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

- The European Union purchases remdesivir for short-term needs of 30,000 patients
- International medicines regulatory agencies agree on acceptable end-points for clinical trials

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:

- €20 million Lithuanian scheme to compensate companies active in the processing of agricultural products in the poultry and eggs sectors for damages caused by coronavirus outbreak
- UK guarantee scheme to stabilize trade credit insurance market in the context of the coronavirus outbreak
- €840 million German guarantee scheme to protect consumers and support the travel industry in the context of the coronavirus outbreak
- €28 million Bulgarian scheme in support of tour operators affected by the coronavirus outbreak
- €35 million Belgian scheme to support potato and ornamental plant growers active in the Flemish region affected by the coronavirus outbreak
- €866 million Czech scheme to support businesses affected by the coronavirus outbreak
- €50 million Belgian scheme for companies active in the events sector in Flanders and affected by the coronavirus outbreak
- €123 million Polish scheme to support companies affected by the coronavirus outbreak
- €1 million Romanian aid scheme for airlines starting or resuming operations at Oradea airport following the coronavirus outbreak
- €19 million Latvian scheme in support of the tourism and events organization sectors affected by the coronavirus outbreak
- Second modification to the French scheme to support economic recovery during the coronavirus crisis
- €165 million Dutch measure to support the travel industry in the context of the coronavirus outbreak

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

The European Union purchases remdesivir for short-term needs

On 29 July 2020, the European Commission announced its agreement with Gilead for the supply of Veklury (remdesivir) to address the short-term needs of about 30,000 patients.

of 30,000 patients (see here)	Veklury is the only medicinal product authorized in the European Union for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia and requiring supplemental oxygen (*see Jones Day COVID-19 Update (no. 15) of 3 July 2020*). Under the €63 million agreement with Gilead, each patient is expected to receive six doses. The price per dose amounts to some €345. However, this price applies only to the current supply and may be revised for eventual future orders by the Commission.
International medicines regulatory agencies agree on acceptable end-points for clinical trials (see here)	On 31 July 2020, the International Coalition of Medicines Regulatory Authorities (IMCRA) published a Report on the second COVID-19 workshop. The Report sets forth the primary endpoints* considered as acceptable by medicines regulatory agencies in relation to ongoing/completed clinical trials. IMCRA members also discussed other endpoints, including progression of disease, number of days not on a ventilator and recovery rates, but the members did not reach a consensus as to their acceptability. The next IMCRA meeting will focus on other significant clinical trials aspects, such as enrolled patient populations and definition of control arm. * *Primary endpoints are the main results measured at the end of a study to determine if a given treatment was effective (e.g., the number of deaths, or the variance in survival rates between the treatment group and control group).*

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