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

- European Commission addresses State aid support in Communication on tackling non-performing loans in the aftermath of COVID-19 pandemic
- European Commission Executive Vice-President Margrethe Vestager speech on hydrogen-related projects, including potential support by COVID-19 recovery funds
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Parliament and EU Member States reach political agreement on new Customs Programme for 2021-2027
- European Commission publishes second Counterfeit and Piracy Watch List

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission grants conditional marketing authorization for Pfizer/BioNTech COVID-19 vaccine
- Moderna COVID-19 vaccine: European Commission purchases additional doses and EMA accelerates approval timeline
- European Commission adopts a proposal for a Council Recommendation on use and validation of rapid COVID-19 tests

Cybersecurity, Privacy & Data Protection

- European Medicines Agency pursues investigation of cyberattack

COMPETITION & STATE AID

State Aid

European Commission addresses State aid support in Communication on tackling non-performing loans in the aftermath of COVID-19 pandemic (see here)

On 16 December 2020, the European Commission published a Communication on tackling non-performing loans in the aftermath of the COVID-19 pandemic, including the use of State aid measures.

The Communication notes that with the significant economic downturn caused by the COVID-19 pandemic, the ratio of non-performing loans ("NPLs") in all EU banks increased for the first time since Q4-2014. NPLs are loans subject to late repayment (i.e. 90 days past due) or unlikely to be repaid by the borrower.

The Communication observes that a key lesson from the last economic crisis is to address, as early as possible, a renewed build-up of NPLs on banks' balance sheets. To do so, the Commission intends, among other actions, to make use of the EU bank crisis management and State aid frameworks.

In particular, the Bank Recovery and Resolution Directive ("BRRD") acknowledges the existence of exceptional situations where the need for extraordinary public financial support will not trigger a declaration that an institution is failing or likely to fail. Under the Commission's Temporary Framework for State aid measures to support the real economy, the COVID-19 crisis is already recognized as a serious disturbance to the economy. Measures taken to remedy such serious disturbances can fall under the BRRD exceptions.

Specifically, the Commission considers that the exception under Article 32(4)(d)(iii) BRRD may be applied during the COVID-19 crisis to banks that are financially viable, but impacted by a system wide event. This exception seeks to enable Member States to provide institutions with a temporary capital buffer to respond to severe adverse conditions and to thereby strengthen confidence in the banking sector and financial stability.

The Communication makes clear that any measures taken under the BRRD exception must demonstrate compatibility with applicable State aid rules.

European Commission Executive Vice-President Margrethe Vestager speech on hydrogen-related projects, including potential support by COVID-19 recovery funds (see here)

On 17 December 2020, Executive VP and Competition Commissioner Margrethe Vestager spoke at an event on the future of European Cooperation in key technologies, including the new launch of the hydrogen IPCEI (Important Project of Common European Interest), with 22 EU Member States and Norway signing a manifesto committing to work together on large-scale joint investment projects to support the development of hydrogen technologies and systems.

Commissioner Vestager indicated that hydrogen technologies can play a key part in the EU's target to reduce emissions to at least 55% by 2030 and to make Europe the first climate-neutral continent by 2050. She also noted that such large-scale and risky projects and innovation will require significant public and private investments and cross-border cooperation. In this respect, she reminded that the State aid framework for IPCEIs, which the Commission is currently updating, was set up in 2014 to serve such purpose.

As not every project relating to hydrogen will qualify for an IPCEI, Commissioner Vestager emphasized that Member States can support innovative projects under the regular EU State aid rules, the EU's rules for

	energy and environmental aid, as well as the Recovery and Resilience Facility put in place to tackle the impact of the COVID-19 pandemic. The European Commission plans on publishing a set of technical guiding templates on how such hydrogen-related projects can be supported under the Recovery and Resilience Facility in line with EU State aid rules. The templates will assist Member States in designing investments in light of the Union's key priorities, in view of either avoiding notification or obtaining rapid approval.
EU approves new and amended Member State measures to support the economy (see here and 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 include: • €40 million Bulgarian scheme to support small enterprises affected by the coronavirus outbreak • Extension to French wage-subsidy scheme to €4.1 billion to support businesses in regions hit hardest by the coronavirus outbreak • €39.2 million Polish scheme to support companies in the pig-breeding sector affected by the coronavirus outbreak • Modifications such as deadline extensions and budget increase to several Lithuanian schemes to support companies affected by the coronavirus outbreak • €500.000 Luxembourgish scheme to support the seed sector affected by the coronavirus outbreak • €15 million Irish scheme to support Ireland-based inbound tourism agents affected by the coronavirus outbreak • €26 million Bulgarian scheme to support tour operators and travel agents in the context of the coronavirus outbreak • €1.1 million UK compensation to a Scottish company active in the poultry sector for revenue losses caused by the coronavirus outbreak • €900 million Slovenian scheme to support uncovered fixed costs of companies affected by the coronavirus outbreak • €90 million Lithuanian guarantee scheme to supply trade credit insurance to help companies weather the coronavirus pandemic • €134 million Danish scheme to compensate public rail transport companies for damages suffered due to the coronavirus outbreak • Danish umbrella scheme to support companies affected by the coronavirus outbreak with an estimated budget of €37.5 million per month • €560.000 Cypriot scheme to support producer groups and producer organizations active in the agricultural sector affected by the coronavirus outbreak • Danish umbrella scheme to support uncovered fixed costs of companies affected by the coronavirus pandemic with an estimated budget of €94 million per month

- Modification to Greek repayable advances scheme to expand its budget to up to €5.7 billion to support companies affected by the coronavirus outbreak
- €650 million Polish support to aid national air carrier LOT aimed at restoring its equity and liquidity position
- €197.000 Slovenian scheme to support farmers and fishermen affected by the coronavirus outbreak
- €30 million Lithuanian scheme to supply companies affected by the coronavirus outbreak with loans with subsidized interest rates
- €150 million Lithuanian aid scheme to support companies affected by the coronavirus outbreak with direct grants
- €29.8 million Slovak scheme to compensate airport operators for damages suffered due to the coronavirus outbreak
- €20 million Czech scheme to support companies active in the sports sector affected by the coronavirus outbreak
- €120 million Greek support to Aegean Airlines for damages suffered due to the coronavirus outbreak
- €2.9 billion Polish scheme to support micro, small and medium-sized enterprises in the context of the coronavirus pandemic
- €73 million Italian support to airline Alitalia to compensate for operating losses incurred between June 16 and October 31 due to the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Parliament and EU Member States reach political agreement on new Customs Programme for 2021-2027 (see here)

On 15 December 2020, the European Parliament and EU Member States reached political agreement on the new Customs Programme for 2021-2027. As noted by the European Commission, the COVID-19 pandemic has highlighted the crucial need for robust and agile customs processes, as well as support for national customs authorities in cooperating and exchanging information.

The new Programme is the continuation of the existing Customs 2020 Programme and its predecessors, which promote cooperation between customs authorities across the EU. These programmes have helped to create a modern Customs Union to ensure the safety of EU citizens, while facilitating growing global trade.

The new €950 million Programme (increased from €523 million during the period 2014-2020) will help further modernize the Customs Union. The new Programme aims at assisting national authorities to strengthen information exchange and to improve efficient risk management strategies to combat, in particular, new forms of fraud and to respond to security threats. The Programme will also assist customs administrations with training and tools to transition to a digital environment.

Adoption of the final text of the Programme is expected in early 2021, subject to formal confirmation by the Council and the European Parliament on the provisional political agreement. Implementation is anticipated by Spring 2021.

European Commission publishes second Counterfeit and Piracy Watch List (see here)	On 14 December 2020, the European Commission published the second Counterfeit and Piracy Watch List, which identifies online and physical marketplaces outside the EU that reportedly engage in, enable, or profit from counterfeiting and piracy. Such activities endanger consumer health and safety, threaten intellectual property rights, and harm businesses and jobs. The Commission notes, in particular, that the COVID-19 pandemic unleashed a flood of counterfeit and falsified products on the EU market, including unproven treatments, test kits and medical equipment and supplies. Among the actions taken in response, a European Anti-Fraud Office (OLAF) inquiry, in partnership with customs and enforcement authorities in Europe and worldwide, led to identifying over 800 suspect companies, contributing to the seizure or detention of more than 14 million counterfeit or substandard items linked to the COVID-19 pandemic. The Watch List seeks to spur operators and intermediaries of potentially problematic marketplaces, as well as local enforcement authorities and governments, to act against intellectual property infringements. The List also aims to alert ordinary citizens to the product safety and other risks of purchasing from these suspect markets.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Commission grants conditional marketing authorization for Pfizer/BioNTech COVID-19 vaccine (see here)	On 21 December 2020, the Commission granted conditional marketing authorization for Comirnaty, the COVID-19 vaccine developed by BioNTech and Pfizer. The Decision was published on 24 December 2020 (see here). The vaccine is recommended to prevent infection by the novel coronavirus in individuals 16 years of age and older and is administered as two injections, at least 21 days apart. Trials showed a 95% reduction in the number of symptomatic COVID-19 cases in participants who received the vaccine and around 95% efficacy in those at risk of severe COVID-19 (see here).
Moderna COVID-19 vaccine: European Commission purchases additional doses and EMA accelerates approval timeline (see here)	On 18 December 2020, the Commission indicated that it had exercised the option to purchase an additional 80 million doses of Moderna's COVID-19 vaccine under the relevant Advanced Purchase Agreement. Additionally, the European Medicines Agency ("EMA") scheduled an extraordinary meeting for 6 January 2021 to conclude its technical review on the conditional marketing authorization for the vaccine. Such meeting was planned for 12 January 2021, but the agency is seeking to accelerate the approval timeline and to issue a conclusive opinion as soon as possible (see here).
European Commission adopts a proposal for a Council Recommendation on use and validation of rapid COVID-19 tests (see here)	On 18 December 2020, the Commission adopted a Proposal for a Council Recommendation on a common framework for the use, validation and mutual recognition of COVID-19 rapid antigen tests in the EU, in view of ensuring the uniform use, validation and recognition of rapid antigen tests across the European Union. The Proposal recognizes that the "*most reliable methodology for testing of cases and contact tracing is the RT-PCR*" (i.e. testing upper and lower respiratory specimens). However, high demand has led to testing material shortages and longer wait times for testing results, thereby hampering the effective implementation of mitigation measures and prompt contact tracing.

The Proposal notes the alternative of rapid tests, which are cheaper and detect COVID-19 in less than 30 minutes. The Commission makes clear, though, that positive rapid test results should always be confirmed by an RT-PCR test.

In light of Member States' increasing use of rapid tests, the Proposal sets out a common approach for the use of such tests and reinforced coordination efforts to facilitate mutual recognition of test results. The Proposal recommends, *inter alia*, that Member States:

- Use rapid antigen tests to strengthen overall testing capacity, in particular for the diagnosis of symptomatic cases, contacts of confirmed cases, outbreak clusters, or for screening in high-risk areas and closed settings;
- Ensure that testing is conducted by trained healthcare personnel, or other trained operators where appropriate, and "*in strict accordance with manufacturer's instructions*";
- Implement strategies aimed to clarify when confirmatory testing by RT-PCR or a second rapid antigen test is required, as specified in the Commission Recommendation of 18 November 2020 (here);
- Update the Commission database (here) on a common list of COVID-19 rapid antigen tests considered appropriate for use and that these tests:
  - are lawfully CE marked; and
  - meet the sensitivity and specificity requirements as defined by Commission and European Centre for Diseases and Control (ECDC, here), by also including details on the methodology and results of such studies, such as: sample type used for validation, setting for assessing use of the test, and other performance elements.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Medicines Agency pursues investigation of cyberattack (see here)

On 22 December 2020, the European Medicines Agency ("EMA") provided its latest update on the cyberattack experienced by EMA on 9 December 2020, affecting BioNTech and Pfizer COVID-19 documents.

Pursuant to EMA's ongoing investigation, in cooperation with law enforcement and other relevant entities, it appears that the data breach was limited to only one IT application. The attackers focused on data related to COVID-19 medicines and vaccines and unlawfully accessed third parties' documentation.

The EMA has informed affected companies, and as the investigation proceeds, the EMA will notify any other third parties whose documents may have been breached.

The EMA reported that it remains fully operational, and the evaluation and approval timelines for COVID-19 medicines and vaccines are not impacted.

EMA will continue to provide information, to the extent possible, on the cyberattack.

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