COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 5 | 24 April 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 Member State measures to support the economy
- Austria requests EU to suspend State aid rules
- Eurogroup Report on the comprehensive economic policy response to the COVID-19 pandemic

Trade / Export Controls

- European Commission renews export authorization requirement for PPE, but limits scope
- The EU and 21 other WTO Members pledge to ensure open and predictable trade in agricultural and food products

Medicines, Medical Devices, and Personal Protective Equipment

- Application of Medical Devices Regulation postponed by one year
- First ICRMA meeting on COVID-19 pandemic
- Update of Q&A guidance on regulatory expectations in the context of COVID-19 pandemic
- EMA update on EU actions to support availability of medicines during COVID-19 pandemic

Cybersecurity, Privacy & Data Protection

- EDPB Guidelines on use of location data and contact tracing tools in the context of COVID-19 outbreak
- EDPB Guidelines on processing data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak
- European Parliament adopts resolution on EU coordinated action to combat the COVID-19 pandemic and its consequences

COMPETITION & STATE AID

State Aid

EU approves new and amended Member State measures to support the economy (see here)	In the 18 April – 24 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 France (€7 billion), the Netherlands (€10 billion), and Poland (€7.8 billion).
Austria requests EU to suspend State aid rules (see here)	Austria is calling for suspension of EU State aid rules to better enable Member States to provide support companies during the COVID-19 crisis, according to a letter of 21 April 2020 to the EU Competition Commissioner, Executive VP Margrethe Vestager. The current Temporary Framework for State Aid, according to Austria, presents a "*considerable administrative burden*" and "*delays the process considerably*." Austria seeks greater pragmatism and efficiency to allow governments to respond more swiftly to the needs of businesses. Austria urges the Commission to pursue measures to, *e.g.*: - exempt anti-crisis subsidies from the ex-ante notification requirement (as in the case of State aid to indemnify damages from natural disasters) - increase the ceiling for direct contributions to SMEs - enable greater flexibility in defining who may receive aid - suspend the guarantee fee - permit additional aid for industries specifically impacted by the crisis Austria notes that within the first week of its State aid measures approved under the Temporary Framework, it received some 600 applications for its guarantee instrument, representing approximately €100 million.
Eurogroup Report on the comprehensive economic policy response to the COVID-19 pandemic (see here)	The Finance Ministers of the Eurozone Member States ("Eurogroup") agreed on a coordinated economic response to the COVID-19 crisis of over €500 billion on 9 April 2020. The response sets out "safety nets" for workers, businesses, and governments, as well as a recovery plan. Measures include credit lines for healthcare systems, a fund to mitigate unemployment, and loans to SMEs. Noting actions taken to date, the Eurogroup Report re-affirmed the need for flexibility in EU rules, including the Commission's recent State aid initiatives. The Report reiterated its earlier approval of the Commission's issuance of a temporary State aid framework to facilitate swifter public support to companies, while safeguarding the necessary level playing field in the EU. The Report also welcomed the temporary framework's recent broadening to cover State aid for research, testing and production relevant in combating the COVID 19 pandemic.

TRADE / EXPORT CONTROL

European Commission renews export authorization requirement for PPE, but limits scope (see here)

The European Commission has renewed the export authorization requirement, but with a narrowed product and geographical scope.

Pursuant to the Commission's new Regulation, the current export authorization requirement (in force until 25 April 2020) will be extended for another 30 days to 26 May 2020. This measure will now be limited to protective spectacles and visors, mouth-nose-protection equipment, and protective garments. In addition, the Western Balkans and Gibraltar will now also be exempted from such export authorization requirement.

Although Turkey was also considered for an exemption, EU Trade Commissioner Phil Hogan indicated that talks with the Turkish government did not result in a guarantee that Turkey would lift its own export restrictions.

The EU and 21 other WTO Members pledge to ensure open and predictable trade in agricultural and food products (see here)

On 22 April 2020, the EU and 21 other WTO Members issued a joint statement, pledging to ensure open and predictable trade in agricultural and food products during the COVID-19 crisis.

The statement calls for its signatories to help safeguard that global agriculture and agri-food supply chains remain fluid and connected during the crisis to avoid food shortages and ensure global food security. The signatories are also called upon to:

- exercise restraint in establishing domestic food stocks of agricultural products traditionally exported;
- refrain from imposing agriculture export restrictions;
- ensure that emergency measures taken in relation to agriculture and agri-food products are targeted, proportionate, transparent, temporary and consistent with WTO rules; and
- inform the WTO as soon as practicable of any trade related COVID-19 measures affecting agriculture and agri-food products.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

Application of Medical Devices Regulation postponed by one year (see here)

On 24 April 2020, Regulation (EU) 2020/561 of the European Parliament and of the Council was published in the Official Journal of the European Union and entered into force on the same day of publication.

It postpones the date of application of the Medical Devices Regulation (MDR) by one year, given the disruption caused by the COVID-19 pandemic. The MDR will therefore become applicable from 26 May 2021.

The Regulation also allows national competent authorities to authorize under the currently applicable Medical Device Directives (upon a duly justified request – in the interest of public health or patient safety or health) the placing on the market or putting into service within the national territory, of a specific device for which the conformity assessment procedures have not been carried out. In exceptional cases, authorizations granted by a Member State can be extended on a Union-wide basis by the Commission for a limited period of time.

First ICRMA meeting on COVID-19

On 21 April 2020, the International Coalition of Medicines Regulatory Authorities (ICMRA) published a summary report of the meeting held on 16 April 2020 on COVID-19-related policy approaches and regulatory flexibility. The meeting was

pandemic (see here)	the first of ICMRA-hosted bi-weekly meetings, which aim to globally exchange information and build synergies for expediting development and approval of COVID-19 medicinal products and avoid medicine shortages. At the kick-off meeting, chaired by the EMA (European Medicines Agency), participants discussed policy issues and regulatory challenges related to the rapid development of potential COVID-19 treatments, as well as ensuring the continued availability of medicinal products during the pandemic, especially those used in intensive care units.
Update of Q&A guidance on regulatory expectations in the context of COVID-19 pandemic (see here)	On 20 April 2020, the European Commission, EMA, and the HMA (Heads of Medicines Agencies) updated the Q&A document on adaptations to the EU regulatory framework to address COVID-19 challenges. In particular, these Q&A updates clarify the validity of GMP/GDP certificates, time-limited manufacturing, and import and distribution authorizations. The updates also provide information on available adjustments to the work of Qualified Persons and instruct MAHs to prioritize reporting of Individual Case Safety Reports (ICSR) associated with medicinal products used for the treatment or prevention of COVID-19.
EMA update on EU actions to support availability of medicines during COVID-19 pandemic (see here)	On 20 April 2020, the EMA provided an update on measures by national authorities to support the availability of medicinal products during the pandemic. The update covers progress made on creating an enhanced monitoring system (i-SPOC) for supply issues relevant to medicines used to treat COVID-19. Through i-SPOC, the EMA will be in charge of overseeing shortage notifications and implementing measures to prevent or mitigate such shortages following coordination with the concerned companies.

CYBERSECURITY, PRIVACY & DATA PROTECTION

EDPB Guidelines on use of location data and contact tracing tools in the context of COVID-19 outbreak (see here)	On 21 April 2020, the European Data Protection Board ("EDPB") published Guidelines on the use of location data and contact tracing tools in the context of the COVID-19 outbreak ("Guidelines"). This follows the EDPB Letter to the Commission on 15 April 2020 on the use of mobile applications during the pandemic (see here). The Guidelines shed light on the conditions and principles for (1) the use of location data and (2) contact tracing tools: (1) Location Data The Guidelines lists two main sources of location data available: i. Location data collected by electronic communication service providers in the course of providing their service (e.g., mobile telecommunication operators); ii. Location data collected by information society service providers' applications whose functionality requires the use of such data (e.g., navigation and transportation services). The Guidelines also stress that the processing of location data by electronic communication providers should comply with Articles 6 and 9 of the ePrivacy Directive (i.e., location data must be anonymized by the provider or prior consent must be obtained from the user).

In general, the EDPB advises to process anonymized data rather than personal data when using location data.

(2) Contact Tracing Apps

The EDPB insists on adherence to the following General Data Protection Regulation ("GDPR") principles and requirements:

- Data controllers: National health authorities could be data controllers, but other controllers could also be envisaged.
- Legal basis for personal data: Under the ePrivacy Directive, service providers should obtain user consent when they store and/or access information already stored on a user's terminal if such operations are not strictly necessary for provision of the service.

  Under GDPR, when public authorities provide a service based on a mandate assigned by and in line with requirements laid down by law (Article 6(3) GDPR), the most relevant legal basis would be the necessity for the performance of a task in the public interest (Article 6(1)(e) GDPR). The EDPB emphasizes that national laws providing for contact tracing apps should include robust safeguards for protecting data subjects' rights. In addition, processing could also be based on consent (Article 6 (1)(a)).
- Legal basis for special categories of personal data (e.g., health data): Data controllers can rely on the following legal basis: (i) users provided their explicit consent (Article 9(2)(a)); or (ii) such data is necessary for reasons of public interest in the area of public health, provided that this is based on EU or national law with appropriate safeguards (Article 9(2)(i) GDPR); or (iii) such data is necessary for scientific research purposes (Article 9(2)(j) GDPR); or (iv) such data is necessary for health care purposes (Article 9(2)(h) GDPR).
- Purpose limitation: The purpose must be clearly specified to avoid any further processing unrelated to management of the COVID 19 crisis (e.g., commercial or law enforcement purposes). Use of the personal data must be adequate, necessary and proportionate.
- Data minimization and data protection by design and by default: Such principles should be observed by using proximity data rather than location tracking; setting measures to avoid re-identification; storing collected data on the user's terminal equipment and collecting only relevant information when absolutely necessary.
- Security and confidentiality: Implementation of such apps can be used via a centralized or decentralized server, as long as adequate security measures are in place. State-of-the-art cryptographic techniques must be implemented to secure stored data.
- Data storage: Personal data should only be kept for the duration of the COVID-19 crisis, after which all personal data should be erased or anonymized.
- Accountability: A data protection impact assessment must be carried out and published before implementing such tools.

Finally, the Guidance also include an annex of general guidance for designers and implementers of contact tracing apps.

EDPB Guidelines on processing data concerning

On 21 April 2020, the EDPB published Guidelines on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak ("Guidelines"). This follows publication of the above-referred

health for the purpose of scientific research in the context of the COVID-19 outbreak (see here)

EDPB Letter sent to the Commission on 15 April 2020 regarding the use of mobile applications during the pandemic.

The Guidelines cover the following legal questions and requirements in accordance with the GDPR:

- Legal basis: The processing of health-related personal data for scientific research purposes can either be based (i) on data subject's consent (Article 6(1)(a) and Article 9(2)(a) GDPR); or (ii) subject to national laws, on Article 6(1)(e) (i.e., necessary for the performance of a task carried out in the public interest) or 6(1)(f) GDPR (i.e., legitimate interests), in combination with the enacted derogations under Article 9 (2)(i) GDPR (i.e., necessary for reasons of public interest in the area of public health) or Article 9(2)(j) (i.e., necessary for scientific research purposes).
- Transparency and information to data subjects: Personal data must be processed fairly and in a transparent manner. In addition, data subjects must be individually informed of the processing activity and the personal (health) data being processed for scientific purposes (Articles 13 and 14 GDPR), except if exemptions apply (Article 14 (5) GDPR).
- Purpose limitation and presumption of compatibility: In principle, personal data must be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes (Article 5 (1)(b) GDPR). However, Article (5)(1)(b) allows for further processing of health-related data for scientific research, provided that such processing is subject to appropriate safeguards under Article 89 (1) GDPR (e.g., abide with principles of data minimization, integrity, confidentiality and data protection by design and by default).
- Data minimization and storage limitation: Data minimization is fostered by specifying research questions and assessing the type and amount of data necessary to properly answer such questions. The EDPB also recommends, where possible, to use anonymized data. As for storage limitations, the EDPB recommends to set proportionate storage periods, taking into account criteria such as the length and purpose of the scientific research.
- Data subject rights: In principle, the current COVID-19 outbreak still allows data subjects to exercise their rights (i.e., Article 12 to 22 GDPR). However, Article 89 (2) GDPR allows national laws to restrict some of these rights in the context of scientific research and subject to conditions.
- International data transfers: In the absence of an adequacy decision (Article 45 (3) GDPR) or appropriate safeguards (Article 46 GDPR), public authorities and private entities may transfer personal data outside of the EU and EEA by relying on the derogations listed at Article 49 GDPR (i.e., specific situations where an international transfer of personal data can take place).

European Parliament adopts resolution on EU coordinated action to combat the COVID-19 pandemic and its

On 17 April 2020, the European Parliament adopted a (non-binding) resolution on EU coordinated action to combat the COVID-19 pandemic and its consequences. This follows publication on 16 April 2020 of the Commission's Toolbox and Guidance regarding mobile applications (see here).

In particular, the European Parliament took note of the Commission's plan to request anonymized and aggregated data from telecoms providers, and the emergence of contact-tracing applications on mobile devices during the COVID-19 pandemic.

The European Parliament indicated that the use of such applications by national authorities should be on a voluntary basis and that the processing of such data

consequences (see here)	should be compliant with the e-Privacy Directive and the GDPR (e.g., respecting data protection principles such as data protection by design and data minimization). The European Parliament highlighted that the generated data should be stored in decentralized databases due to the risk of abuse and loss of trust. In addition, the European Parliament stressed the need for transparency in relation to (non-EU) commercial interests of developers of such applications, as well as the functioning of contact tracing apps.

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