



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 Commission receives Recovery and Resilience Plans from 14 Member States
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- EU-Republic of Korea Trade Agreement enabled sustained trade despite pandemic
- European Commission releases biennial Report on the Protection and Enforcement of Intellectual Property Rights (IPR) in Third Countries

Medicines and Medical Devices

- European Medicines Agency starts rolling review of COVID-19 Vaccine (Vero Cell) Inactivated
- European Medicines Agency commences assessment of Pfizer//BioNTech COVID-19 vaccine for younger population
- European Commission launches public consultation on the European Health Data Space

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

COMPETITION & STATE AID

State Aid

European Commission receives Recovery and Resilience Plans from 14 Member States (see [here](#))

As of 4 May 2021, the Commission has received Recovery and Resilience Plans from 14 Member States (see also *Jones Day COVID-19 Update No. 45 of 28 April 2021*).

These Member State plans set out the reforms and public investment projects foreseen for implementation with the support of the Recovery and Resilience Facility (RRF), the key component of NextGenerationEU, the EU's plan for rebounding from the COVID-19 crisis. The RRF will provide up to €672.5 billion to finance reforms and investments (i.e., grants totaling €312.5 billion and €360 billion in loans).

The 14 Member State plans request the following total amounts under the RRF.

- Austria (€4.5 billion)
- Belgium (€5.9 billion)
- Denmark (€1.6 billion)
- France (€40.9 billion)
- Germany (€27.9 billion)
- Greece (€30.5 billion)
- Italy (€191.5 billion)
- Latvia (€1.8 billion)
- Luxembourg (€93 million)
- Poland (€23.9 billion)
- Portugal (€16.6 billion)
- Slovakia (€6.6 billion)
- Slovenia (€2.5 billion)
- Spain (€72 billion)

Commission assessment of plans. The Commission will assess the Member State plans within the next two months.

The RRF guidelines, notably, make clear that the investment projects included in Member State recovery plans must comply with State aid rules. The Commission published practical guidance for swift treatment of projects under State aid rules, as well as a number of sector-specific templates to help Member States design and prepare the State aid elements of their recovery plans (*Jones Day Commentary, "EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, see [here](#)*).

In assessing the Member State plans, the Commission will also, in particular, determine whether the plans dedicate at least 37% of expenditure to investments and reforms that pursue climate objectives and 20% to the digital transition.

Based on the Commission's proposals, the Council will then have four weeks to approve the Member State plans.

The Commission will continue to closely engage with the remaining Member

States to deliver robust national recovery plans.

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:

- €4 million Portuguese employment aid scheme to preserve jobs on Azores Islands during the coronavirus outbreak
- €2.5 million Belgian scheme to support professional sport clubs in Flemish and Brussels Regions in the context of the coronavirus outbreak
- €40 million Dutch subsidized soft bridge loans scheme to support start-ups affected by the coronavirus outbreak
- €12 million in Portuguese support in favor of SATA Air Açores - Sociedade Açoriana de Transportes Aéreos S.A. ('SATA Air Açores') as compensation due to damages suffered as a direct result of travel restrictions imposed due to the coronavirus outbreak.
- €90 million Slovak scheme to support operators in tourism sector in context of coronavirus outbreak

TRADE / EXPORT CONTROLS

EU-Republic of Korea Trade Agreement enabled sustained trade despite pandemic (see [here](#))

On 29 April 2021, the EU and the Republic of Korea held the 9th meeting of the Trade Committee of the EU-Republic of Korea Trade Agreement, ahead of the Agreement's upcoming 10th anniversary. Executive Vice-President and Commissioner for Trade Valdis Dombrovskis and Korean Minister for Trade Yoo Myung-hee co-chaired the in-person discussions.

The co-chairs emphasized that the Trade Agreement remains central to the bilateral economic relationship and will serve as a strong basis for economic recovery and growth following the COVID-19 pandemic.

With the pandemic, global trade flows dropped 11% globally. Between the EU and the Republic of Korea ("Korea"), by contrast, bilateral trade flows dropped only by 1.6%, with bilateral trade in goods at some €90 billion in 2020. Since the Trade Agreement's start of provisional application in 2011, total bilateral trade in goods had increased by 46% in 2020, while bilateral trade in services had leaped by 86% in 2019 compared to 2010.

During this 9th meeting, notably, the EU and Korea agreed to broaden the list of geographical indications (GIs) protected in the Annexes of the EU-Republic of Korea agreement by 43 EU GIs and 41 Korean GIs.

The parties also signed an amendment to the automotive annex of the Trade Agreement, which is viewed as important in providing transparency and predictability in the business environment for companies in both the EU and Korea.

The EU and Korea, furthermore, announced their shared ambitions for

climate neutrality and how implementation of the Trade Agreement could further boost climate action, as well as co-operation in digital trade.

European Commission releases biennial Report on the Protection and Enforcement of Intellectual Property Rights (IPR) in Third Countries (see [here](#) and [here](#))

On 27 April 2021, the Commission released its biennial Report on the Protection and Enforcement of Intellectual Property Rights (IPR) in Third Countries.

This Report is part of the EU's broader effort to protect European companies when trading outside the EU's borders and to ensure EU consumer safety. Particularly during the COVID-19 pandemic, criminals have shown the ability to rapidly exploit the new trade environment by infiltrating legitimate supply chains with counterfeit and often dangerous products. The pandemic led to a surge in the European market of counterfeit and falsified products such as unproven treatments, test kits, and medical equipment and supplies.

The Report, in particular, updates the Commission's list of "priority countries" whose IPR deficiencies are seen as causing the greatest economic harm to EU interests and aims at focusing the Commission's efforts and resources on specific areas of concern in view of improving IPR protection and enforcement worldwide.

According to the Report, China remains the Priority 1 country for the EU, due to the scale and persistence of IPR-related problems. Over 80% of seizures of counterfeit and pirated goods by EU customs authorities originate from China and Hong Kong (China).

India, Russia, Turkey and Ukraine remain Priority 2 countries, while Indonesia's recent reform of its patent law led to its removal from the Priority 2 countries to join the Priority 3 countries. Argentina, Brazil, Ecuador, Indonesia, Malaysia, Nigeria, Saudi Arabia and Thailand remain Priority 3 countries.

The Report, furthermore, seeks to raise awareness in right holders, in particular small and medium-size enterprises, of potential risks to their IP arising from business activities in certain third countries. This knowledge will assist them in preparing appropriate business strategies.

MEDICINES AND MEDICAL DEVICES

European Medicines Agency starts rolling review of COVID-19 Vaccine (Vero Cell) Inactivated (see [here](#))

On 4 May 2021, the European Medicines Agency (EMA) started the rolling review of COVID-19 Vaccine (Vero Cell) Inactivated, developed by Sinovac Life Sciences Co., Ltd, based on favorable results from laboratory and clinical studies

The rolling review procedure enables the EMA to review data as they become available from ongoing studies, in view of shortening the timeline for the approval of a medicinal product while ensuring compliance with the common standards for effectiveness, safety and quality.

During the rolling review, and throughout the pandemic, EMA and its scientific committees are supported by the COVID-19 EMA pandemic task force (COVID-ETF). This group gathers experts from across the European medicines regulatory network to advise on developing, authorizing, and monitoring the safety of medicines and vaccines for COVID-19 and to facilitate swift and coordinated regulatory action.

<p>European Medicines Agency commences assessment of Pfizer/BioNTech COVID-19 vaccine for younger population (see here)</p>	<p>On 3 May 2021, the EMA announced that it had commenced an accelerated assessment of the application filed by BioNTech to extend the use of the COVID-19 vaccine Comirnaty to include young persons between 12 and 15 years of age.</p> <p>EMA's human medicines committee (CHMP) will review data submitted by the market authorization holder, including results from a large ongoing clinical study involving adolescents from 12 years of age, in order to decide whether to recommend the extended use.</p> <p>Based on the CHMP's opinion, the European Commission will issue a final legally binding decision applicable in all EU Member States.</p> <p>The outcome of EMA's evaluation is expected in June 2021, unless supplementary information is needed. Comirnaty was first authorized in the EU in December 2020.</p>
<p>European Commission launches public consultation on the European Health Data Space (see here)</p>	<p>On 3 May 2021, the Commission published an open public consultation on the proposed European Health Data Space (EHDS), which is one the key priorities of in the area of health for the years 2019-2025.</p> <p>The EHDS builds upon the Commission Communication on an “<i>European strategy for Europe</i>” adopted last year (here) and aims to promote access to health data for research and innovation on new strategies for prevention and diagnosis of diseases, as well as new treatment solutions, while preserving individuals' rights to control their own personal data.</p> <p>The Commission notes that the COVID-19 pandemic highlighted the importance of timely access to health data for research and policy-making purposes, and the European Council has recognized the urgency of creating the EHDS.</p> <p>In particular, the Commission plans to define a legislative framework by end-2021 in pursuit of the goal of:</p> <ul style="list-style-type: none"> i. Implementing a genuine single market in digital health, covering both health services and products, including tele and mobile health; ii. Fostering the development, deployment and application of digital health products and services, including those incorporating artificial intelligence. <p>The Commission welcomes feedback to the EHDS evaluation roadmap through a questionnaire (here) until 26 July 2021.</p>

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