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
- European Commission expresses concern over discrepancies in State aid

Trade / Export Controls

- Chair of INTA sends letter to EU Trade Commissioner on intellectual property rights and counterfeit trade in context of COVID-19
- Upcoming INTA meeting to discuss impact of COVID-19 on trade

Medicines, Medical Devices, and Personal Protective Equipment

- Cooperation on observational research on COVID-19: International Coalition of Medicines Regulatory Authorities
- European Commission Guidelines on adopting Union-wide derogations for medical devices
- European Commission considers introducing insurance coverage for COVID-19 vaccines

Cybersecurity, Privacy & Data Protection

- ENISA publishes recommendations on Securing smart infrastructure during the COVID-19 pandemic

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: • Finnish State guarantee on €600 million loan to Finnair in the context of coronavirus outbreak. • €70 million Italian direct grants scheme to support companies active in the agricultural and fishery sectors affected by coronavirus outbreak in Campania region. • €84 million Austrian regional aid schemes to support companies and investment in research, development, testing and production of coronavirus relevant products. • €99 million Hungarian scheme to support the agri-food, aquaculture and forestry sectors affected by coronavirus outbreak. • €9 billion Italian "umbrella" scheme to support economy in coronavirus outbreak. • €8 billion Austrian scheme to compensate companies for damage caused by coronavirus outbreak.
European Commission expresses concern over discrepancies in State aid (see here)	European Commission Executive Vice President Margrethe Vestager has expressed concern over "huge differences" in State aid provided in EU Member States. The Commission believes, according to statements to the media, this is starting to distort the EU's single market. Vestager indicated in recent interviews that different levels of State aid would distort competition and therefore slow the economic recovery from the COVID-19 pandemic. The European Commission is expected to put forward a Recovery Plan on 27 May, which is anticipated to include measures to restore a level playing field between financially well-resourced Member States, such as Germany, and Member States currently lacking the financial means for similar levels of spending.

TRADE / EXPORT CONTROL

Chair of INTA sends letter to EU Trade Commissioner on intellectual	On 15 May 2020, the Chair of INTA (European Parliament Committee on International Trade) sent a letter to EU Trade Commissioner Hogan inquiring on the role of intellectual property rights (IPRs) for medicines in the context of the COVID-19 pandemic.

property rights and counterfeit trade in context of COVID-19 (see here)	The letter asks the Commission to elaborate on the impact of IPRs on the eventual global availability of a vaccine. The INTA also seeks guidance on tools available under the EU's existing free trade agreements and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in view of securing such a vaccine or other needed medicines produced abroad, including the possibility of compulsory licensing. In addition, the letter raises the issue of counterfeit trade in medical goods and medicines, which has affected several Member States during the current pandemic. The letter inquires as to any plans to strengthen the EU's anti-counterfeiting activities to avoid problems such as delivery of sub- standard goods or outright fraud.
Upcoming INTA meeting to discuss impact of COVID-19 on trade (see here)	The next meeting of INTA (European Parliament Committee on International Trade) will take place on 28 May 2020 with remote participation and will be webstreamed. The Committee will discuss, inter alia, COVID-19's impact on trade with EU Trade Commissioner Hogan.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

Cooperation on observational research on COVID-19: International Coalition of Medicines Regulatory Authorities (see here)	On 20 May 2020, regulatory authorities (including the European Medicines Agency) participating in the International Coalition of Medicines Regulatory Authorities (IMRA) agreed to cooperate on observational research in the context of COVID-19. The cooperation will focus on three key areas: (i) Pregnancy research: Assessing the impact of COVID-19 on pregnancy and the use of available treatments on pregnant women and their unborn babies; (ii) Medicinal products used in treating the virus: Establishing international clinical cohorts of patients with the goal of gathering stronger data quality and increasing the effectiveness of trials; and (iii) Monitoring of vaccine safety and effectiveness by creating a strong monitoring infrastructure.
European Commission Guidelines on adopting Union-wide derogations for medical devices (see here)	On 19 May 2020, the Commission Communication was published on "*Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745*" ("Guidelines"). Article 59 of the Medical Device Regulation allows Member State Regulatory Authorities (MRAs) to authorize a derogation for the placing on the market/putting into service within their territory of a specific device for which the conformity assessment procedures have not been carried out. A derogation for such device must be in the interest of public health or patient safety/health, upon a duly justified request. In response to COVID-19 disruptions, however, the date of application of the Medical Device Regulation was recently postponed until May 2021. This amended regime nonetheless provides that MRAs may still rely on the Article

	59 derogation under the currently applicable regime of the Medical Device Directive. Member States relying upon Article 59 must inform the Commission and the other Member States of any such decision to authorize the placing on the market/putting into service of a device for more than a single patient. In such case, the Commission can broaden the validity of a national derogation for a limited period of time to the full territory of the Union ('Union-wide derogation'). Such Union-wide derogations should only to be considered in exceptional cases to ensure patient health or safety or to protect public health. The Guidelines illustrate the procedural steps and justification requirements that must be followed in order to adopt EU-wide derogations. In particular, at least one derogation must be granted by an MRA and notified to the Commission, together with the justification and the technical documentation relevant to the device. The Guidelines also clarify that when granting EU-wide derogations, the Commission may request additional information and impose stricter conditions than those established at Member State level by MRAs.
European Commission considers introducing insurance coverage for COVID-19 vaccines (see here)	According to recent press reports, the European Commission is contemplating the introduction of insurance coverage through the Emergency Support Instrument (ESI), which is currently funded with EUR 2.7 billion. Such eventual insurance coverage is in the context of a wider effort to boost vaccine development in the EU. The insurance would make vaccine manufacturing more attractive to pharmaceutical companies, which might otherwise refrain from developing new products because of concerns over potential liability claims in case of – lack of safety and/or efficacy of the newly developed products.

CYBERSECURITY, PRIVACY & DATA PROTECTION

ENISA publishes recommendations on Securing smart infrastructure during the COVID-19 pandemic (see here)	On 18 May 2020, the European Union Agency for Cybersecurity (ENISA) published recommendations on Securing smart infrastructure during the COVID-19 crisis ("Recommendations"). The Recommendations shed light on the shift in daily habits, occurring mainly from home, causing an increase in cybersecurity vulnerabilities. The Recommendations focus on securing (i) the home and (ii) business premises. **(i) Securing the home**. To secure smart devices the ENISA advises the following: • Use long passwords, two or multi-factor authentication and, if available biometrics of additional PINS. • Use different passwords for different devices. • Enable relevant security features during the initial setup and apply user guides. • Set up update notifications and perform updates on a regular basis. • Avoid sharing sensitive information and use caution in the way information is used.

- Turn off and unplug devices when no longer in use.
- Set up multiple networks on routers and keep smart devices on a separate Wi-Fi network.
- Wipe clean with a "factory reset" any device before disposing or returning them back.

(ii) Securing business premises. ENISA recommends to secure networks, monitor network anomalies, identify malicious behavior including social engineering, check phishing attempts, and review Internet of Things (IoT) security configurations. In addition, the ENISA recommends to:

- Enable firewall protection, and ensure the corporate network is only accessible from whitelisted services.
- Disable unused ports.
- Apply network micro-segmentation by creating virtual networks to isolate IoT systems from other critical IT systems.
- Enable monitoring and diagnostics and review them regularly.
- Prepare and update incident response plans with current risks.

LAWYER CONTACTS

Renato Antonini
Partner, Government Regulation; Antitrust & Competition Law
Brussels
rantonini@jonesday.com
+32.2.645.14.19

Dr. Jörg Hladjk
Partner, Cybersecurity, Privacy & Data Protection; Government Regulation; Technology
Brussels
jhladjk@jonesday.com
+32.2.645.15.30

Kaarli H. Eichhorn
Partner, Antitrust & Competition Law; Government Regulation; Technology
Brussels
keichhorn@jonesday.com
+32.2.645.14.41

Cristiana Spontoni
Partner, Health Care & Life Sciences; Government Regulation
Brussels
cspontoni@jonesday.com
+32.2.645.14.48