



# COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 26 | 3 November 2020

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

- European Commission announces proposed Single Window Customs initiative
- European Commission extends temporary relief from customs duties and VAT for imports of medical goods and PPE

### Medicines, Medical Devices, and Personal Protective Equipment

- European Medicines Agency's reply to open letter concerning transparency and evaluation of vaccines for COVID-19
- European Commission adopts Communication on additional COVID-19 response measures
- European Commission adopts Recommendation on COVID-19 testing strategies

### 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:

- €39.6 million Greek scheme to support certain vegetable producers affected by the coronavirus outbreak
- €450 million Greek scheme to support companies active in certain sectors affected by the coronavirus outbreak
- €9.35 million Portuguese employment aid scheme to preserve jobs on the Azores Islands during the coronavirus outbreak
- €7.7 million Greek scheme to support cultural activities in the Municipality of Athens in the context of the coronavirus outbreak
- €378 million Slovenian scheme to support farmers and other self-employed affected by the coronavirus outbreak
- €13 million Polish scheme to support companies active in the wood sector affected by the coronavirus outbreak
- €99.4 million Danish scheme to support cafés, restaurants, nightclubs, discotheques, venues and their suppliers in context of the coronavirus outbreak

## TRADE / EXPORT CONTROLS

#### **European Commission announces proposed Single Window Customs initiative (see [here](#))**

On 28 October 2020, the European Commission announced the proposed so-called "EU Single Window Environment for Customs." As previously reported (see *Jones Day Update No. 23 of 29 Sept 2020*), this new initiative is part of the Commission's Action Plan to improve the management of EU customs and, in particular, to reinforce crisis-preparedness for events like the COVID-19 pandemic.

The proposed Single Window will enable businesses to complete all border formalities (for customs and other purposes such as health and product safety) in one electronic step in an individual Member State. This will accelerate border clearance of goods for import and export by lifting the burden of submitting information to multiple authorities. The Single Window will also facilitate cooperation and coordination between different Member State authorities, as well as promote a clearer overview of goods that enter or leave the EU.

This new streamlined approach is anticipated to provide, in particular, faster clearance of essential medical equipment into the EU and the prevention from entry of counterfeit or unsafe medical goods.

#### **European Commission extends temporary**

On 29 October 2020, the European Commission provided a second extension (until 31 April 2021) of the temporary exemption from customs duties and VAT for third country imports of medical devices and PPE. The measure's original

**relief from customs duties and VAT for imports of medical goods and PPE (see [here](#))**

period of application (from 30 January 2020 until 31 July 2020) was previously extended until 31 October 2020 (see *Jones Day Update No. 18 of 24 July 2020*). This latest extension is considered necessary, as many Member States continue to report shortages of goods needed to combat the COVID-19 pandemic.

For the UK, the extension will only apply until the end of the transition period under the Withdrawal Agreement, i.e. until 31 December 2020.

## MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

**European Medicines Agency's reply to open letter concerning transparency and evaluation of vaccines for COVID-19 (see [here](#))**

In an open letter published on 29 October 2020, the European Medicines Agency's (EMA) Executive Director Guido Rasi addressed concerns regarding the potential approval of COVID-19 vaccines.

The letter confirms that the EMA will continue to apply the highest regulatory standards of quality, efficacy, and safety for the approval of medicinal products. Within this framework, and in response to the COVID-19 pandemic, the EMA is using the so-called "rolling review" to accelerate the agency's ability to evaluate data from medicinal products developers as soon as these become available.

The EMA's first rolling review commenced on 30 April 2020 with Gilead's Velkury (remdesevir), which was granted a conditional marketing authorization for the treatment of adults and adolescents affected by pneumonia and requiring supplemental oxygen. As concerns COVID-19 vaccines, the first rolling review began on 1 October 2020 with the AstraZeneca vaccine, based on promising preliminary results from non-clinical and early clinical studies (see *Jones Day Update No. 24 of 13 October 2020*).

Regarding transparency, the EMA confirmed that it will publish all clinical data submitted in the context of a marketing authorization application of a medicine intended to treat or prevent COVID-19. The standard rules on anonymization and redaction for commercially confidential information will continue to apply in compliance with the so-called EMA Policy 0070.

**European Commission adopts Communication on additional COVID-19 response measures (see [here](#))**

On 28 October 2020, the European Commission adopted a Communication on additional COVID-19 response measures, which sets out the next steps in key areas to reinforce the EU's response.

In particular, the Commission plans to:

- Ensure accurate, comprehensive, and timely information on epidemiological data, as well as on testing and contact tracing, and improve information flow on the disease's spread to enable informed decision-making by Member States;
- Establish more effective and rapid testing, and in particular, the Commission has mobilized €100 million under the Emergency Support Instrument for the purchase and distribution of rapid antigen tests to Member States;
- Make full use of contact tracing and warning apps across borders;
- Purchase certain doses of COVID-19 vaccines via the APA mechanism and foster national vaccination campaigns;

- Secure essential supplies via joint procurement initiatives, like those launched for certain medical devices and personal protective equipment (PPE);
- Facilitate safe travel within the EU borders and safeguard free movement within the Schengen area.

Furthermore, the Communication provides that the Commission will adopt a package of initiatives on 11 November 2020, which will include:

- A proposal on tackling serious cross-border health threats; and
- The adoption of certain amendments to the mandates of the European Centre for Disease Control (ECDC) and the EMA to improve their capacities to contribute to crisis preparedness and response.

**European Commission adopts Recommendation on COVID-19 testing strategies (see [here](#))**

On 28 October 2020, the Commission adopted a Recommendation on COVID-19 testing strategies, including the use of rapid antigen tests.

The Recommendation sets out guidance for Member States on key elements to be considered for testing strategies and the use of rapid COVID-19 detection testing kits.

As a matter of urgency, in relation to rapid tests, the Commission will work with Member States to establish a framework for the evaluation, approval and mutual recognition of rapid tests, as well as for mutual recognition of test results.

In addition, an information repository of rapid antigen tests and validation study results will be built on the basis of the existing “COVID-19 In Vitro Diagnostic Devices and Test Methods Database” (see [here](#)).

## LAWYER CONTACTS

---

**Renato Antonini**

Partner, Government Regulation;  
Antitrust & Competition Law  
Brussels  
[rantonini@jonesday.com](mailto:rantonini@jonesday.com)  
+32.2.645.14.19

**Dr. Jörg Hladjk**

Partner, Cybersecurity, Privacy & Data  
Protection; Government Regulation;  
Technology  
Brussels  
[jhladjk@jonesday.com](mailto:jhladjk@jonesday.com)  
+32.2.645.15.30

**Kaarli H. Eichhorn**

Partner, Antitrust & Competition Law;  
Government Regulation; Technology  
Brussels  
[keichhorn@jonesday.com](mailto:keichhorn@jonesday.com)  
+32.2.645.14.41

**Cristiana Spontoni**

Partner, Health Care & Life Sciences;  
Government Regulation  
Brussels  
[cspontoni@jonesday.com](mailto:cspontoni@jonesday.com)  
+32.2.645.14.48