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

Multi-sectoral
(Competition / Trade / Medicines / Cybersecurity)

- EU releases €1.85 trillion Recovery Plan

Competition & State Aid

- *EU Recovery Plan*: Controversial proposal for new ex ante competition tool
- Adverse effects of State aid on EU internal market –European Parliament members express concerns
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- *EU Recovery Plan*: Trade-related measures
- Expiry of PPE export authorization requirement

Medicines, Medical Devices, and Personal Protective Equipment

- *EU Recovery Plan*: European Commission's proposal for a Regulation on the establishment of the EU4Health Programme
- Revised Q&A on regulatory expectations for medicinal products for human use during COVID-19 pandemic
- EMA reminder on risks of chloroquine and hydroxychloroquine to treat patients affected by COVID-19
- EMA to launch independent research for real-world monitoring of COVID-19 vaccines

Cybersecurity, Privacy & Data Protection

- *EU Recovery Plan*: Digital transformation measures

MULTI-SECTORAL
(Competition / Trade / Medicines / Cybersecurity)

EU releases €1.85 trillion Recovery Plan Communication: "Europe's moment: Repair and Prepare for the Next Generation" (see here)

On 27 May 2020, the EU Commission published its Communication, "Europe's moment: Repair and Prepare for the Next Generation," setting out a proposal for a new €1.85 trillion EU Recovery Plan, composed of a new recovery instrument "Next Generation EU" (€750 billion) and a reinforced long-term EU budget (€1.1 trillion).

The Commission Communication puts forward a number of measures in view of repairing the immediate economic and social damage caused by the coronavirus pandemic, promoting the EU's economic recovery, as well as preparing for the EU's planned green and digital transitions.

Selected sector-specific aspects of the EU Recovery Plan are set out below for Competition & State Aid; Trade; Medicines; and Cybersecurity.

COMPETITION & STATE AID

Competition

***EU Recovery Plan*: Controversial proposal for new ex ante competition tool (see here)**

On 27 May 2020, the Commission published its adjusted work programme, as part of the above-referred €1.85 trillion EU Recovery Plan to lead Europe out of the COVID-19 crisis (see here). The work programme now lists an ex ante competition tool to address the "gatekeeping" function of digital platforms. Such tool is expected to emerge as a Commission legislative proposal by late 2020.

European Commission Executive Vice-President Margrethe Vestager had previously expressed the need for gatekeeper regulation, in view of providing "fair conditions on all platforms" and including "a concise list of do's and don'ts".

The Commission and third-party complainants have expressed concerns about the current length of investigations under current competition rules, in particular in fast-moving tech markets, as investigations can stretch out for years.

A controversial proposal. It is unclear whether the gatekeeper legislation will ultimately apply to only the digital sector, or whether the outcome will be a broader piece of legislation with enforcement powers applicable more widely in the economy. Its institutional design must also be determined, i.e., what agency (or agencies) would be in charge.

The new enforcement regime is expected to raise a number of sensitive questions on conducting investigations, defense rights for companies, and the legitimacy of remedies imposed. Decisions can also be expected to be subject to appeals and judicial review, which would hold up final outcomes and deny the objective of swift resolutions.

Next steps. A legislative proposal is anticipated by Q4 2020, based on two Treaty articles (Article 103 – Competition - and 114 TFEU – Internal Market) and subject to a legislative process involving the EU Member States in the Council and the European Parliament.

A public consultation will precede such proposal, which is expected to attract significant interest and stakeholder advocacy efforts with lawmakers.

State Aid	
Adverse effects of State aid on EU internal market – European Parliament members express concerns (see here)	Members of the European Parliament's Economic and Monetary Affairs Committee voiced concerns about the EU's internal market during a debate on 26 May 2020 with European Commission Executive Vice-President Margrethe Vestager. MEPs indicated substantial differences between EU Member States' "fiscal firepower" in addressing the challenges posed by the COVID-19 pandemic. They cited, *inter alia,* data that German companies had received almost 50% of all State aid provide in the EU to date. They argued that the different resources made available in Member States would likely lead to long-lasting consequences for the cohesion of the EU's internal market. Executive Vice-President Vestager had earlier acknowledged the "huge differences" in aid provided in different EU Member States (see here), but noted that German spending would benefit companies across the EU, given the "interdependence of the EU economy and interlinked value chains". She also assured MEPs that State aid is intended to be temporary, limited and designed to protect from bankruptcies and lay-offs.
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: • € 1.6 billion Polish scheme to compensate companies for damages suffered due to coronavirus outbreak and provide liquidity support • €713 million Dutch guarantee scheme to support SMEs affected by coronavirus outbreak. • €32 million Danish scheme to compensate media companies for damage caused by decrease in advertising revenues due to coronavirus outbreak • €600 million Finnish aid scheme to support maritime companies in the context of the coronavirus outbreak. • €2.2 billion Polish subsidized loan scheme for large enterprises affected by coronavirus outbreak. • Lithuanian fund to enable up to €1 billion of liquidity and capital support to medium-sized and large enterprises affected by the coronavirus outbreak. • €71 million loan guarantee by France in favor of automotive supplier NOVARES in the context of the coronavirus pandemic.

TRADE / EXPORT CONTROL

***EU Recovery Plan*:** **Trade-related measures (see here)**	On 27 May 2020, the EU Commission published its above-referred Communication on the proposal for the creation of a new €1.85 trillion EU Recovery Plan to lead Europe out of the COVID-19 crisis. The actions proposed in the Communication include the following **trade-related** items: • Pursuing a model of **open strategic autonomy**. This will entail developing mutually beneficial bilateral relations with trading partners, while protecting the EU from unfair and abusive practices. An accompanying Commission Staff Working Paper (see here) also highlights the EU's need to strengthen its strategic autonomy and reduce its dependence on imports of critical goods and services, such as medical products, pharmaceuticals, critical raw materials and strategic digital infrastructure (e.g. 5G, quantum communication infrastructure). The Paper explains that autonomy should not necessarily lead to producing everything within the EU, but for some sectors, ramping up self-sufficiency can be achieved through diversifying and strengthening global supply chains. • Reinforcing the **Foreign Direct Investment screening** mechanism to avoid undue third-country control of strategic EU assets, infrastructure and technologies. • Issuing an upcoming Commission White Paper on an **instrument on foreign subsidies**, where such subsidies could bring imbalance to the level playing field in the Single Market. • Facing potentially persistent differences worldwide in climate ambition levels, the Commission is planning to propose a **carbon border adjustment mechanism** in 2021, to reduce the risk of carbon leakage, in full compatibility with WTO rules. According to President von der Leyen's speech to the European Parliament (see here), introducing the new Recovery Package, the tax would serve to counterbalance imports of cheap products from abroad that damage the climate. • Undertaking a **Trade Policy Review** to ensure the continuous flow of goods and services worldwide and to reform the World Trade Organization.
Expiry of PPE export authorization requirement (see here)	On 26 May 2020, the EU export authorization requirement for personal protective equipment (PPE) ceased to apply. First introduced in March 2020, such requirement sought to ensure the sufficient supply of these products in the EU during the COVID-19 crisis. In assessing this measure's application, the Commission concluded that it had served its purpose. There have been no requests to prolong the scheme.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT	
EU Recovery Plan: **European Commission's proposal for a Regulation on the establishment of the EU4Health Programme (see here)**	On 28 May 2020, the European Commission issued a proposal for a Regulation on the establishment of a programme on Union's action in the field of health for the period 2021-2027 ("EU4Health Programme"). This initiative is part of the above-referred €1.85 trillion EU Recovery Plan to lead Europe out of the COVID-19 crisis (see here). The EU4Health Programme aims at prioritizing financial resources to enable healthcare systems to cope with unforeseeable events, such as the COVID-19 crisis, to foster innovation, and to modernize the public and private healthcare sectors in the long-term. In this context, the Commission identified three key objectives to pursue: (i) protecting EU citizens from serious cross-border health threats and improving crisis management capacity; (ii) ensuring availability and promoting innovation of medicinal products, medical devices and other crisis relevant products; and (iii) reinforcing the health systems and health care workforce. To achieve these objectives, the Commission envisages the allocation of €9.4 billion, which will be added to the financial resources already made available under existing initiatives in the field of healthcare and digitalization.
Revised Q&A on regulatory expectations for medicinal products for human use during COVID-19 pandemic (see here)	On 26 May 2020, the European Medicines Agency (EMA), the European Commission, and the Heads of Medicine Agencies (HMA) updated the Q&A document on adapting the regulatory framework for pharmaceutical companies in the context of the pandemic. The update concerns certain flexibilities on Good Distribution and Manufacturing Practices (GDP/GMP) and the suspension of on-site inspections of plasma collection centers. As concerns GDP, the guidance provides certain temporary flexibilities for the responsible person, the use of new equipment or newly authorized storage/distribution premises, and deviations from normal practices (e.g. certain documentation, audits, non-conformities, and training). Regarding GMP flexibilities, the guidance grants companies the possibility of relying on limited prospective qualification to introduce new premises and/or equipment and to make temporary changes to certain quality related tasks. In order to ensure availability of medicines for the treatment of COVID-19, the Q&A allows for postponing or waiving testing in third countries and to conduct such testing within the EEA.
EMA reminder on risks of chloroquine and hydroxychloroquine to treat patients affected by COVID-19 (see here)	On 28 May 2020, the EMA issued a reminder addressed to healthcare professionals to closely monitor patients affected by COVID-19 who are under chloroquine or hydroxychloroquine treatment. This reminder is in light of the serious side effects that could result from use of such active ingredients. The reminder follows EMA's first statement of 23 April 2020 on the potential side effects of chloroquine/hydroxychloroquine and certain resolutions adopted by some national competent authorities (such as the Italian and French medicines agencies), which prohibited the use of such active

	ingredients outside the context of clinical trials for the treatment of patients affected by COVID-19.
EMA to launch independent research for real-world monitoring of COVID-19 vaccines (see here)	On 27 May 2020, the EMA announced that it signed a contract with Utrecht University, which will serve as coordinator of the EU Pharmacoepidemiology and Pharmacovigilance Research Network, a public-academic partnership of 22 research centers. In this context, the Network will launch the ACCESS (vACcine Covid-19 monitoring readinESS) project to establish an infrastructure for monitoring pre- and post-authorization data of COVID-19 vaccines generated by means of real-world evidence. In particular, the Network will collect information from different sources, such as health insurance records and hospital health records, and examine these from a safety and effectiveness perspective. Primary outcomes are expected for August 2020, with the final research results to be delivered by end-2020.

CYBERSECURITY, PRIVACY & DATA PROTECTION

EU Recovery Plan: **Digital transformation measures (see here)**	On 27 May 2020, the EU Commission published its above-referred Communication on a proposal for the creation of a new €1.85 trillion EU Recovery Plan to lead Europe out of the COVID-19 crisis. The actions proposed in the Communication include the following key elements for digital recovery: • **Investing in connectivity**. The digital society will benefit from 5G deployment, which will in turn increase Europe's strategic autonomy. • **Strengthening industrial and technological presence** in parts of the digital supply chain by investing in strategic digital capacities and capabilities (e.g., artificial intelligence, cybersecurity, secured communication, data and cloud infrastructure, 5G and 6G networks, blockchain…). • **Building an effective data economy** as a motor for innovation and job creation by implementing common European data spaces in key sectors and areas. In this respect, the Commission intends to present legislative action on data sharing and governance, which will facilitate the creation of common data spaces and strengthen governance on issues such as data portability or access. Subsequently, the EU Commission intends to develop a Data Act to establish the conditions for improved access and control of industrial data. • **Creating a fairer and easier business environment.** The lockdown has boosted online business models, but the online environment is currently dominated by large platforms. Therefore, the Digital Services Act will address issues stemming from such business models by providing a clear legal framework for digital services. • **Creating a new Cybersecurity Strategy.** The lockdown has provided a breeding ground for cyber threats and attacks. To prevent these issues, the Commission intends to review the Directive on Security of

Network Information Systems (NIS Directive) and propose additional measures on Critical Infrastructure Protection.

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