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 consults on proposed amendments to General Block Exemption Regulation
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- United States–European Commission Joint Statement: Launch of the Joint COVID-19 Manufacturing and Supply Chain Taskforce

Medicines and Medical Devices

- EMA recommendations on extra COVID-19 vaccine doses and boosters
- EMA commences evaluation of application for marketing authorization of monoclonal antibody Regkirona for treating COVID-19

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

COMPETITION & STATE AID

State Aid

European Commission consults on proposed amendments to General Block Exemption Regulation (see here)

On 6 October 2021, the Commission opened its consultation with Member States and interested parties to comment on certain proposed amendments to the General Block Exemption Regulation (Commission Regulation (EU) No 651/2014 ("GBER")).

To recall, the GBER deems specific categories of State aid as compatible with the Treaty, where these satisfy certain conditions, and exempts such categories from the requirement of prior notification to and approval by the Commission.

The GBER's rules are complementary to those provided in various sets of State aid Guidelines, which outline the conditions under which the Commission assesses whether State aid measures are deemed compatible with the Single Market, where these are not block-exempted and must thus be notified to the Commission. According to the Commission, this dual set of rules together provide a comprehensive rulebook for certain areas of State aid law.

The GBER was most recently amended on 23 July 2021, in particular, in view of broadening the ability to provide State aid to support sustainable and resilient economic recovery from the coronavirus pandemic, including exempting new aid categories from the notification obligation for certain measures falling under high EU priority policy areas for the twin green and digital transition Regulation (*see also Jones Day COVID-19 Update No. 57 of 26 July 2021*).

This latest proposed GBER revision seeks to take into account changes to various sets of State aid Guidelines under review (namely, the Regional Aid Guidelines; the Climate, Energy and Environmental State aid Guidelines; the Risk Finance Guidelines; and the Research, Development and Innovation Framework), as well as to further promote public support for the EU's ecological and digital transition. With these new rules, the Commission aspires to reinforcing the foundations of a sustainable economy in view of responding to the COVID-19 crisis.

Member States and other interested parties can respond to the consultation until 8 December 2021. Adoption of the revised GBER is anticipated in the first half of 2022.

European Commission approves new and amended Member State measures to support the economy (see here and here)

Since the onset of the coronavirus outbreak, the Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the Temporary Framework.

- €2.7 million Croatian scheme to support the poultry sector in the context of the coronavirus outbreak.
- €2 million Belgian scheme to support social economy companies in the context of the coronavirus outbreak.
- €150 million German scheme to support organizers of trade fairs and exhibitions in the context of the coronavirus outbreak.

TRADE / EXPORT CONTROLS

United States–European Commission Joint Statement: Launch of the Joint COVID-19 Manufacturing and Supply Chain Taskforce (see here)	On 22 September 2021, the US and EU issued a Joint Statement on the launch of the Joint COVID-19 Manufacturing and Supply Chain Taskforce. The Taskforce's formation was announced on 15 June 2021 at the first European Union – United States Summit in seven years (*see also Jones Day COVID-19 Update No. 52 of 21 June 2021*). The Taskforce aims at strengthening EU-US cooperation and addressing issues concerning the expansion of vaccine and therapeutics production capacity. Among its priority work areas, this includes coordinating efforts to tackle critical supply chain bottlenecks and other disruptive factors for global COVID-19 vaccine and therapeutics production. This will include regular status updates on any potential import–export issues between the US and EU. In seeking to expand vaccine and therapeutics production capacity, the Taskforce will also focus on building new production facilities and promoting voluntary sharing of know-how and technology on mutually-determined terms. The Taskforce is one pillar of the broader US-EU Agenda for Beating the Global Pandemic, also announced on 22 September 2021 (see here), and builds on the momentum ahead of the G20 Summit on 30-31 October 2021. This US-EU Agenda sets forth a coordinated US and EU strategy to expand cooperation for global action toward vaccinating the world, saving lives, and building better health security.

MEDICINES AND MEDICAL DEVICES

EMA recommendations on extra COVID-19 vaccine doses and boosters (see here)	On 4 October 2021, the Human Medicines Committee (CHMP) of the European Medicines Agency (EMA) announced its determination that an extra dose of the COVID-19 vaccines Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna) can be administrated to those with severely weakened immune systems, at least 28 days after their second dose (*see also Jones Day COVID-19 Update No. 62 of 4 October 2021*). The CHMP conclusion relies on positive clinical trial results showing that an extra dose of either the Comirnaty or Spikevax vaccine increased the ability in organ transplant patients with weakened immune systems to produce antibodies against the virus causing COVID-19. As concerns booster doses, the CHMP concluded that Comirnaty booster doses may be considered at least 6 months after the second dose for people with normal immune systems and aged 18 years and older. This finding was based on data for Comirnaty showing increased antibody levels when a booster dose is given approximately 6 months after the second dose in persons aged 18 to 55 years. The product information of both COVID-19 vaccines will be updated reflecting these CHMP conclusions.
EMA commences evaluation of application for	On 4 October 2021, the EMA announced the start of the evaluation of the application for a marketing authorization (MAA) submitted by Celltrion Healthcare Hungary for the monoclonal antibody Regkirona to treat adults

marketing authorization of monoclonal antibody Regkirona for treating COVID-19 (see here)	with increased risk of progressing to severe COVID-19 and who do not require supplemental oxygen therapy. The EMA will assess the MAA under an accelerated timeline, as the CHMP has already reviewed certain pre- and clinical data during a rolling review that allowed assessing data as this became available during the development of the vaccine and prior to the MAA's filing. Furthermore, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) completed the preliminary assessment on the risk assessment plan. The EMA's Pediatric Committee (PDCO) also issued an opinion on the pediatric investigation plan (PIP) that details how Regkirona should be developed and assessed for use in children. The CHMP's final opinion on the MAA is expected to be issued within two months, depending on the robustness of the data provided and whether further information is required to support the evaluation.

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