COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 6 | 30 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

- DG COMP launches dedicated web pages for COVID-19-related information
- EU approves Member State measures to support the economy
- EU consults Member States on proposal to further expand State aid Temporary Framework to subordinated debt

Trade / Export Controls

- Commission Report on the impact of the COVID-19 pandemic on global and EU trade
- EU notifies the WTO of new set of coronavirus-related measures

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission and EMA update Guidance on management of clinical trials during COVID-19 pandemic
- ICMRA members pledge clinical, regulatory support for COVID-19 products
- MDGC Guidance on Regulatory Requirements for Ventilators and Related Accessories

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

COMPETITION & STATE AID

General

DG COMP launches dedicated web pages for COVID-19-related information

The European Commission's Directorate-General for Competition (DG COMP) has launched COVID-19-dedicated web pages for State aid, antitrust, and merger control, respectively.

These web pages gather all relevant information for these areas, including legal acts, forms/templates, statements and press releases, procedural guidance, contact details etc. They can be accessed through the below links:

- State aid (see here).
- Antitrust (see here).
- Merger control (see here).

State Aid

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.

On 30 April 2020, DG COMP published an exhaustive overview of these measures. The document is available here.

The most recent measures adopted to support the economy and companies affected by coronavirus outbreak include:

(i) a €16.6 billion Polish repayable advance scheme for companies,

(ii) two additional Estonian schemes for companies,

(iii) a €1.55 billion Hungarian guarantee scheme for companies,

(iv) a German "umbrella" scheme to support research, development, testing and production of coronavirus relevant products,

(v) €900 million Hungarian schemes for companies, and

(vi) a €5 billion loan guarantee by France to the Renault group to mitigate the economic impact of the coronavirus outbreak.

EU consults Member States on proposal to further expand State aid Temporary Framework to subordinated debt (see here)

On 24 April 2020, the European Commission consulted the Member States on a draft proposal to extend the State aid Temporary Framework for a second time.

The amendment aims to complement the existing framework on loans by defining conditions under which EU Member States could grant subordinated debt on favorable terms to support their economies during the coronavirus outbreak.

The proposal also aims to ensure sufficient safeguards to limit the distortion of competition in the EU internal market.

TRADE / EXPORT CONTROL

Commission Report on impact of COVID-19 pandemic on global and EU trade (see here)

On 17 April 2020, the EU Commission published a Report containing the results of DG TRADE's analysis of the anticipated impact of the COVID-19 pandemic on international trade in 2020.

Some key forecasts highlighted in the Report include:

- A 9.7% decrease in global trade for 2020;
- A reduction of 9.2% in extra-EU27 exports of goods and services, and an 8.8% decrease in extra-EU27 imports in 2020. In absolute terms, compared to the latest available statistics, this amounts to a reduction of exports by about €285 billion and of extra-EU imports by €240 billion (goods and services combined);
- Manufacturing sectors, in particular exports of transport equipment and electrical machinery, will be the most strongly affected.

EU notifies WTO of new set of coronavirus-related measures (see here)

On 24 April 2020, the EU notified the WTO of a new set of measures undertaken by the EU and Member States to tackle the COVID-19 pandemic. This follows a previous notification on a first round of measures on 7 April 2020.

The trade measures notified were:

- the renewed export authorization requirement for PPE;
- the Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak;
- the Commission Notice regarding the consequences of the COVID-19 outbreak on anti-dumping and anti-subsidy investigations;
- the Commission Guidance to Member States concerning foreign direct investment and free movement of capital from third countries;
- EU Member State measures in reaction to COVID-19 related to exports of essential products; services and investment; and economic support.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Commission and EMA update Guidance on management of clinical trials during COVID-19 pandemic (see here)

On 28 April 2020, the European Commission and European Medicines Agency (EMA) updated the "*Guidance on managing clinical trials during the coronavirus disease (COVID-19) pandemic*".

In particular, the updated version provides new recommendations on distributing investigational medicinal products (IMPs) and data verification under social distancing measures.

The Guidance also clarifies how sponsors should communicate urgent issues to regulatory authorities. It recommends that regulatory authorities should amend the distribution of IMPs in order to avoid treatment disruptions. Moreover, the document illustrates that remote source data verification (SDV) will only be considered for either (i) clinical trials involving products to treat or prevent COVID-19 or (ii) in the final data cleaning steps for pivotal trials of products for serious/life-threatening conditions that lack sufficient treatment options. In this

	context, the Guidance (Annex 1) provides a series of recommendations on the protection of trial participants' rights during SDV. Finally, guidance is provided on the classification and notification to competent authorities of urgent actions, where taken in the context of clinical trials with the purpose of protecting participants against immediate hazards and in relation to other changes affecting patient safety or data robustness.
ICMRA members pledge clinical, regulatory support for COVID-19 products (see here)	On 28 April 2020, members of the International Coalition of Medicines Regulatory Authorities (ICMRA) pledged to work together to accelerate the development and approval of medicinal products for the treatment of COVID-19, towards aligning regulatory processes and requirements. The statement follows a series of ICMRA meetings aimed at developing a consensus on data requirements for phase 1 clinical trials for COVID-19 vaccines, as well as gaining and using real-world evidence data in the context of clinical trials. The ICMRA also focused on possible solutions for granting access to medicines and medical devices in low- and middle-income countries, given the risk of an uncontrolled spread of the virus among the relevant population.
MDGC Guidance on Regulatory Requirements for Ventilators and Related Accessories (see here)	On 24 April 2020, the European Commission's Medical Device Coordination Group (MDCG) published guidance on "*Regulatory Requirements for Ventilators and Related Accessories*". The document provides guidance on the types of ventilators and their relevant classification. It also illustrates the different regulatory options available for supplying parts or placing finished devices on the market. In this regard, the guidance emphasizes the possibility, introduced last week via amendments to the Medical Device Regulation, for Member States to authorize the placing on the market of medical devices for which the conformity assessment procedures have not been finalized.

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