



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 launches public consultation on revision of IPCEI Communication
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission publishes Communication on Trade Policy Review, including addressing challenges of COVID-19 pandemic

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission announces adoption of a European bio-defense preparedness plan against COVID-19 variants
- European Commission enters into second agreement with Moderna for the purchase of additional COVID-19 vaccine doses

Cybersecurity, Privacy & Data Protection

- *No noteworthy items for this issue*

COMPETITION & STATE AID

State Aid

European Commission launches public consultation on revision of IPCEI Communication (see [here](#))

On 23 February 2021, the Commission opened a public consultation on the proposed revision of the Communication on the criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest (“Communication”).

The Communication, adopted in 2014, sets out the conditions under which State aid for the execution of important projects of common European interest (“IPCEI”) may be considered to be compatible with the internal market. It aims at facilitating the emergence of large-scale cross-border projects of significant benefit to the EU economy and its citizens by addressing important market failures in strategic value chains

The Commission notes that IPCEIs represent a very significant contribution to a sustainable recovery following the serious economic disturbances caused by the COVID-19 pandemic.

While the Commission indicates that the current provisions of the IPCEI Communication have overall worked well, it proposes a number of targeted changes, including to:

- clarify notions (e.g., the definition of “integrated project”) and provide further guidance on certain criteria set out in the Communication, such as the rules applicable when public support from different sources is combined to fund an IPCEI;
- facilitate the direct and indirect involvement in IPCEIs of small and medium-sized enterprises;
- further enhance the open character of IPCEIs and their consistency with EU policies.

The current IPCEI Communication has been extended until end-2021 for predictability and legal certainty reasons.

Stakeholders can respond to the consultation until 20 April 2021. Adoption of the new IPCEI Communication is planned for the second half of 2021.

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:

- €3.2 million Estonian scheme to support organizers of cultural events in Ida-Viru County and Harju County in the context of the coronavirus outbreak
- €26.3 million Estonian scheme to support companies in Ida-Viru and Harju Counties affected by the coronavirus outbreak
- €19.8 million Greek scheme to support a certain category of bus companies (K.T.E.L. bus companies) in the context of the coronavirus outbreak

- €500 million Greek scheme to support small and medium-sized businesses affected by the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Commission publishes Communication on Trade Policy Review, including addressing challenges of COVID-19 pandemic (see [here](#))

On 18 February 2021, the Commission published a Communication on Trade Policy Review - An Open, Sustainable and Assertive Trade Policy, which sets out Europe's new trade strategy for the coming years.

The Commission emphasizes that trade will be critical to the EU's recovery from the COVID-19 economic downturn. It reminds that the EU is the largest exporter and importer of goods and services worldwide. This includes 46 trade agreements with 78 partners, with 34% of EU external trade arising from trade with these partners in the amount of €1,398 billion.

The EU's new trade strategy will focus on three core objectives:

- Supporting the recovery and fundamental transformation of the EU economy in line with its green and digital objectives;
- Shaping global rules for a more sustainable and fairer globalization;
- Strengthening the EU's capacity to pursue its interests and enforce its rights, including autonomously where needed.

To meet these objectives, the Commission will focus on promoting key areas such as, e.g., WTO reform; the EU's partnerships with neighboring, enlargement countries and Africa; implementing and enforcing trade agreements; and responsible and sustainable value chains.

In particular, concerning value chains, the Commission notes that due to the scale of COVID-19's impact, disruptions in certain sectors were inevitable. These revealed vulnerabilities in the health sector due to a flood of demand for certain health related critical products. The Commission will seek to address these vulnerabilities, noting that trade policy can contribute to supply chain resilience by providing a stable, rules-based trading framework, opening up new markets to diversify sources of supply, and developing cooperative frameworks for fair and equitable access to critical supplies.

The Commission, furthermore, affirmed the importance of public consultation in developing this new trade strategy, which followed a broad public consultation that included over 400 submissions from a wide range of stakeholders. Stakeholder dialogue will remain ongoing, with particular focus to be given to implementation and enforcement, focusing on ensuring that the EU's interests are fully met as concerns the anticipated benefits of trade agreements.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Commission announces adoption of a European bio-defense

On 17 February 2021, the Commission announced the creation of the Health Emergency Preparedness and Response Authority incubator ("HERA incubator") to prepare Europe for an increased threat of coronavirus variants.

The HERA incubator, bringing together scientists, industry, and public authorities, will serve as a basis for a permanent structure for risk modelling,

preparedness plan against COVID-19 variants (see [here](#) and [here](#))

manufacturing capacity, supply chain risk mapping, and medicine research and development.

More particularly, the HERA incubator seeks to:

- Detect and analyze COVID-19 variants by: (i) developing specific tests for new variants; (ii) supporting genomic sequencing with €75 million in funding; (iii) stepping up research and data exchange on variants with €150 million in funding; and (iv) launching the VACCELERATE COVID-19 clinical trial network to boost cooperation on COVID-19 pediatric trials design and clinical data exchange. Such network is composed of 16 Member States and non-EU associated countries, such as Israel and Switzerland;
- Speed up the regulatory approval of adapted vaccines. In particular, the Commission plans to: (i) introduce a new regulatory procedure for the approval of adapted vaccines that would allow developers to submit a limited set of additional data on a rolling basis to the European Medicines Agency (EMA); (ii) provide developers with specific guidance on COVID-19 variants data requirements; (iii) facilitate the certification of new or repurposed manufacturing sites; and (iv) evaluate the introduction of an “emergency authorization” for vaccines;
- Ramp up the manufacturing of COVID-19 vaccines. The Commission aims to: (i) update existing and enter into new Advance Purchase Agreements; (ii) support the manufacturing of additional vaccines addressing new variants; (iii) develop a voluntary licensing mechanism to facilitate technology transfer and support cooperation between companies; and (iv) ensure adequate EU manufacturing capacity (“EU FAB project”).

The HERA incubator will also lay the groundwork for the creation of an European Health Emergency Preparedness and Response Authority (“Authority”).

The Authority will be tasked with remedying structural gaps in EU preparedness and response to health crises, as well as engaging with industry towards boosting manufacturing capacities and fostering research and development.

The Commission will present a legislative proposal for establishing the Authority towards end-2021.

European Commission enters into second agreement with Moderna for the purchase of additional COVID-19 vaccine doses (see [here](#))

On 17 February 2021, the Commission entered into a second agreement with US-based Moderna for the additional purchase of up to 300 million doses of the COVID-19 vaccine.

The contract provides for the supply of 150 million doses in 2021 and the option for another 150 million in 2022.

Member States may donate vaccine purchases to lower and middle-income countries or re-direct these to other EU countries.

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