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

- European Court of Auditors reviews risks, challenges and opportunities in the EU's economic policy response to the COVID-19 crisis
- 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 medicines agencies network presents Strategy to 2025
- EMA further expands transparency in relation to COVID-19 medicinal products
- EMA commences evaluation for granting marketing authorizations for two COVID-19 vaccines
- EMA starts rolling review of COVID-19 vaccine

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

COMPETITION & STATE AID

State Aid

European Court of Auditors reviews risks, challenges and opportunities in the EU's economic policy response to the COVID-19 crisis (see here)

On 9 December, 2020, the European Court of Auditors ("ECA") published a review on "Risks, challenges and opportunities in the EU's economic policy response to the COVID-19 crisis." The ECA, in particular, highlights a "major challenge" facing competition enforcers in light of State aid packages adopted by Member States in response to the pandemic.

Under the Temporary Framework for national state aid schemes (see below list of latest measures), the European Commission ("Commission") adopted a set of objective criteria to limit distortions to competition on the internal market. Data on fiscal measures now shows great variances in the intensity of crisis-related State aid relief adopted by the Member States, with Germany accounting for almost half of the overall State aid decisions granted in the EU (€1 trillion).

EU Commission Executive Vice President Margrethe Vestager has earlier mentioned the risks and opportunities raised by the different levels of fiscal space available in Member States to support the economy. She referred, for example, to Germany's decision to take full advantage of the EU's relaxed State aid rules as a possible "locomotive" for Europe. But, Executive Vice President Vestager has also noted the EU's recovery fund's important role in levelling the playing field and avoiding potential distortions in the internal market.

The ECA's review also indicates that these divergent national reactions to the crisis may persistently distort the level playing field between companies in the single market and widen the economic lead of Member States that can support their economies more abundantly.

The ECA notes that the Commission faced a similar situation with the financial crises of 2007-2008, where it also used such type of temporary framework. The ECA further mentions that the Commission subsequently did not adapt State aid rules applied to the financial sector to changing market realities and regulatory frameworks.

As observed by the ECA, the Commission's challenge remains to monitor market developments and substantial volumes of State aid. Additionally, in the face of ongoing confinement measures and border controls, the ECA notes that the Commission shall continue to play a key role in defending the functioning of the single market and fundamental European freedoms through oversight of the proportionality of such national measures.

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:

- €11.7 million Croatian scheme to compensate Croatia Airlines for damage caused by the coronavirus outbreak

- €15 million Bulgarian scheme to support micro, small and medium-sized coach companies affected by the coronavirus outbreak
- €3.5 billion German scheme allowing German federal and regional authorities to provide capital support to enterprises affected by the coronavirus outbreak
- €20 million UK scheme to compensate Scottish airports for damage suffered due to the coronavirus outbreak
- €625 million Italian scheme to support tour operators and travel agencies affected by the coronavirus outbreak
- €500 million Italian scheme to sustain business activities in historic centers of the most touristic cities affected by the coronavirus outbreak
- €300 million budget increase and timeline extension for Italian scheme to support companies active in agriculture, forestry, fishery, aquaculture and other related sectors affected by the coronavirus outbreak
- €1.5 million Luxembourg scheme to support the meat sector affected by the coronavirus outbreak
- €132.5 million Hungarian scheme to support catering, culture sports and accommodation sectors in the context of the coronavirus outbreak
- Danish umbrella scheme to support self-employed undertakings affected by the coronavirus outbreak with an estimated budget of €67 million per month
- €9.3 million Croatian scheme to support enterprises active in primary agricultural sector affected by the coronavirus outbreak
- French measures of €106.7 million restructuring aid and €30.2 million compensation for damages suffered due to the coronavirus outbreak in favor of French airline Corsair
- Creation of €200 billion Pan-European Guarantee Fund managed by the European Investment Bank (EIB) to support mainly small and medium-size enterprises affected by the coronavirus outbreak in the 21 participating Member States
- Danish scheme to support organizers of events with 350 or more participants that are subject to restrictions due to the coronavirus outbreak with an estimated budget of €2 million per month
- Modifications to Spanish umbrella scheme to further support the economy in light of the coronavirus outbreak

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European medicines agencies network presents Strategy to 2025 (see here)	On 8 December 2020, the European medicines agencies network (EMRN) presented its "*Strategy to 2025: Protecting public health at a time of rapid change*", laying down high-level goals and supporting recommendations that will shape and feed into the work plans of EMRN members in the next five years.

	Acting under the supervision of the Commission, the EMRN comprises the national medicine authorities of the 27 EU Member States, as well as those of Iceland, Liechtenstein and Norway, under the aegis of the Heads of Medicines Agencies (HMA) and the centralized regulator and coordinating body, the European Medicines Agency (EMA). The Strategy outlines six focus areas, in line with the forthcoming Pharmaceutical Strategy for Europe (*see Jones Day Update no. 28 of 1 December 2020*). In particular, the EMRN Strategy will focus on: – Availability and accessibility of medicines; – Data analytics, digital tools and digital transformation; – Innovation; – Antimicrobial resistance and other emerging health threats; – Supply-chain challenges; and – Sustainability of the network and operational excellence. Each focus area is accompanied by a list of specific actions, as detailed in the Strategy (Annex 1), to be developed and implemented in the EMRN members' multi-annual work plans.
EMA further expands transparency in relation to COVID-19 medicinal products	In December 2020, the EMA broadened the exceptional transparency measures for medicinal products aimed at treating or preventing COVID-19. Such measures aim at shortening EMA's standard publishing timeframes and publishing information not ordinarily published for other medicines. Adding to a variety of existing enhanced transparency measures for COVID-19 medicines, the EMA will now also publish both monthly safety updates for vaccines, as well as assessment reports of safety signals (i.e. information on a new or known adverse event potentially caused by a medicine and warranting further investigation) (here). Furthermore, the EMA has published information on studies for the approval of COVID-19 vaccines, together with a summary of information to help laypersons to understand the Agency's scientific assessment for the approval of such products (here).
EMA commences evaluation for granting marketing authorizations for two COVID-19 vaccines	On 1 December 2020, the EMA received applications for conditional marketing authorizations (CMAs) for COVID-19 vaccines from Moderna (here) and Pfizer (here). The two CMAs are expected to be granted in the coming weeks.
EMA starts rolling review of COVID-19 vaccine (see here)	On 1 December 2020, the EMA also commenced the rolling review of the Janssen-Cilag COVID-19 vaccine, following preliminary results from lab studies and early clinical studies in adults. The EMA's rolling review will continue until sufficient evidence is available for a formal marketing authorization application.

LAWYER CONTACTS

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

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

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

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