



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

- EU relaxes competition rules for cooperation in dairy, potatoes, and flowers sectors
- EU approves new and amended Member State measures to support the economy
- EU rejects Austrian proposal to put State aid rules on hold

Trade / Export Controls

- UK and US start trade negotiations amidst the COVID-19 pandemic

Medicines, Medical Devices, and Personal Protective Equipment

- ICMRA meeting on aligning policy approaches and regulatory flexibility during COVID-19 pandemic
- EMA and European Commission Q&A document on regulatory flexibility for veterinary medicines
- EMA initiatives for accelerating development support and evaluation procedures for COVID-19 treatments and vaccines

Cybersecurity, Privacy & Data Protection

- European Union Agency for Cybersecurity (“ENISA”) publishes recommendations on phishing and COVID-19

COMPETITION & STATE AID

Competition

EU relaxes competition rules for cooperation in dairy, potatoes, and flowers sectors (see [here](#))

On 4 May 2020, the European Commission announced the adoption of temporary derogations from EU competition rules to allow certain types of cooperation in the [milk and milk products](#), [live plants and flowers](#), and [potatoes](#) sectors. The derogations are part of a wider package of exceptional measures to support the agri-food industry during the ongoing coronavirus pandemic.

These derogations will apply for a maximum period of six months, starting on 5 May 2020 for the live plants and flowers and potatoes sectors, and retroactively on 1 April 2020 for the dairy sector.

State Aid

Second extension of State aid Temporary Framework (see [here](#))

On 8 May 2020, the European Commission adopted a second amendment to extend the scope of the State aid Temporary Framework (adopted on 19 March 2020) to support the economy during the COVID-19 pandemic. This follows a first amendment adopted on 3 April 2020.

Complementing the types of measures already covered by the Temporary Framework and existing State aid rules, this second amendment seeks to further respond to the critical need for liquidity, as follows:

Recapitalization aid to companies: Facing a constricted ability to supply goods and services, European companies are suffering losses that have diminished their equity and their ability to borrow on the markets. The second amendment thus expands the Temporary Framework to facilitate public interventions in the form of recapitalization aid to non-financial companies, along with safeguards to preserve competition.

Additionally, Member States are free to design national measures in line with further policy objectives, such as promoting the green and digital transformation of their economies or preventing fraud and tax evasion.

The following conditions are set out for recapitalization aid:

- (i) **Necessity, appropriateness and size of intervention:** Recapitalization aid should only be granted if no other appropriate solution is available. The aid must be limited to preserving the company's viability and should not extend beyond restoring the beneficiary's capital structure to before the coronavirus outbreak.
- (ii) **State's entry in the capital of companies and sufficient State remuneration:** Governments must be adequately remunerated for the risks they assume through recapitalization aid. Furthermore, remuneration mechanisms must incentivize beneficiaries and/or their owners to buy out shares acquired by the State using State aid to ensure the temporary nature of the State's intervention.
- (iii) **Exit of the State from capital of concerned companies:** Beneficiaries and Member States must formulate an exit strategy, particularly in the case of large companies receiving substantial recapitalization aid. If a State's exit is

in question six years after recapitalization aid to publicly listed companies, or up to seven years for other companies, the Commission must receive a restructuring plan for the beneficiary.

(iv) **Governance restrictions:** Prior to the State's exit in full, beneficiaries are subject to bans on dividends and share buybacks. Furthermore, a strict limitation on remuneration of management, including a ban on bonus payments, will apply until at least 75% of the recapitalization is redeemed.

(v) **No cross-subsidization and no acquisitions:** To preserve fair competition, recapitalization aid cannot be used to support economic activities of integrated companies that were in economic difficulty prior to 31 December 2019. Until at least 75% of the recapitalization is redeemed, beneficiaries (other than SMEs) are in principle prohibited from acquiring a stake of over 10% in competitors or other operators in the same line of business, including upstream and downstream operations.

Public transparency and reporting: Member States must publish the identity of companies that have received aid and the aid amount within three months of the recapitalization, where recapitalization aid is granted to beneficiaries as part of a Member State's recapitalization scheme.

Beneficiaries, other than SMEs, must publish information on use of the aid received. This includes how such use reinforces the company's activities in line with EU and national obligations in connection with the green and digital transformation.

Aid to companies in the form of subordinated debt: Under this second amendment to the Temporary Framework, Member States may now assist undertakings in difficulty due to the coronavirus outbreak by providing subordinated debt to companies at favorable terms.

This measure concerns debt instruments subordinated to ordinary senior creditors in the context of insolvency proceedings. This complements measures available to Member States under the existing Temporary Framework, including to grant debt with senior ranking to companies in need.

Next steps: The amended Temporary Framework is applicable until 31 December 2020. However, solely for recapitalization measures, these extend until 1 July 2021, as solvency issues may only later arise as this crisis unfolds. The Commission will continue to assess the need to extend these dates.

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.

The most recent measures adopted to support the economy and companies affected by coronavirus outbreak up to 8 May 2020 include:

- 8 May: €650 million Dutch scheme to compensate companies in the floriculture, specialty horticulture and potato sectors for damage caused by coronavirus outbreak.
- 7 May: €7.3 million Czech scheme to support research and development activities related to coronavirus outbreak.

- 7 May: €314 million Hungarian guarantee scheme to support SMEs active in the agri-food value chain during the coronavirus outbreak. 30 April: Modification of Greek guarantee measure to support companies affected by the coronavirus outbreak.
- 6 May: €40 million Finnish direct grant schemes to support companies in the agriculture and fishery sectors affected by coronavirus outbreak.
- 5 May: €5.2 billion Czech guarantee scheme for loans to large exporting companies affected by coronavirus outbreak.
- 5 May: Belgian €250 million subordinated loan scheme to support start-ups, scale-ups and SMEs affected by the coronavirus outbreak.
- 5 May: €296 million Danish loan schemes to support start-ups affected by coronavirus outbreak.
- 5 May: €10 million Greek scheme to support companies in the floriculture sector affected by the coronavirus outbreak.
- 4 May: French plans to provide €7 billion in urgent liquidity support to Air France.
- 4 May: €30 million Italian scheme to support SMEs in the agriculture and fishery sectors affected by coronavirus outbreak
- 30 April: €101.5 million Lithuanian rent compensation scheme to support sectors affected by coronavirus outbreak.
- 30 April: €2 billion Slovenian guarantee and rent relief schemes to support companies affected by coronavirus outbreak.
- 30 April: Guarantee scheme of up to €530 million to support the Walloon economy in coronavirus outbreak.
- 30 April: €130 million Danish schemes to support SMEs affected by coronavirus outbreak.

EU rejects Austrian proposal to put State aid rules on hold (see [here](#))

On 30 April 2020, EU Executive Vice President and Commissioner for Competition Margrethe Vestager rejected Austria's proposal of 21 April 2020 to suspend EU state aid rules to further assist Member States in supporting companies during the COVID-19 crisis. This was communicated, as reported in the press, in a letter by Vestager to Austrian Finance Minister Gernot Blumel and Economy Minister Margarete Schramboeck.

TRADE / EXPORT CONTROL

UK and US start trade negotiations amidst the COVID-19 pandemic (see [here](#))

On 5 May 2020, the UK and US governments commenced negotiations on a UK-US Free Trade Agreement (FTA). The first round of talks will take place on a virtual basis over the next two weeks to allow the negotiations to progress during the COVID-19 pandemic. Subsequent rounds are scheduled to occur approximately every six weeks and will also be carried out remotely until it is safe to travel.

As stated by the UK International Trade Secretary Liz Truss: “*The US is our largest trading partner and increasing transatlantic trade can help our economies bounce back from the economic challenge posed by Coronavirus.*” Talks will cover all areas set out in the UK’s negotiation objectives, including goods and services trade, digital trade, investment and supporting SMEs.

The UK and US negotiating teams have already paved the way to an ambitious agreement through the UK-US Trade and Investment Working Group, which met six times in the lead up to the present negotiations. As the teams have already discussed the full set of topics typically included in FTAs, this is expected to allow the current talks to rapidly get underway.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

ICMRA meeting on aligning policy approaches and regulatory flexibility during COVID-19 pandemic (see [here](#))

On 5 May 2020, the European Medicines Agency (EMA) chaired the International Coalition of Medicines Regulatory Authorities (ICMRA) meeting. Participating regulatory authorities, in particular, once again emphasized the importance of alignment on common study protocols.

Members also discussed the development, evaluation and use of diagnostic tests in the fight against COVID-19. In this context, they agreed to establish an inventory of approved tests, in collaboration with the World Health Organization (WHO).

ICMRA is an international coalition of key regulators from every region in the world. It provides a global strategic focus for medicines regulators, as well as strategic leadership on shared regulatory issues and challenges.

EMA and European Commission Q&A document on regulatory flexibility for veterinary medicines (see [here](#))

Towards addressing certain COVID-19 related issues in the veterinary sector, on 4 May 2020, the EMA and the European Commission published a Q&A providing specific guidance on adaptations to the regulatory framework for companies developing, manufacturing and distributing veterinary medicines.

The Q&A provides guidance on certain available regulatory flexibilities on marketing authorization procedures, safety monitoring and inspections of manufacturing facilities, and good manufacturing practice (GMP).

This Q&A for veterinary medicines is analogous to the earlier issued Q&A for medicinal products for human use (see [here](#)), which is under continuous update.

EMA initiatives for accelerating development support and evaluation procedures for COVID-19 treatments and vaccines (see [here](#))

On 4 May 2020, the EMA published an overview of the tools that it will use to facilitate the expedited development and authorization of medicinal products and vaccines for the treatment and prevention of COVID-19.

In particular, as regards the development phase, the EMA will provide rapid: (i) scientific advice (20 days, rather than 40-70); and (ii) agreement of pediatric investigation plans (PIPs) and related compliance checks (review time for PIPs will be 20 days, rather than up to 120).

As concerns the authorization and post-authorization phases, the EMA will rely on “rolling reviews” (enabling the agency in emergency contexts to assess data as they become available for very promising applications), as

well as accelerated assessments. Such mechanisms will be also available for applications for line extensions aimed at including the treatment of COVID-19 in the marketing authorization of a product.

Compassionate use programmes remain under the remit of Member States, but the EMA will provide recommendations for medicines eligible for centralized procedure upon the request of national competent authorities.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Union Agency for Cybersecurity (“ENISA”) publishes recommendations on phishing and COVID-19 (see [here](#))

On May 6, 2020 the European Union Agency for Cybersecurity (“ENISA”) published recommendations on coping with a tremendous spike in phishing during the COVID-19 pandemic (“Recommendations”).

The COVID-19 sanitary crisis has led companies to increase remote activities such as teleworking. This has attracted cybercriminals, leading to an estimated 600% rise in phishing attacks since end-February 2020.

The Recommendations set out the following issues and advice:

- **Scammers’ tactics.** Scammers typically operate by sending malicious emails with attachments purportedly relating to the COVID-19 crisis, embedding malicious software that allow cybercriminals to take control of the recipient’s device.
- **Spotting phishing.** Phishing emails rely on various ploys to trick users (e.g., emails that look identical to messages from official or reputable organizations; emails that use language inciting fear or suggesting an emergency situation; emails requesting to download documents).
- **Protecting against phishing attacks.** Individuals can take measures against phishing attacks (e.g., take time to reflect on a request to provide personal data and whether it is appropriate; check for suspect email addresses and links; watch out for telltale spelling/grammatical mistakes; protect devices with anti-spam, anti-spyware and anti-virus software).
- **Next steps after an attack.** Following a phishing attack, various steps should be taken (e.g., changing passwords, updating security software, reporting the incident to the IT department, etc...).

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