of the situation in Syria). This Regulation prohibits exporting goods of potential use for military activities or internal repression. A number of exceptions, however, are envisaged under the Regulation, notably for humanitarian purposes. Accordingly, the Guidance stipulates that, in principle, goods such as ventilators for medical purposes, other medical

	devices, PPE, COVID-19 testing kits, medicines, disinfectants, detergents or chemical used to fight the COVID-10 pandemic do not fall under the scope of the export restrictions of the Regulation concerning Syria. Nevertheless, for certain items, a case-by-case assessment and/or prior authorization by a national competent authority (NCA) may be needed before allowing their export. This concerns, in particular, power respirators, certain items used as PPE, such as masks, gloves and protective shoes, and some chemical substances, as these products could also be used for military purposes.
EU seeks to increase cooperation with the US to mitigate COVID-19's impact (see here)	The EU is pursuing new trade negotiations with the US, according to a press report, in view of ending their trade disputes and agreeing to work together to mitigate the effects of the COVID-19 crisis. In a letter to the US Trade Representative Robert Lighthizer dated 30 April 2020, EU Trade Commissioner Phil Hogan put forward "a transatlantic agenda for recovery", calling for the EU and US to come together to avoid future shortages of medical supplies. Ideas raised by the EU include the creation of "joint reserves" of medical equipment, as inspired by a similar arrangement established after the 1973 oil shock. Other discussion topics include seeking to facilitate transatlantic trade in medical devices and vaccines.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

EMA recommendation on expansion of Remdesivir compassionate use (see here)	On 11 May 2020, the European Medicines Agency (EMA) recommended extending the compassionate use of remdesivir to additional groups of patients on the basis of preliminary study results obtained in recent weeks. In particular, preliminary results of a U.S. National Institutes of Health study found that patients treated with remdesivir had a 31% quicker time to recovery than those receiving a placebo. In light of such findings, EMA recommendations for compassionate use of remdesivir now go beyond those on invasive mechanical ventilation. Such use now includes hospitalized patients who require supplemental oxygen, non-invasive ventilation, high-flow oxygen devices, or extracorporeal membrane oxygenation. Moreover, the EMA now recommends a shortened five-day treatment duration for certain patients (in addition to the longer ten-day course) based on the results of another study that found that such shorter treatment period did not affect the efficacy results for patients not on ventilators or extracorporeal membrane oxygenation. Such briefer course of treatment will allow more patients to access remdesivir, which is globally in high demand.

CYBERSECURITY, PRIVACY & DATA PROTECTION

ENISA provides cybersecurity advice in healthcare sector during COVID-19	On 11 May 2020, the European Union Agency for Cybersecurity (ENISA) issued advice to support hospitals and the healthcare sector in combating phishing campaigns and ransomware attacks during the COVID-19 crisis.

pandemic (see here)	The pandemic has provided fertile ground for hackers, especially in the healthcare sector, whose focus is on its primary role of fighting the virus. The healthcare sector has become particularly vulnerable for multiple reasons such as the high demand of healthcare products (e.g., protective masks, disinfectants and household products), and greater reliance on teleworking, but often without experience and planning. To address such cybersecurity issues, ENISA recommends the following: • Share information and raise awareness on the ongoing situation of cyberattacks and vulnerabilities amongst staff members (e.g., inform hospital staff not to open suspicious emails). In case of an attack, inform and ask staff to disconnect from the network to contain the spread). • If systems are compromised, freeze any activity in the system, disconnect infected machines from others and from any external drive or medical device, disconnect from the network and immediately contact the national CSIRT. • Ensure business continuity through effective backup and restoring procedures. Business continuity plans should be established whenever the failure of a system may disrupt the hospital's core services, and the role of the supplier in such cases must be well-defined. • In case of an impact on medical devices, the incident response should be coordinated with the device manufacturer, as well as in close collaboration with vendors to address incidents on medical devices or clinical information systems. • Favor network segmentation to isolate and/or filter traffic to limit and/or prevent access between network zones. ENISA added that the cybersecurity community is mobilized to address these issues and support the healthcare sector as the pandemic evolves.
eHealth Network published Interoperability guidelines for approved contact tracing mobile applications in the EU (see here)	On 13 May 2020, the eHealth Network published Interoperability Guidelines for approved contact tracing mobile applications in the EU ("Guidelines"). The Guidelines address the interoperability framework for mobile contact tracing apps following the eHealth Network's Toolbox published on 16 April 2020 (see earlier *Key EU Developments (No. 4)*) The Guidelines aim at ensuring that mobile contact tracing apps are efficient throughout Europe by providing for their interoperability. Interoperability consists of an app's ability to exchange information necessary for app users, regardless of whether or not they are located in the EU. This will allow app users to be alerted if they have been in proximity with another user who has notified the app that s/he has tested positively to COVID-19. The alerts and follow-up measures must, however, comply with the procedures defined by public health authorities. Next steps. Based on these Guidelines, the eHealth Network and the New Generation Internet community will agree on further technical details to ensure

	the operationalization of interoperability. The Commission will also create a collaborative website to dialog with app developers.

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