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

- Commission prolongs temporary relief from customs duties and VAT for imports of medical equipment from non-EU countries

Medicines, Medical Devices, and Personal Protective Equipment

- European Medicines Agency establishes real-world data infrastructure for COVID-19 medicines and vaccines monitoring during pregnancy

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

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: • French reinsurance scheme to support the credit insurance market in the context of the COVID-19 epidemic • €720,000 Maltese scheme to support Bluefin tuna fishermen • €148 million Danish scheme to compensate companies for damages still suffered due to coronavirus outbreak • €2.6 billion Polish scheme to support companies affected by coronavirus outbreak • €51.23 million Greek scheme to support farmers active in primary agricultural and livestock sectors affected by the coronavirus outbreak

TRADE / EXPORT CONTROLS

Commission prolongs temporary relief from customs duties and VAT for imports of medical equipment from non-EU countries (see here)	On 23 July 2020, the European Commission decided to prolong the temporary exemption from customs duties and VAT for third country imports of PPE and medical devices until 31 October 2020. This measure includes masks and protective equipment, as well as testing kits, ventilators and other medical equipment. The Commission considered this three month extension as necessary, given ongoing shortages of such goods to combat the COVID-19 pandemic reported in many Member States. The measure's original period of application ran from 30 January 2020 until 31 July 2020.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Medicines Agency establishes real-world data infrastructure for COVID-19 medicines and vaccines monitoring during	On 21 July 2020, the European Medicines Agency (EMA) signed a contract with Utrecht University to establish an electronic infrastructure for monitoring real world data (RWD) on the safety and efficacy of vaccines and medicinal products for COVID-19 during pregnancy (CONSIGN project (COVID-19 infectiOn aNd medicineS In preGNancy)). The CONSIGN project will provide RWD on vaccine indications (i.e. targeted medical conditions), immunization policies and treatment options for pregnant women via the analysis of electronic health records and hospital data.

pregnancy (see here)	CONSIGN is among the EMA's initiatives launched with strategic partners, such as other recent agreements with: • Utrecht University, to identify a European-wide network of data sources (*e.g.*, health insurance records and hospital health records) and to assess their utility for safety and effectiveness monitoring of COVID-19 vaccines (ACCESS project (*see Jones Day COVID-19 Update of 29 June 2020*)); • IQVIA and the European Health Data & Evidence Network, to identify large national cohorts of COVID-19 patients and suitable comparator groups towards developing a study protocol template for multinational clinical trials and creating a framework to support collaborations between researchers. The results of all initiatives will be integrated into the works of the COVID-19 EMA pandemic Task Force and EMA's scientific committees. Such evidence will be used in developing scientific opinions on the best use of the medicines and vaccines at stake.

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