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

Trade / Export Controls

- *No noteworthy developments for this issue*

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission launches Database on COVID-19 in-vitro diagnostic devices and test methods
- European Commission Guidance on regulatory requirements for medical face masks
- EMA recommends granting the first conditional marketing authorization for COVID-19 treatment in the EU
- International Council of Medicines Regulatory Authorities' (ICMRA) meeting on COVID-19 vaccine trials harmonization
- European Commission, EMA and FDA agree on new collaboration priorities

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:

- €145 million Hungarian scheme to compensate large companies for damages suffered due to the coronavirus outbreak
- €21 million Belgian scheme to support the production of coronavirus-relevant products in the Flemish region
- €40 million Portuguese scheme to support companies affected by the coronavirus outbreak in the autonomous region of Madeira
- €6 billion German measure to recapitalize Lufthansa
- €50 million Lithuanian measures in support of companies operating in the travel sector affected by the coronavirus outbreak
- €280 million Cypriot schemes to support companies and self-employed affected by the coronavirus outbreak
- €2.6 million Czech scheme to support companies affected by the coronavirus outbreak in the Moravia-Silesia region
- €7.6 billion Italian tax schemes to support companies and self-employed workers affected by the coronavirus outbreak

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Commission launches Database on COVID-19 in-vitro diagnostic devices and test methods (see here)

On 26 June 2020, the Commission launched the COVID-19 in-vitro diagnostic devices (IVDs) and test methods database (Database), in application of the European Commission's *Guidelines on COVID-19 in vitro diagnostic tests and their performance* (here).

The Database's purpose is to collect all publicly available information on the performance of CE-marked IVDs, as well as in-house laboratory-developed devices and related test methods for COVID-19. The Database, in particular, provides the following information:

- For CE-marked devices, information includes only performance details and information that manufacturers have made publicly available;
- Devices labelled as "for research use only", or "under development", are listed solely for information purposes;
- In-house or laboratory developed devices used in healthcare institutions (authorized under national law and not commercially available) do not appear in the list of devices, but pertinent scientific publications and related test methods are included in the Database section on "Scientific literature".

European Commission Guidance on regulatory requirements for medical face masks (see here)	On 26 June 2020, the European Commission published *Guidance on regulatory requirements for medical face masks*. The Guidance summarizes the classification of masks used in the context of the COVID-19 pandemic. In particular, face masks that are medical devices are distinguished from those falling under the definition of personal protective equipment (PPE) and "face covers" that "*do not meet the legal definitions of a PPE and neither they meet the legal definition of a medical device, as there is no intended medical or personal protection purpose made by the manufacturer*." The Guidance illustrates the regulatory options for placing medical face masks on the European Union market as medical devices, particularly in view of facilitating swift supply under the current circumstances and given that various industries have expressed interest in supporting and ramping up the production of medical face masks. For face masks considered as PPE, these fall under the scope of Regulation (EU) 2016/425 on personal protective equipment. For face covers, specific legislation may apply at national level.
EMA recommends granting the first conditional marketing authorization for COVID-19 treatment in the EU (see here)	On 25 June 2020, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended granting a conditional marketing authorization (MA) to Veklury (*remdesivir*) for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen. This is the first medicine in the European Union to be recommended for COVID-19. The data submitted by Veklury mainly relate to the NIAID-ACTT-11 study, a trial sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID), which evaluated the effectiveness of a planned 10-day course of remdesivir in over 1,000 hospitalized patients affected by COVID-19. Veklury must also submit quality and mortality data to the EMA by August 2020, as well as final reports of relevant studies by December 2020. Following this positive CHMP opinion, the European Commission shall now adopt a final decision granting, or refusing, the conditional MA for Veklury. Following a positive decision, the medicine would become available at national level in accordance with the national laws of the EU Member States.
International Council of Medicines Regulatory Authorities' (ICMRA) meeting on COVID-19 vaccine trials harmonization (see here)	On 22 June 2020, the International Council of Medicines Regulatory Authorities (ICMRA) held a virtual meeting on the necessity for international convergence in order to proceed to phase 3 trials for COVID-19 vaccines. In particular, representatives of the regulatory agencies emphasized the importance of harmonizing clinical and non-clinical aspects of phase 3 clinical trials, such as: eligibility criteria and selection of primary endpoints. Harmonization of these key aspects will streamline both the development and authorization process of COVID-19 vaccines. This meeting's conclusions will be agreed upon and published in the coming days.

European Commission, EMA and FDA agree on new collaboration priorities (see here)	On 22 June 2020, the European Commission, European Medicines Agency (EMA), and Food and Drug Administration (FDA) published the conclusions of their annual bilateral dialogue, which agreed on new priorities for collaboration in relation to medicinal products. The regulators are collaborating, *inter alia*, on sharing their experiences in facilitating the development, review and availability of COVID-19 vaccines and on generating reliable real world data to support regulatory decision-making. Moreover, the regulators indicated that the currently applicable mutual recognition agreement on good manufacturing practice (GMP) inspections could be extended by July 2020 to include vaccines, plasma-derived medicinal products, and veterinary products.

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