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

- Proposed expansion of State aid Temporary Framework to recapitalization
- EU approves Member State measures to support the economy

Trade / Export Controls

- European Commission seeks to narrow export authorization requirements
- Informal meeting of EU Trade Ministers
- Statement by EU Trade Commissioner Phil Hogan
- UK and EU agree to three negotiating rounds for post-Brexit trade deal

Medicines, Medical Devices, and Personal Protective Equipment

- Guidelines on COVID-19 in vitro diagnostic tests and their performance
- Testing kits for COVID-19: What is the EU doing?
- Q&A on regulatory expectations for medicinal products for human use during the COVID-19 pandemic

Cybersecurity, Privacy & Data Protection

- Commission Guidance on Apps supporting the fight against COVID 19 pandemic in relation to data protection
- Common EU Toolbox for Member States on Mobile applications to support contact tracing in the EU's fight against COVID-19
- Joint European Roadmap towards lifting COVID-19 containment measures
- EDPB Letter concerning the European Commission's draft Guidance on applications supporting the fight against the COVID-19 pandemic

COMPETITION & STATE AID

State Aid

Proposed expansion of State aid Temporary Framework to recapitalization measures (see here)	The European Commission is anticipated to further extend the scope of the Temporary Framework by enabling Member States to provide recapitalizations (public support in the form of equity or hybrid capital instruments) to severely affected companies. The Commission's draft proposal is currently under Member State consultation. On 16 April 2020, Executive Vice President Margrethe Vestager indicated that Member States had provided positive responses to the draft proposal, but that the amended Temporary Framework is still "*some days away*". Since such public interventions may significantly impact competition in the Single Market, the European Commission considers these as measures of last-resort. These measures are also likely to be subject to conditions with regard to the State's entry, remuneration and exit from the companies concerned, as well as strict governance provisions and appropriate measures to limit potential distortions of competition.
EU approves new and amended Member State measures to support the economy (see here)	In the 10 April – 17 April 2020 period, the European Commission approved a significant number of requests for State aid to support Member State economies, including larger individual schemes in Belgium (€50 billion), Flanders (€3 billion), and Romania (€3.3 billion). The European Commission also approved amendments to previously cleared schemes in France and Germany.

TRADE / EXPORT CONTROL

European Commission seeks to narrow export authorization requirements (see here)	On 14 April 2020, the Commission commenced consultations with EU Member States on a draft regulation to adjust the export authorization scheme for PPE (Personal Protective Equipment) established on 15 March 2020. The new regulation is anticipated to apply for a period of 30 days (as of 26 April 2020) and would cover only protective masks, which the Commission considers as the only product category that still requires an export authorization scheme in order to ensure an adequate supply. The proposed new scheme also sets forth some modifications in geographical scope. In addition to previously existing exceptions, further exemptions from the authorization requirement would apply to exports to the Western Balkans, as well as Gibraltar and Member State territories excluded from the EU customs union.
Informal meeting of EU Trade Ministers (see here)	On 16 April 2020, the EU Trade Ministers, together with EU Trade Commissioner Phil Hogan, met by videoconference. The Ministers expressed support for the Commission's proposal for a new (narrowed) export authorization scheme, including the proposed changes to its product and geographical scope (see above). The Ministers also welcomed the Commission's recently published guidelines on FDI screening.

Statement by EU Trade Commissioner Phil Hogan: **Free, rules-based trade essential for economic recovery after pandemic (see here)**	Speaking at the videoconference of EU Trade Ministers (see above), EU Trade Commissioner Phil Hogan highlighted that free, rules-based trade will be key to economic recovery once the COVID-19 crisis is over. He also outlined the EU's ongoing trade actions in response to the crisis, including the export authorization scheme, the removal of tariffs from medical supplies, and FDI screening guidelines. With respect to FDI screening, the Commission intends to set up an informal cooperation with Member States, consisting of monitoring ongoing and planned foreign acquisitions and sharing relevant information, as well voluntary exchanges on pending FDI screening cases among Member States. Mr. Hogan further informed that a short background paper on the estimated impact of the crisis on EU exports and imports will soon be shared with the Trade Policy Committee. Finally, Mr. Hogan praised advances in the interim dispute settlement mechanism, which the EU initiated due to the current paralysis of the WTO Appellate Body.
UK and EU agree to three negotiating rounds via videoconference for post-Brexit trade deal (see here)	The EU and UK are continuing negotiations on a post-Brexit trade deal. On 15 April 2020, Michel Barnier, the European Commission's Chief Negotiator, and David Frost, the UK's Chief Negotiator, held a meeting via videoconference. They agreed on further negotiating rounds (also via videoconference, due to COVID-19 crisis) to take place during the weeks of April 20, May 11 and June 1.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

Guidelines on COVID-19 in vitro diagnostic tests and their performance (see here)	On 15 April 2020, the European Commission adopted a Communication on Guidelines on COVID-19 in vitro diagnostic tests and their performance. These Guidelines outline the regulatory context of COVID-19-related in vitro diagnostic testing devices and provide an overview of various types of tests and their purposes. The Guidelines also discuss device performance and relevant validation.
Testing kits for COVID-19: what is the EU doing? (see here)	On 15 April 2020, the European Commission adopted a factsheet on testing kits. The factsheet briefly summarizes the Commission's current activities and upcoming initiatives.
Q&A on regulatory expectations for medicinal products for human use during the COVID-19 pandemic (see here)	On 10 April 2020, the European Commission, the EMA (European Medicines Agency) and the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) issued a joint Q&A document. Recognizing the need to minimize the risks of shortages, the Q&A provides guidance to manufacturers and marketing authorization holders on regulatory expectations and flexibility, in view of facilitating action against the pandemic. More particularly, the Q&A provides clarifications on marketing authorizations, importation, distribution, labelling and quality issues. The Q&A document will be continually updated to address new regulatory issues that may arise in the context of COVID-19.

CYBERSECURITY, PRIVACY & DATA PROTECTION

Guidance on Apps supporting the fight against COVID 19 pandemic in relation to data protection (see here)

On 16 April 2020, the European Commission published Guidance on Apps supporting the fight against COVID 19 pandemic in relation to data protection. This follows publication of the Commission's Joint European Roadmap towards lifting COVID-19 containment measures (see below).

The Guidance aims at providing Member States and app developers with features and requirements that voluntary apps (i.e., apps downloaded, installed and used on a voluntary basis by individuals) should meet to comply with EU privacy and personal data protection legislation, in particular the GDPR and ePrivacy Directive.

The Guidance underlines the following data protection principles:

- Data controller: National health authorities or entities (carrying out tasks in the public interest in the field of health) should be data controllers of such apps.
- Individuals rights: Data subjects should remain in control of their personal data (e.g., downloading the app should be voluntary, individual rights should be guaranteed, and individuals should receive information on the processing of their personal data).
- Legal basis: Possible legal bases are either (i) Article 6(1)(c) GDPR (processing is necessary to comply with a legal obligation under EU or Member State law pursuant to Article 6(3) GDPR) in combination with Article 9 (2)(i) GDPR (processing is necessary for reasons of public interest in the area of public health); or (ii) Article 6(i)(e) GDPR (processing is necessary for the performance of a task carried out in the public interest).
- Data minimization: Only processing personal data that is adequate, relevant and limited to what is necessary in relation to the purpose.
- Limitation of access and/or disclosure of data: Subject to the type of personal data processed and purposes of such processing, health authorities may have access to such personal data where complying with GDPR requirements.
- Purpose limitation: The purposes for processing personal data through the apps must be precise.
- Limited data storage: Data cannot be kept for longer than what is necessary, based on medical relevance and administrative requirements.
- Data security: Data should be stored on an individual's terminal device in an encrypted form using state-of-the-art cryptographic techniques.
- Data accuracy: Personal data should be accurate to minimize the risk of recording "false positives" cases. Technologies enabling a more precise assessment of the contact should be used (e.g., Bluetooth technology).
- Data protection authorities (DPA): National DPAs should be involved and consulted in developing such apps.

Mobile applications to support contact tracing in the EU's fight against COVID-19:

Common EU Toolbox for

On 16 April 2020, the European Commission published a Common EU Toolbox for Mobile applications to support contact tracing in the EU's fight against COVID-19. Focusing on technical solutions, this Toolbox follows publication of the Commission's Joint European Roadmap towards lifting COVID-19 containment measures (see below).

Addressed to EU Member States, the Toolbox sets out practical approaches regarding technological solutions to enable contacting and testing at-risk

Member States (see here)	individuals as quickly as possible. It emphasizes the following requirements applicable to national mobile applications: • Voluntary use; • Approved by national health authority; • Privacy-preserving (i.e., the application must securely encrypt personal data); • Deleted as soon as no longer necessary; • Complies with cybersecurity requirements.
Joint European Roadmap towards lifting COVID-19 containment measures (see here)	On 15 April 2020, the European Commission published a Communication on a Joint European Roadmap towards lifting COVID-19 containment measures. The Communication refers to establishing a framework for contact tracing and warning through the use of mobile applications, in compliance with data protection and data privacy principles. The Communication emphasizes that use of such mobile applications should be voluntary, based on users' consent and subject to high transparency requirements. As soon as the pandemic is over, the mobile applications should be deactivated and any remaining data erased.
EDPB Letter concerning the European Commission's draft Guidance on applications supporting the fight against the COVID-19 pandemic (see here)	On 15 April 2020, the European Data Protection Board ("EDPB") published a letter sent to the Commission on use of mobile applications during the pandemic. The EDPB welcomed the Commission's initiative to develop a coordinated pan-European approach and emphasized the importance of complying with privacy and data protection principles such as: • Accountability (e.g., conducting data protection impact assessments); • Data accuracy; • Storage options (either on data subjects' devices or centralized); • Data retention period (personal data should be erased or anonymized at the end of the pandemic); • Possibility for public authorities to process health-related data by using the legal basis of "the necessity for the performance of a task carried out in the public interest" (Article 6(i)(e) GDPR), subject to obtaining an appropriate legal mandate. The EDPB plans to issue additional guidance during the week of 20 April 2020 on tracing, scientific research and teleworking.

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