COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 23 | 29 September 2020

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 launches new Action Plan on Taking the Customs Union to the Next Level

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission publishes Q&A on COVID-19 and EU Vaccines Strategy

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issues*

COMPETITION & STATE AID

State Aid

EU approves new and amended Member State measures to support the economy (see 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:

- €32 million Polish aid scheme to compensate airports for damage suffered due to coronavirus outbreak
- €26 million German scheme to compensate youth hostels, school country homes, youth education centres and family holiday centres in Bavaria for damages suffered due to the coronavirus outbreak
- €10 million Belgian scheme to support potato producers affected by coronavirus outbreak in Wallonia
- €1.5 billion Greek scheme to support micro and small enterprises in 12 regions affected by the coronavirus outbreak
- €2.2 million Belgian aid measures to support Flemish airports in the context of the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Commission launches new Action Plan on Taking the Customs Union to the Next Level (see here)

On 28 September 2020, the Commission announced a new Action Plan on Taking the Customs Union to the Next Level, aimed at making EU customs more innovative and efficient over the next four years. This includes better preparedness to handle crises like the COVID-19 pandemic.

The Action Plan highlights that the challenges raised by the pandemic have heightened the importance of improving the management of EU customs, *inter alia*, towards enabling the swift clearance of essential medical equipment and preventing counterfeit or unsafe goods from entering the EU. Its various initiatives focus on the following areas:

- **Improved risk management**, including greater availability and use of data and data analysis at EU level for customs purposes and intelligent, risk-based supervision of supply chains. This will include establishing a new analytics hub within the Commission for collecting, analyzing and sharing data across the EU that can inform critical decisions and facilitate the tasks of customs authorities.
- **Greater vigilance over e-commerce**, as customs authorities face serious difficulties in ensuring tax and customs compliance of goods purchased online, which is even more difficult with the additional obligation of verifying goods for safety purposes. To tackle the challenges of e-commerce, obligations on payment service providers and online sales platforms will be strengthened, including new reporting obligations on postal services to better ensure the safety and security of imports.

- **Promoting efficiency in compliance**, as the forthcoming 'Single Window' initiative will enable businesses to complete all border formalities for customs and other purposes, such as health and product safety, through a single electronic portal. This will accelerate border clearance of goods upon import and export. The measure will also facilitate collaborative processing by Member State authorities, including through wider sharing and exchange of information, and better risk assessment.

- **Strengthening all customs authorities** to address imbalances between Member States in customs controls. The Action Plan details the roll-out of modern and reliable customs equipment under the next EU budget. Moreover, a new advisory group formed of Member States and business stakeholders is proposed in view of making the Customs Union more technologically advanced and more crisis-proof, including through methods to better forecast problems and accelerated reaction mechanisms, drawing from the lessons learnt from the COVID-19 crisis.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Commission publishes Q&A on COVID-19 and EU Vaccines Strategy (see here)

On 24 September 2020, the European Commission published a Q&A document on COVID-19 and the EU Vaccines Strategy (*see Jones Day Alert No. 13 of 17 June 2020*).

The Q&A, in particular, provides clarifications regarding Advanced Purchase Agreements (APAs) for COVID-19 vaccines (i.e. the process leading to granting a marketing authorization of such vaccines), liability and indemnification, regulatory standards, and vaccine distribution.

As concerns APAs, negotiations may lead to the following agreements:

- APAs requiring Member States to purchase the vaccine. In such case, Member States have 5 working days to notify if they wish to opt-out, and the contract is only signed if at least four Member States are ready to be bound by it;

- APAs foreseeing only an option for Member States to purchase the COVID-19 vaccine at a later stage. In this case, the Commission signs the APA. Member States decide later whether to exercise the option and will be responsible for purchase of the vaccine once available.

Regarding liability and indemnification, the Q&A clarifies that the general rules on product liability shall apply to vaccines. However, the APAs provide that, under specific conditions set out in the contract, Member States shall indemnify manufacturers for possible liabilities. This is to compensate for potential risks undertaken by manufacturers due to the unusually tight timeframe for vaccine development.

As concerns the regulatory process for the approval of COVID-19 vaccines, the Commission has ensured that the European Medicines Agency (EMA) in its technical-scientifically review, will uphold the high standards of safety and efficacy that it always applies in authorizing any medicinal product.

Finally, the Q&A states that once ready for distribution, Member States shall have equal access to available doses and will determine which category of subjects will receive the vaccine doses.

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