COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 38 | 3 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

- Use of EU COVID-19 recovery funds to roll out very high capacity telecoms networks must adhere to State aid rules
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Parliament International Trade Committee discussion on Communication on Trade Policy Review, including COVID-19 concerns
- European Commission consults on emergency contingency plan to ensure food supply during times of crisis, including assessing the role of trade

Medicines, Medical Devices, and Personal Protective Equipment

- EMA publishes Reflection Paper on regulatory requirements for vaccines against variants of SARS-CoV-2
- European Commission launches Structured Dialogue on security of medicines supply

Cybersecurity, Privacy & Data Protection

- European Commission to propose an EU-wide digital COVID-19 vaccination passport

COMPETITION & STATE AID

State Aid

Use of EU COVID-19 recovery funds to roll out very high capacity telecoms networks must adhere to State aid rules (see here)

On 2 March 2021, the European Parliament published the response by Executive Vice-President and Competition Commissioner Margrethe Vestager to parliamentary questions relating to use of the Recovery and Resilience Facility ("RRF") to promote 5G and gigabit connectivity across Europe while safeguarding fair competition in telecoms markets.

To recall, the recently adopted RRF (see here) will make €672.5 billion in loans and grants available to support reforms and investments by Member States to mitigate the economic and social impact of the coronavirus pandemic.

Commissioner Vestager, responding on behalf of the Commission, indicated as follows:

The Commission encourages Member States to develop Recovery and Resilience plans that include investments and reforms aimed at, among other elements, the fast rollout of very high capacity networks.

Member State plans should ensure that support measures will adhere to all applicable rules, including State aid and public procurement rules, irrespective of the final beneficiary of the measure. Commissioner Vestager reminds that these rules are key in safeguarding the level playing field and ensuring that public funding does not distort competition or crowd out private investments. In this respect, she affirms that the Commission stands ready to assist Member States in structuring their plans in line with State aid rules.

Commissioner Vestager further notes that alongside the monitoring of the RRF's implementation, the Commission will continue its vigorous enforcement of existing EU rules, including antitrust and merger rules, where applicable.

Member States should submit their Recovery and Resilience plans, setting out their reform and investment agendas until 2026, by 30 April 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:

- €34 million Belgian scheme to support tourism companies in Flanders in the context of the coronavirus outbreak
- €115 million Czech rent compensation scheme to support businesses affected by the coronavirus outbreak
- €26 million Irish aid scheme to compensate airport operators in the context of the coronavirus outbreak
- €61.4 million Italian scheme to support private employers in the context of the coronavirus outbreak
- €40 million Italian aid measure to support coronavirus related research and development activities

- €110 million Czech scheme to support enterprises active in the primary agricultural sector and food production affected by the coronavirus outbreak
- €1 million Finnish scheme to support fishery and aquaculture sector affected by the coronavirus outbreak
- Modification of Luxembourg scheme (50% increase in the budget, to €180 million, and a prolongation until June 2021) to support uncovered fixed costs of companies affected by the coronavirus outbreak
- €10 million Italian public support to compensate Toscana Aeroporti for damage caused by the coronavirus outbreak
- €240 million in budget of existing Latvian scheme to support companies affected by the coronavirus outbreak
- €15 million Portuguese scheme to support micro, small and medium-sized enterprises in Azores region in the context of the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Parliament International Trade Committee discussion on Communication on Trade Policy Review, including COVID-19 concerns (see here and here)

During the 24 February 2021 meeting of the European Parliament's International Trade Committee, Executive Vice-President and Trade Commission Valdis Dombrovskis provided remarks on the recent Communication on Trade Policy Review. To recall, the Communication follows the Commission's assessment of its trade policies following the COVID-19 outbreak, which disrupted global supply chains and brought EU vulnerabilities to light (*see also Jones Day COVID-19 Update No. 37 of 24 February 2021).*

Commissioner Dombrovskis emphasized that in the face of the global recession due to the COVID-19 pandemic, trade is needed more than ever to support the creation of growth and jobs. Noting that 85% of global growth will occur outside of the EU in the next decade, Commission Dombrovskis urged that Europe must continue to trade with its global partners to support recovery from the pandemic and ensure Europe's prosperity.

He further referred to the Communication's detailed EU agenda for reform of the WTO, which must be modernized in order to respond to today's most urgent problems, including the pandemic's effects. The Communication's agenda addresses all three core WTO functions, including negotiation; monitoring and deliberation; and dispute settlement.

Within the EP's International Trade Committee, MEPs largely welcomed the revamping of the EU's medium-term trade policy.

On the diversification of supply chains, MEPs asked Commissioner Dombrovskis about diversifying supply chains to guarantee the supply of, for example, microchips and semiconductors. While several MEPs called for sanctions in case of non-compliance with environmental and labour clauses in trade deals, the Commissioner emphasized: "*Dialogue and cooperation is needed, instead of sanctions and penalties which should be tools of last resort.*" He also commented that while trade and sustainability provisions in existing trade agreements would not be renegotiated, the Commission would "*seek how to engage more forcefully*" with trade partners on such conditions.

European Commission consults on emergency contingency plan to ensure food supply during times of crisis, including assessing the role of trade (see here)

On 1 March 2021, the Commission announced the opening of a consultation on an emergency contingency plan to ensure food supply and food security across the EU in times of crisis, as announced in the "Farm to Fork" strategy launched in May 2020.

The Commission notes that the ongoing COVID-19 pandemic serves to remind of the need to ensure a resilient food system that continues to function regardless of large-scale disruptions.

Existing EU policies shielded against a food crisis during the pandemic, including through cooperation with EU trade partners. However, the Commission notes that there are "*lessons to be learned from recent experience about preparation for and response to crises*."

The planned contingency plan would seek to strengthen both preparation for any type of crisis that could significantly impact food security in the EU, as well as coordination across the policy areas relevant to the food system.

The consultation questionnaire seeks to collect insights of food system stakeholders in relation to the COVID-19 pandemic, previous crises, and expectations for the future.

Trade-related questions include, for example, the extent to which:

- EU food security could be threatened by, e.g., lack of access to key imported food commodities and agri-food products when a crisis occurs (including export bans by exporting countries) and large-scale trade disputes;
- further EU action would be most useful to better prepare for future crises affecting the EU's food system, such as through engagement in further cooperation with the EU's trade partners.

Responses to the consultation may be submitted until 3 May 2021.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

EMA publishes Reflection Paper on regulatory requirements for vaccines against variants of SARS-CoV-2 (see here)

On 25 February 2021, the European Medicines Agency ("EMA") published a Reflection Paper on the regulatory requirements for vaccines intended to provide protection against variant strain(s) of SARS-CoV-2 ("Paper").

The Paper provides guidance to developers of vaccines against COVID-19 in relation to quality, nonclinical and clinical data requirements to support approval of variant vaccines (i.e., vaccines to protect against one or more SARS-CoV-2 variants).

The requirements laid down in the Paper apply only where:

- the originally licensed vaccine (i.e. "parent vaccine") has already been granted a marketing authorization in the EU; and
- the variant vaccine is developed: (i) by the same manufacturer; and (ii) uses processes, controls and facilities for vaccine production that are "*the same or very similar*" as those used for the parent vaccine.

The Paper notes that the relevance of variant(s) included in a variant vaccine intended for use in the EU must be justified, based on disease surveillance and characterization of strains circulating at the time of selecting the variant(s).

	As soon as a global forum is established to support SARS-CoV-2 strain selection for vaccines (e.g. by the WHO), the Paper notes that recommendations from such forum should be consulted when selecting variant strain(s). Furthermore, the Paper indicates that its concepts may be subject to revision as additional evidence is generated and as circumstances evolve.
European Commission launches Structured Dialogue on security of medicines supply (see here)	On 26 February 2021, the Commission launched a Structured Dialogue initiative aimed at facilitating discussions between industry players, public authorities and other interested parties to strengthen the resilience of pharmaceutical supply chains and to ensure the availability of medicines. This initiative builds on the Pharmaceutical Strategy for Europe, adopted in November 2020. In particular, the Structured Dialogue is a two-phase process: (1) gaining an in-depth understanding of the functioning of global pharmaceutical supply chains and identifying root causes of potential vulnerabilities; and (2) developing concrete measures, based on information gathered in phase 1, to address identified issues. As concerns phase 1, the Commission identified four parallel work streams, each tasked with producing a written report, and focusing respectively on: – Robust supply chains, with the goal of analyzing key criteria to achieve resilience and flexibility; – Critical medicinal products, in view of identifying medicinal products vital to public health and discussing methodology to outline EU manufacturing capacity; – Vulnerabilities, towards pinpointing causes of supply chain disruption and the most frequent/severe challenges to supply, as well as the financial impact of addressing such challenges; and – Innovation, with the aim of identifying modernization needs, such as priority R&D areas and fostering competitive production capacity in the EU, while integrating green investment considerations, digital transformation, and innovative manufacturing processes. The Structured Dialogue's first broad operational meeting is planned for 25 March 2021.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission to propose an EU-wide digital COVID-19 vaccination passport (see here)	On 1 March 2021, the President of the European Commission Ursula von der Leyen announced that the Commission would present a legislative proposal this month for a "Digital Green Pass", i.e. an EU-wide digital vaccination passport. The purpose of the Digital Green Pass is to provide proof of vaccination, for work and tourism purposes. In addition, the Digital Green Pass will display the results of COVID-19 tests for individuals not yet vaccinated, as well as information on their recovery after contracting the virus. According to the President von der Leyen, "*the Digital Green Pass will respect data protection, security and privacy*".

The Commission is expected to present an initiative on 17 March 2021 focusing on travel and mobility, including the Digital Green Pass.

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