COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY ALERT

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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

- Guidance on allowing limited cooperation among businesses
- EU approves Member State measures to support the economy

Trade / Export Controls

- Commission waives customs duties and VAT on import of medical equipment from non-EU countries
- EU notifies WTO on coronavirus-related actions

Medicines, Medical Devices, and Personal Protective Equipment

- Guidelines on optimal and rational supply of medicines to avoid shortages during COVID-19 outbreak
- MDCG Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions
- Guidance on collection and transfusion of convalescent COVID-19 plasma
- First-time “ERAvsCorona” action plan
- EU authorities establish new drug shortage reporting system
- Commission Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context

Cybersecurity, Privacy & Data Protection

- European Commission recommendation on use of mobile applications in the context of COVID-19
- European Data Protection Board 20th plenary session

COMPETITION & STATE AID

Mergers

Guidance on allowing limited cooperation among businesses (see here and here)

On 8 April 2020, the European Commission published a Communication: "*Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak".*

The Communication sets out:

- the main evaluation criteria that the Commission will follow in assessing possible cooperation projects aimed at addressing the shortage of essential products and services during the COVID-19 outbreak, and in setting its enforcement priorities during this crisis, and
- a temporary process that the Commissions has exceptionally set up to provide, where appropriate, ad hoc written comfort letters to companies in relation to specific cooperation projects.

The Commission mentions a number of collaborations that do not raise antitrust concerns, i.e., those with appropriate safeguards and when managed, for example, by an independent advisor/association/public body.

These are set out in the Communication, with pharmaceuticals as the example:

a. Coordinating joint transport for input materials;

b. Contributing to identifying those essential medicines for which, in view of forecasted production, there are risks of shortages;

c. Aggregating production and capacity information, without exchanging individual company information;

d. Working on a model to predict demand on a Member State level, and identifying supply gaps;

e. Sharing aggregate supply gap information, and requesting participating undertakings (on an individual basis and without sharing that information with competitors) to indicate whether they can fill the supply gap to meet demand, either through existing stocks or increase of production.

The Commission notes that "*cooperation in the health sector might even need to go further to overcome critical supply shortages*", for instance, "*coordinating the re-organisation of production*". Because of the "*exceptional circumstances*" the Commission states such cooperation "*would not be problematic*" and would not be an "*enforcement priority*".

The Commission requires such measures, however, to be (i) designed and objectively necessary to actually increase output in the most efficient way to address or avoid a shortage of supply of essential products or services, (ii) temporary in nature, and (iii) not exceeding what is strictly necessary to achieve the objective of addressing or avoiding the shortage of supply.

Such measures must be documented and information be provided to the Commission upon request.

The Commission further notes that cooperation is also allowed in urgent situations related to the COVID-19 outbreak, if in response to "*an imperative request from public authorities".*

The Commission has applied the Communication as from 8 April 2020 and will do so until further notice.

State Aid	
EU approves Member State measures to support the economy (see here)	Between 3 April – 10 April 2020, the European Commission approved a significant number of requests for state aid to support Member State economies, including larger individual schemes in Austria (€15 billion), Greece (€2 billion), Poland (€4.8 billion), and the UK (£50 billion).

TRADE / EXPORT CONTROL

Commission waives customs duties and VAT on the import of medical equipment from non-EU countries (see here)	On 3 April 2020, the Commission issued a Decision approving requests from Member States and the UK to temporarily waive customs duties and VAT on imports of medical devices and protective equipment used to address the COVID-19 crisis. This measure includes masks and protective equipment, as well as testing kits, ventilators and other medical equipment. It takes effect retroactively from 30 January 2020 and will apply for a period of 6 months, with a possibility for further extension.
EU notifies the WTO on coronavirus-related actions (see here)	On 7 April 2020, the EU notified the World Trade Organization of the following steps it has taken in the fight against COVID-19: • Import duty and VAT relief on products to combat COVID-19; • Guidelines on border management, including the introduction of Green Lanes to ensure availability of essential goods and services; • Facilitation of air cargo operations; • Guidance on customs issues related to the COVID-19 emergency; • Human, animal and plant health, and animal welfare measures to contain risks linked to control system disruptions due to COVID-19; • Public procurement guidance relating to emergency provisions in current legislation to allow for quicker purchasing of necessary goods; • Export authorization requirements to support supply sufficiency and meet vital demand for personal protective equipment in the EU.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

Guidelines on optimal and rational supply of medicines to avoid shortages during COVID-19 outbreak (see here)	On 8 April 2020, the EU Commission issued Guidelines on rational supply, allocation and use of medicines to treat COVID-19 patients and a relevant factsheet. Member States are called upon to undertake the following: • Lift export bans on medicines within the internal market and avoid national stockpiling, as a demonstration of solidarity; • Ensure supply of essential medicines, such that Member States must ensure that pharmaceutical manufacturing continues at full capacity. To achieve this, Member States are recommended to, *inter alia*, grant regulatory flexibility to the pharmaceutical industry during the crisis, and to ensure and facilitate wholesalers activities and transportation measures;

- Facilitate the optimal use of medicines in hospitals, e.g. by reallocating stock between hospitals depending on need and considering using alternative medicines in case of shortages of first-line treatments;
- Introduce measures to avoid patients/consumers from hoarding medicines from pharmacies, e.g. only allowing a maximum of one package per customer of non-prescription medicines and temporarily limiting online sales of essential medicines.

MDCG Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions (see here)	On 8 April 2020, the Medical Device Coordination Group ("MDCG," composed of representatives of all Member States and chaired by the European Commission) issued Guidance on temporary alternative solutions for carrying out mandatory on-site audits by Notified Bodies under the medical devices legislation. The Guidance covers the audits that Notified Bodies are requested to carry out as part of medical device conformity assessments, including: • surveillance audits; • audits conducted for re-certification purposes; • where a manufacturer submits a change notification to a Notified Body that would typically require an on-site audit or verification; and • where a manufacturer terminates the contract with a Notified Body and enters into a contract with a new one. The following principles and arrangements are envisaged: • Postponing on-site surveillance audits based on *force majeure*; • Replacing on-site audits with remote audits; • Off-site assessment of documents/records; • Considering taking into account existing recent results from other audits.
Guidance on collection and transfusion of convalescent COVID-19 plasma (see here)	On 8 April 2020, the EU Commission adopted, in collaboration with the European Centre for Disease Prevention and Control (ECDC), a Guidance document on the collection and transfusion of convalescent COVID-19 plasma. This Guidance aims at facilitating a common approach across EU Member States to the donation, collection, testing, processing, storage, distribution and monitoring of convalescent plasma for treating COVID-19 patients. The Guidance, which is not legally binding, was developed in collaboration with the European Centre for Disease Prevention and Control (ECDC) and is endorsed by the 27 Member State competent authorities for blood and blood components. In collaboration with the European Blood Alliance (EBA), the European Commission (DG DIGIT) is building a database to collect data on plasma donation and patient outcome. The database will go live in April 2020 and will be open to all EU/EEA blood establishments that wish to participate, via the EBA. This open-access database will gather data from monitored use, as well as from randomized clinical trials, and will consolidate EU evidence on the safety and effectiveness of this therapy.
First-time "ERAvsCorona" action plan (see here)	On 7 April 2020, EU Research Ministers met to support the first "*ERAvsCorona*" action plan. It contains 10 short-term priority actions to be implemented at EU level to combat the spread of the coronavirus, including: • coordination of R&I funding; • extension and support of large EU wide clinical trials; • funding for innovative and rapid health-related approaches; • increased support to innovative companies;

- establishment of a platform to exchange research data on COVID-19.

EU authorities establish new drug shortage reporting system (see here)	The European Medicines Agency ("EMA"), Commission and national competent authorities established a new EU Executive Steering Group on Shortages of Medicines Caused by Major Events ("Group"). The Group is establishing, together with stakeholders, an industry single point of contact system aimed at speeding up interactions between industry and the Group as concerns drug shortages. Under this new system, each company will report directly to the EMA on anticipated or current shortages of critical medicines used in the context of COVID-19, in relation to both centrally authorized and nationally authorized medicines.
Commission issues Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context (see here)	On 3 April 2020, the EU Commission released Q&A Guidance on medical devices in the context of COVID-19, addressing the following: • definition of a medical device, active implantable medical device and an in vitro diagnostic medical device; • placing devices on the market; • use of standards under current legislation; • possibility of derogation from conformity assessment procedures; • registration; • off-label use.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission recommendation on use of mobile applications in the context of COVID-19 (see here)	On 8 April 2020, the European Commission adopted a Recommendation on a common Union toolbox for the use of technology and data to combat the COVID-19 crisis, and in particular mobile applications and anonymized mobility data. The Recommendation presents a process for developing a common approach ("Toolbox") to using technology and data to tackle the crisis, consisting of practical measures focusing on two priorities: 1. Developing a pan-European approach for COVID-19 mobile applications between the Member States and the Commission, in association with the European Data Protection Board and the European Data Protection Supervisor. 2. Creating a common scheme for the use of anonymized and aggregated mobility data necessary for (i) mapping and predicting the spread of the virus and the correlating impact on needs in the Member State health systems; and (ii) optimizing the effectiveness of measures to contain the spread of the virus and to address their effects, including confinement (and de-confinement), and to obtain and use those data. The Toolbox, to be guided by privacy and data protection principles (particularly when using COVID-19 mobile apps), lists the following privacy and data protection principles: • Protect personal data and confidentiality of communications. • Favor the least intrusive yet effective measures (e.g., use of proximity data instead of data on location or movements of individuals and use of anonymized and aggregated data where possible). • Implement technical requirements concerning appropriate technologies (e.g., Bluetooth Low Energy) to establish device proximity, encryption,

data security, storage of data on the mobile device, possible access by health authorities, and data storage.
- Adopt effective cybersecurity requirements to protect the availability, authenticity, integrity, and confidentiality of data.
- Restrict the processing of data to the sole purpose of combating the COVID-19 virus and exclude the sharing of data with any third party.
- Ensure the deletion of personal data within 90 days or at the latest once the pandemic is declared to be under control.
- Adopt transparency requirements on privacy settings to ensure trust in concerned applications.

A pan-European approach for COVID-19 mobile applications is expected to be published by the Commission on 15 April 2020 and will be complemented by privacy and data protection-related guidance.

European Data Protection Board 20th plenary session (see here)

During its 20th plenary session on 7 April 2020, the European Data Protection Board ("EDPB") mandated its expert subgroups with developing guidance on several aspects of data processing in the fight against COVID-19. These mandates cover the following topics:

- Processing health data for research purposes in the context of COVID-19; and
- Use of geolocation and other tracing tools in the context of the COVID-19 outbreak.

Due to the urgency of the topics mentioned above, the EDPB has postponed its guidance work on teleworking tools and practices in the context of COVID-19.

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