COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 39 | 10 March 2021

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 Commission pursues Fit for Future Platform to simplify EU law, including in the area of State aid, particularly in response to the pandemic
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- EU and U.S. agree to suspend all tariffs linked to Airbus and Boeing WTO disputes, benefitting both sides during the pandemic
- European Commission pursues Fit for Future Platform to simplify EU law, including in the area of Customs, particularly in response to the pandemic

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission and EMA open pilot project investigating deferred market launches of centrally authorized medicinal products
- EMA commences rolling review of Sputnik COVID-19 vaccine
- European Commission pursues Fit for Future Platform to simplify EU law, including in the area of Health, particularly in response to the pandemic

Cybersecurity, Privacy & Data Protection

- *No noteworthy items for this issue*

COMPETITION & STATE AID

State Aid

European Commission pursues Fit for Future Platform to simplify EU law, including in the area of State aid, particularly in response to the pandemic (see here)

On 5 March 2021, the Commission announced the Fit for Future Platform's selection of 15 initiatives aimed at simplifying EU law.

Launched in May 2020, the Platform gathers a high-level expert group to assist the Commission with simplifying existing EU laws and reducing administrative burdens for businesses and citizens, which are particularly needed in the face of the COVID-19 pandemic.

As explained by Maroš Šefčovič, Vice-President for Interinstitutional Relations and Foresight and Chairman of the Fit for Future Platform: "*Simplification has become more important than ever, as we seek to kick-start Europe's economy, hit by the pandemic…. We must ensure that EU laws provide the intended benefits for the economy and society, while simplifying existing legislation, reducing burden wherever possible and staying forward-looking*."

The 15 targeted areas span a range of sectors, including competition, customs, and health, as well as finance, the environment, statistics and transport, and the internal market.

In particular, the area of State aid focuses on revision of the Guidelines on State aid to the Agricultural and Forestry Sectors and in Rural Areas and Agricultural Block Exemption Regulation.

The Platform will issue opinions on the 15 targeted topics, which will contribute to the Commission's ongoing work to simplify existing EU laws. Stakeholders are invited to comment on each of these topics until 30 April 2021, for consideration by the Platform in preparing its 2021 opinions.

For further details on the Platform, see below Section on Trade/Export Controls and Section on Medicines.

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:

- Modification of €1.2 billion Danish "umbrella" scheme to support self-employed affected by the coronavirus outbreak
- French guarantee scheme mobilizing up to €20 billion support from private investors for companies affected by the coronavirus outbreak
- €34 million Danish tax deferral scheme to support SMEs affected by the coronavirus outbreak
- €5 million Swedish scheme to support companies active in air ambulance services in the context of the coronavirus outbreak
- €26 million Greek scheme to support enterprises active in the primary agricultural sector affected by the coronavirus outbreak

	• €38.5 million Czech scheme to support ski resort operators affected by the coronavirus outbreak • €400,000 Croatian scheme to support fattening pig farmers affected by the coronavirus outbreak • €55 million Irish "umbrella" scheme to support companies active in tourism or in directly related sectors in the context of the coronavirus outbreak • €39.7 million Latvian measures to recapitalize Riga International Airport
TRADE / EXPORT CONTROLS	
EU and U.S. agree to suspend all tariffs linked to Airbus and Boeing WTO disputes, benefitting both sides during the pandemic (see here)	On 5 March 2021, the EU and U.S. agreed to a four-month suspension of all retaliatory tariffs on EU and U.S. exports imposed in the Airbus and Boeing disputes. The suspension will enable both sides to focus on resolving the long-running World Trade Organization (WTO) Aircraft disputes. As stated by European Commission Executive Vice-President and Trade Commissioner Valdis Dombrovskis: "*This is a significant step forward. It marks a reset in our relationship with our biggest and economically most important partner. Removing these tariffs is a win-win for both sides, at a time when the pandemic is hurting our workers and our economies…. A positive EU-U.S. trade relationship is important not only to the two sides but to global trade at large*." The four-month suspension will provide a significant boost to EU exporters, as the U.S. had been authorized to raise tariffs on $7.5 billion of EU exports to the U.S. Similarly, EU tariffs will be suspended on approximately $4 billion worth of U.S. exports into the EU. In a Joint EU and US Statement on the WTO Aircraft disputes, also issued on March 5, both sides signaled their commitment to a fresh start to their relationship and to reaching a comprehensive and enduring solution to the disputes.
European Commission pursues Fit for Future Platform to simplify EU law, including in the area of Customs, particularly in response to the pandemic (see here)	On 5 March 2021, the Commission announced the Fit for Future Platform's selection of 15 initiatives aimed at simplifying EU law and reducing administrative burdens for businesses and citizens, viewed as particularly needed in responding to the COVID-19 pandemic. In the area of customs, this includes an interim evaluation of the implementation of the Union Customs Code (Regulation (EU) No 952/2013 of 9 October 2013 laying down the Union Customs Code). *For further details on the Platform, see above Section on Competition & State Aid and below Section on Medicines.*
MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT	
European Commission and EMA open pilot project	On 4 March 2021, the European Commission and the European Medicines Agency ("EMA") opened a pilot project on the "*Market Launch of Centrally Authorised Products*" ("Pilot Project").

investigating deferred market launches of centrally authorized medicinal products (see here)	The Pilot Project builds on the Pharmaceutical Strategy adopted in November 2020, whereby the Commission committed, *inter alia*, to investigate the "*root causes of deferred market launches*". Such deferrals cause certain authorized medicinal products to become available in some Member States with significant delay or not at all. The Pilot Project intends to assist regulators in understanding the reasons leading to such marketing delays of certain medicinal products following the granting of marketing authorization. In particular, marketing authorization applicants for medicines for treating rare diseases and cancer are invited to (confidentially) share their market launch intentions, at the latest upon the positive opinion of the EMA's Committee for Medicinal Products for Human Use ("CHMP"). Applicants are also requested to comment on challenges to ensuring the availability of their medicines in the EU. The information gathered under the Pilot Project will be shared by the EMA, the Commission (Directorate General Santé ("DG Santé") and competent national authorities. The Pilot Project will run from March 2021 to August 2022.
EMA commences rolling review of Sputnik COVID-19 vaccine (see here)	On 4 March 2021, the EMA commenced the rolling review of Gam-COVID-Vac ("Sputnik V"), a potential COVID-19 vaccine developed by Russia's Gamaleya National Centre of Epidemiology and Microbiology. The marketing authorization applicant for the vaccine is R-Pharm Germany GmbH. The CHMP's decision to start the rolling review is based on positive results from laboratory and clinical studies in adults showing that the medicine may protect against COVID-19. The EMA will assess data as it becomes available to determine if the benefits outweigh the risks. The rolling review will continue until enough evidence is available for formal marketing authorization application. EMA will assess Sputnik V's compliance with the usual EU standards for effectiveness, safety and quality.
European Commission pursues Fit for Future Platform to simplify EU law, including in the area of Health, particularly in response to the pandemic (see here)	On 5 March 2021, the Commission announced the Fit for Future Platform's selection of 15 initiatives aimed at simplifying EU law and reducing administrative burdens for businesses and citizens, viewed as particularly needed in responding to the COVID-19 pandemic. In the area of health, this includes an evaluation of the Directive on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU of 9 March 2011). *For further details on the Platform, see above Sections on Competition & State Aid and Trade/Export Controls*.

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