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

- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission issues FAQs on export requirements for COVID-19 vaccines
- European Parliament welcomes appointment of new Director-General of the World Trade Organization

Medicines, Medical Devices, and Personal Protective Equipment

- Janssen-Cilag applies to EMA for conditional marketing authorization for a COVID-19 vaccine
- EMA starts rolling review of CureVac's COVID-19 vaccine

Cybersecurity, Privacy & Data Protection

- *No noteworthy items for this issue*

COMPETITION & STATE AID

State Aid

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:

- €38.7 million Dutch scheme to support zoos in the context of the coronavirus outbreak
- €240.000 Slovenian scheme to support managers of hunting grounds affected by the coronavirus outbreak
- €1.4 billion Swedish scheme to support uncovered fixed costs of companies affected by the coronavirus outbreak
- €4 million Italian scheme to support SMEs active in fuel distribution services on Italian motorways in the context of the coronavirus outbreak
- €1.2 billion Czech scheme to support self-employed and partners in small limited liability companies affected by the coronavirus outbreak
- €35 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 Commission issues FAQs on export requirements for COVID-19 vaccines (see here)

On 12 February 2021, the European Commission published Export Requirements for COVID-19 vaccines – Frequently Asked Questions ("FAQs").

These FAQs follow the Commission's recent Regulation establishing an export transparency and export authorization mechanism for COVID-19 vaccines, addressing exports outside of the EU market (*see Jones Day COVID-19 Update No. 34 of 3 February 2021*).

To recall, as stated by the Commission, the Regulation aims at ensuring timely access to COVID-19 vaccines for all EU citizens and rectifying the lack of transparency of vaccine exports outside the EU.

The FAQs' clarifications, which are not legally binding and solely for informative purposes, address a range of key topics, such as:

Relevant factors for deciding to accept or reject a request for export authorization (e.g. based on elements such as information requested from vaccine manufacturers on the number of vaccine doses distributed in the EU and data on their exports);

Products subject to the authorization scheme (i.e. exports of either the finished vaccine in its final form or any product essential for its manufacturing, including, for example, exports of small quantities);

	Exclusions from the scope of the Regulation (e.g. exports to any organization appearing on the Commission's (non-exhaustive) list of humanitarian aid partners); Customs procedures (e.g. the Regulation applies to exports of EU goods (not to re-exports of non-EU goods) and does not cover goods placed in temporary storage). The Commission further notes that it shall periodically publish information on the authorizations granted and refused, with due account taken of the confidentiality of data submitted. The Commission intends to extend the export authorization measures until 31 March 2021.
European Parliament welcomes appointment of new Director-General of the World Trade Organization (see here)	On 15 February 2021, MEPs Bernd Lange and Sven Simon issued a statement welcoming the appointment of Dr Ngozi Okonjo-Iweala as the new Director-General of the World Trade Organization ("WTO"). She will serve as the first female and the first Director-General from Africa. MEP Lange is chair of the European Parliament Committee on International Trade. He and MEP Simon also serve as co-chairs of the Steering Group of the PCWTO (Parliamentary Conference on the World Trade Organisation*). The MEPs highlighted that Dr Okonjo-Iweala's appointment comes during "*probably the most difficult period in [WTO] history".* Among other factors, the WTO must confront *"the repercussions of the COVID-19 pandemic: we need to work together more on digitalisation and health. The new Director-General will need to be a crisis manager and reformer at the same time to get rules-based trade back on track".* Praising Dr. Okonjo-Iweala's "*extensive knowledge, impressive track-record and innovative approach*," MEPs Lange and Simon stated that her new role as Director-General "*bodes well for the functioning of the WTO and the multilateral trade system as a whole. As the first African Director General she will bring new perspectives to international trade policy*". * *The PCWTO is a joint project of the European Parliament and the Inter-Parliamentary Union (a global organization of national parliaments), aimed at enhancing the transparency of the WTO and making the WTO, an inter-governmental organization, accountable to elected representatives of the people*.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

Janssen-Cilag applies to EMA for conditional marketing authorization for a COVID-19 vaccine (see here)	On 16 February 2021, the European Medicines Agency ("EMA") received the conditional marketing authorization application ("CMA") submitted by Janssen-Cilag International N.V. for a COVID-19 vaccine. The opinion of the EMA's Committee for Medicinal Products for Human Use (CHMP) on the vaccine's safety and efficacy is anticipated by mid-March 2021. This accelerated timetable is possible only because the EMA has already reviewed certain data during a rolling review. On the grounds of the CHMP opinion, the European Commission will decide whether to grant a CMA to the vaccine.

	This is the fourth CMA application for a COVID-19 vaccine, following the EMA's assessment of vaccines from BioNTech/Pfizer, Moderna and AstraZeneca, which are now authorized in the EU.
EMA starts rolling review of CureVac's COVID-19 vaccine (see here)	On 12 February 2021, the EMA commenced the rolling review of CVnCoV, the COVID-19 vaccine developed by CureVac AG. The rolling review procedure enables the EMA to speed up the assessment of a promising medicinal product during a public health emergency by evaluating clinical trials data as they become available. The decision to start the rolling review is based on preliminary results from positive results of laboratory and early clinical studies in adults. Additional clinical trials are currently underway to assess the vaccine's safety and efficacy. Once the results of the trials will be available, CureVac may formally file a marketing authorization application for the vaccine.

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