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

- DG COMP COVID-19 website and mailbox for informal guidance
- Extension of State aid Temporary Framework
- Public short-term export credit insurance available

Trade / Export Controls

- Commission Guidance on customs issues related to COVID-19 crisis
- G20 trade ministerial meeting
- EU's planned suspension of tariffs, VAT on medical supplies
- UK waives import duties and VAT on vital medical equipment
- Europe sells medical goods to Iran in first bypass of US sanctions
- INTA supports export authorization requirement for PPE, but urges to exempt the Western Balkans

Medicines, Medical Devices, and Personal Protective Equipment

- Commission Proposal to delay entry into full effect of Medical Devices Regulation
- EU Emergency Support Instrument for the healthcare sector
- Commission Guidance on public procurement framework in COVID-19 crisis
- UK MHRA Statement on Phase I clinical trials

COMPETITION & STATE AID

Mergers

DG COMP COVID-19 website and mailbox for informal guidance (see here)

DG COMP has established a dedicated COVID-19 website.

The website includes a **dedicated mailbox** (COMP-COVID-ANTITRUST@ec.europa.eu) to enable seeking **informal guidance** on specific company cooperation initiatives. In this respect, companies are asked to provide details, including:

(i) the firm(s), product(s) or service(s) concerned;

(ii) the scope and set-up of the cooperation;

(iii) the aspects that may raise concerns under EU antitrust law; and

(iv) the benefits that the cooperation seeks to achieve, and an explanation of why the cooperation is necessary and proportionate to achieve those benefits in the current circumstances.

The European Commission will also continue to *"**closely and actively monitor … [and] detect companies which take advantage of the current situation to breach EU antitrust law**"*. It urges, *e.g.*, individual whistleblowers to continue to come forward anonymously (using the Commission's whistleblower tool) and provide information on potential breaches.

State Aid

Extension of State aid Temporary Framework (see here)

On 19 March 2020, the European Commission adopted a Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak.

The initial version provided for **five types of aid**: (i) **Direct grants, tax advantages**, **and repayable advances**, (ii) **State guarantees for loans from banks**, (iii) **Subsidized public loans to companies**, (iv) **Public guarantees and loans, channeled through banks**, and (v) **Short-term export credit insurance.**

On 3 April 2020, the European Commission extended the State Aid Temporary Framework to enable Member States to accelerate the research, testing and production of coronavirus relevant products, to protect jobs and to further support the economy. The amendments add **additional support** possibilities for **five types of aid**:

Additional support for -

(i) **coronavirus related research and development**,

(ii) **construction and upgrading of testing facilities** for **products relevant to tackling the coronavirus outbreak** (such as medicinal products (including vaccines) and treatments, medical equipment and devices, disinfectants, data collection and processing tools useful to fight the spread of the virus), including Member State grants of no-loss guarantees to provide incentives for company investments,

(iii) **production of products relevant to tackling the coronavirus outbreak** (see products listed in preceding (ii)), including Member State grants of no-loss guarantees, as well as the following:

Targeted support measures -

(iv) **deferral of tax payments and/or suspensions of employers' social security contributions to help avoid lay-offs** due to the coronavirus (in specific, hardest hit regions or sectors), and

(v) **wage subsidies for employees to help avoid lay-offs** due to the coronavirus crisis (in specific, hardest hit regions or sectors).

The above "targeted" support possibilities seek to give Member States more flexibility to selectively intervene based on greatest need.

In addition, the adapted Temporary Framework expands the existing types of support that Member States can give to companies in need. In particular, it now enables Member States to give zero-interest loans, guarantees on loans covering 100% of the risk, or provide equity up to the nominal value of €800.000 per company. This can be combined with so-called *de minimis* aid (to bring the aid per company to up to €1 million) and other types of aid. This seeks to address SMEs' urgent liquidity needs in particular.

The Temporary Framework applies retroactively to any aid granted by Member States since 1 February 2020 and will be in place until 31 December 2020. The European Commission indicates that it may, however, extend it to a further date.

Public short-term export credit insurance made available (see here)

As the European Commission holds that export subsidies can adversely affect competition, it has long **condemned export aid for intra-EU trade and for exports outside the EU**. Thus, the Commission has regulated State aid in the area of short-term export-credit insurance, not only among exporters in different Member States, but also among export-credit insurers operating in the EU.

Under the 2012 Short-term export-credit Communication, **trade** within the EU and certain non-EU countries listed in its Annex with a maximum risk period of up to two years entails marketable risks and**, in principle, should not be insured by the State or State supported insurers.** As private insurers may offer such insurance, the European Commission considers that the State is not needed to offer similar insurance.

However, in light of the present coronavirus crisis, the European Commission decided on 27 March 2020 to **temporarily remove all countries from the list of "marketable risk"** countries under the Short-term export-credit Communication.

This enables Member States to **make available public short-term export credit insurance** in light of the **increasing insufficiency of private insurance capacity** for exports to all countries in the current crisis.

TRADE / EXPORT CONTROL

Commission issues Guidance on customs issues related to the COVID-19 crisis (see here)

The EU Commission has issued new Guidance on tackling various customs issues related to the COVID-19 crisis. The document clarifies how customs authorities and economic operators can rely on provisions of the UCC (Union Customs Code) and the UCC Delegated Act to deal with exceptional situations that may result from the crisis.

To facilitate trading during this crisis, the Guidance sets out that traders may rely upon a variety of means, including:

- Requesting the **extension of certain time limits** for customs decisions and other customs procedures, e.g. the time-limit for lodging a supplementary declaration (Article 146 UCC DA);
- **Invoking serious economic or social difficulties**, on the basis of which customs authorities may suspend implementation of a customs decision or payment of a customs debt, even without a guarantee;
- Using **simplified procedures**, e.g. simplified customs declarations (Article 166 UCC), to comply with their obligations;
- Relying on the **temporary admission procedure for critical goods** such as ambulances and certain medical equipment, which should be considered as disaster relief material under Article 221 UCC DA. As such, these goods are eligible to be declared for temporary admission, including total relief from import duty.

G20 trade ministerial meeting	A virtual G20 trade ministers meeting took place on 30 March 2020, in which ministers pledged to facilitate trade of vital medical products amid the coronavirus pandemic. The trade ministers promised that any emergency measures would "*not create unnecessary barriers to trade or disruption to global supply chains, and are consistent with WTO rules*." EU Trade Commissioner Phil Hogan defended the EU's export authorization measure for PPE as a "*monitoring tool for the trade of medical products at a vital point in time — nothing more, nothing less*". Addressing the G20 meeting, Hogan stressed that governments should refrain from unnecessary trade restrictions in responding to the COVID-19 outbreak and that any hurdles to trade should be "*targeted, proportionate, transparent and temporary.*"
EU's planned suspension of tariffs, VAT on medical supplies (see here)	The European Commission is planning to temporarily suspend tariffs and VAT on imports of vital medical supplies. This EU-wide relief will reportedly apply retroactively and cover a range of essential medical products such as protective masks and personal garments.
UK waives import duties and VAT on vital medical equipment (see here)	The UK has waived customs duties and import VAT on certain medical goods coming from outside the EU, including ventilators, coronavirus testing kits, face masks and protective clothing. This new measure will be in place until 31 July 2020.
Europe sells medical goods to Iran in first bypass of US sanctions	The UK, Germany and France announced the sale of medical goods to Iran in the first transaction under the Instex trade mechanism, established to bypass US sanctions on Iran, which is battling a major outbreak of the COVID-19 pandemic.

INTA supports export authorization requirement for PPE, but urges to exempt the Western Balkans (see here)

A letter of 2 April 2020 by the European Parliament's INTA Committee (Committee on International Trade) to EU Trade Commissioner Phil Hogan expressed INTA's support for the Commission's implementing regulation on export authorizations for PPE.

However, INTA also stressed the importance of keeping such measure temporary and avoiding an outright export ban. In addition, INTA strongly suggested to exempt the six non-EU countries in the Western Balkans from the export authorization requirement.

INTA also urged Member States to implement the PPE export authorization measure transparently and with a minimum of bureaucratic burden, notably by making use of new facilitating elements (e.g. e-licensing and information sharing platforms) raised during the modernization of the EU dual-use regulation.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

Proposal to delay entry into full effect of Medical Devices Regulation (see here)

On 3 April 2020, the European Commission adopted a proposal that aims at providing, for exceptional reasons due to the current COVID-19 outbreak, **a one-year deferral** of the date of application of the bulk of the provisions of Regulation (EU) 2017/745 on medical devices ("MDR"). The original date of application of 26 May 2020 is now proposed to be delayed to 26 May 2021. The net effect is that the existing directives on medical devices (i.e., Directives 90/385/EEC and 93/42/EEC) would continue to apply.

The proposal also introduces the possibility for the European Commission to adopt EU-wide derogations to certain pre-market requirements in order to address potential EU-wide shortages of vitally important medical devices. In particular, the Commission proposes to (exceptionally) authorize at EU level the placing on the market of medical devices for the purpose of protecting public health and/or patient safety or health, even if the relevant conformity assessment procedures have not been carried out.

The proposal is not yet law, pending approval by the European Council and the Parliament which should happen before 26 May 2020. This is an exceptionally short timeframe, and it reflects the emergency triggered by COVID-19.

EU Emergency Support Instrument for the healthcare sector (see here)

On 2 April 2020, the Commission published a Q&A on the "European Union Emergency Support Instrument for the healthcare sector". In combating the coronavirus pandemic, the Commission seeks to directly provide targeted support to healthcare systems in the Member States and regions most affected.

To finance this action, the Commission is mobilizing €3 billion from the EU budget, in order to (i) directly purchase or procure emergency support on behalf of Member States and distribute medical supplies; (ii) financially support and co-ordinate pressing needs, such as transporting medical equipment and patients in cross-border regions; and (iii) support the construction of mobile field hospitals.

To implement this initiative, the Commission will work closely with Member State national authorities, as well as international organizations and the NGO sector.

Guidance from European Commission on

On 1 April 2020, the European Commission published a Guidance document on the options available under the EU public procurement framework for the

using the public procurement framework in the emergency situation related to the COVID-19 crisis (see here)	purchase of supplies, services, and works needed to address the COVID-19 crisis. It essentially focuses on procurement in cases of extreme urgency. The Commission also underscores the possibility for public buyers to rely on the negotiated procedure without publication (under Article 32 of Directive 2014/24/EU). It provides guidance on the following required conditions: (i) the events are unforeseeable; (ii) extreme urgency making compliance with general deadlines impossible; and (iii) a causal link between the unforeseen event and the extreme urgency (the Commission deems such link to be present "*for the satisfaction of the immediate needs of hospitals and health institutions*" under the current COVID-19 crisis). However, the Guidance also reminds that this negotiated procedure without publication can only be used to bridge the gap until more stable solutions are found.
UK MHRA Statement on the status of Phase I clinical trials (see here)	On 31 March 2020, the UK Medicines and Healthcare products Regulatory Agency (MHRA) reached out to sponsors conducting Phase I clinical trials to confirm that such sponsors have conducted a risk assessment of COVID-19's potential impact on their studies.
Commission issues Q&A to help increase production of safe medical supplies (see here)	On 30 March 2020, the Commission issued guidance to assist manufacturers in the production of essential medical equipment and material in three areas: (i) production of masks and other personal protective equipment ("PPE"), such as masks, gloves and surgical gowns (Conformity assessment procedures for protective equipment), (ii) leave-on hand cleaners and hand disinfectants (Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.)), and (iii) 3D printing and 3D printed products for medical use (Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19) in the context of the coronavirus outbreak. Guidance on medical devices will also be issued in the coming days. These guidelines also aim to assist manufacturers and market surveillance authorities in ensuring that these products are effective and comply with necessary safety standards.
Updated Guidance on the management of clinical trials during the COVID-19 pandemic (see here)	On 27 March 2020, the European Medicines Agency (EMA), the European Commission, and the Heads of Medicines Agencies (HMA) updated the "Guidance on the management of clinical trials during the COVID-19 (coronavirus) pandemic" to cover safety reporting, the distribution of in-vitro diagnostics and medical devices and auditing. The updated guidance also incorporates changes in other areas, in particular on communicating with authorities, informed consent, and the distribution of investigational medicines.
Harmonized standards for medical devices to respond to	On 25 March 2020, the Commission adopted decisions on harmonized standards to allow manufacturers to place on the market high performing devices to protect patients, health care professionals and citizens in general. The standards will facilitate a faster and less expensive conformity assessment procedure. The revised harmonized standards relate to critical devices such as:

urgent needs (see here)	• medical face masks • surgical drapes, gowns and suits • washer-disinfectors • sterilization
Guidance issued by the Belgian FAMHP on supply shortages due to COVID-19	On 24 March 2020, the Belgian Federal Agency for Medicines and Health Products (FAMHP) announced that it is closely monitoring stocks of medicinal products used in the fight against COVID-19 (see here) and that a working group (Task Force) has been established to devise immediate solutions to remedy the shortage of protective equipment and medical equipment on the Belgian market (see here).
European standards for medical supplies made freely available to facilitate increase of production (see here)	On 20 March 2020, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) agreed to make freely available a number of European standards for certain medical devices and PPE. This action will help both EU and non-EU manufacturers to swiftly start production and place products on the internal market more easily, while ensuring a high degree of safety.
Decision of the Italian National Bar Association against unscrupulous COVID-19 claims	On 1 April 2020, the Italian National Bar Association issued an unprecedented decision threatening disciplinary sanctions against those practitioners who may seek to take advantage of the current crisis by instigating legal action against healthcare professionals ("HCPs") and volunteers who are fighting the current emergency. The Bar expressed its solidarity to all those fighting COVID-19 in Italy and expressed its "*forceful condemnation of any behavior that in any way constitutes a grave violation of shared ethical principles at the very core of the legal profession*" and that dishonors the Italian bar as a whole. This decision came after news reports of lawyers inciting legal action against HCPs in connection with their work in the coronavirus pandemic.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Data Protection Board statement on processing of personal data in the context of the COVID-19 outbreak (see here)	On 19 March 2020, the European Data Protection Board (EDPB) adopted a statement on processing personal data in the context of the COVID-19 outbreak. The EDPB stated that data protection rules applicable in Europe (e.g., the General Data Protection Regulation, "GDPR") do not prevent measures taken to fight the pandemic. However, even in these exceptional circumstances, the protection of personal data by data controllers and data processors must be ensured. When processing personal data, data controllers and data processors should consider and comply with the following data protection requirements: • Lawfulness and transparency of the processing of personal data; • Necessity and proportionality principles (i.e., personal data can be processed for specified and explicit purposes only);

- Adoption of adequate security measures and confidentiality policies;
- Appropriate documentation of measures implemented to manage the current emergency and the underlying decision-making process.

The list of requirements above is non-exhaustive. For any additional specific personal data-related questions (e.g., employment and location data), the EDPB advises data controllers and data processors to refer to Member States' national laws.

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