



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 comments on the future of competition policy
- European Commission expresses caution in curtailing State aid and extends Poland's scheme for the resolution of certain smaller banks
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission publishes first Report on Implementation and Enforcement of EU Trade Agreements
- European Commission publishes EU Aid for Trade –Progress Report 2021

Medicines and Medical Devices

- European Council publishes G20 Rome Leaders' Declaration
- EMA reviews certain potential medical conditions and COVID-19 vaccines
- European Parliament and Council reach provisional agreement on proposed Regulation on a Reinforced Role for the EMA in Crisis Preparedness and Management

Cybersecurity, Privacy & Data Protection

- European Council publishes G20 Rome Leaders' Declaration
- President of EU General Court rejects interim measure to suspend application of Regulation on EU Digital COVID-19 Certificates
- ENISA publishes 2021 Threat Landscape Report

COMPETITION & STATE AID

Competition

European Commission comments on the future of competition policy (see [here](#))

On 29 October 2021, Executive Vice-President and Competition Commissioner Margrethe Vestager provided remarks on the future of competition policy, particularly in light of the COVID crisis and the broader policy landscape.

According to Commissioner Vestager, the “*built-in flexibility*” of the competition law framework enabled a rapid response to the pandemic, notably by approving subsidies for businesses impacted by the crisis through temporary State aid and antitrust frameworks.

Commissioner Vestager also observed that the pandemic forced new ways of living, working, and learning, and that the pre-pandemic world would not return.

Against the backdrop of this new reality, Commissioner Vestager indicated that the Commission’s current review of its competition rules is “*unprecedented in its scope and ambition*”. By simultaneously reviewing all of its competition instruments, the Commission seeks to ensure their suitability and their contribution to a more resilient Europe and the green and digital transition.

Commissioner Vestager highlighted, in particular, the Commission’s activity in technology-related areas such as:

- Digital markets. Given what the Commission considers to be the distinctive features of digital markets, the Commission is reviewing the existing Market Definition Notice from 1997;
- E-commerce and online platforms. The Commission is reviewing the rules on horizontal and vertical agreements in view of setting out the types of restrictions that such businesses can include in their agreements;
- Broadband networks, including Gigabit and 5G networks. The Commission is reviewing the Broadband State aid Guidelines and General Block Exemption Regulation with the intent to facilitate the deployment and take-up of such networks where the market cannot deliver;
- “Gatekeepers”. The proposed Digital Markets Act (DMA) will provide ex ante rules that set out do’s and don’ts for what the Commission has labelled as “gatekeepers” (defined by the Commission as large online platforms with a significant impact on the internal market and active in multiple EU countries). The Commission has stated that the DMA will serve as a complement to the Commission’s existing instruments;
- Data. The Commission argues its proposed Data Governance Act and the planned Data Act will seek to promote suitable conditions for encouraging access to data to protect consumers and enable smaller competitors to share in some of the benefits.

Commissioner Vestager further noted that a large part of the Commission’s current review focuses on “greening competition,” especially as concerns State aid. The Commission will soon adopt guidelines on State aid for climate, energy and the environment to expand the list of project types

eligible for support.

Finally, Commissioner Vestager noted that to break some “*bad environmental habits*”, e.g. in packaging or logistics, companies in those markets may need to cooperate to achieve a more sustainable equilibrium. In such cases, the Commission intends to provide legal certainty on keeping in line with the EU’s rules on cartels.

State Aid

European Commission expresses caution in curtailing State aid and extends Poland’s scheme for the resolution of certain smaller banks (see [here](#))

On 28 October 2021, Olivier Guersent, Director-General of the European Commission’s Directorate General for Competition, expressed his view to the media that more harm than good would arise if Europe shut off its flow of State aid too soon in the wake of the COVID-19 pandemic.

According to Mr. Guersent, even for businesses that had resisted the crisis without needing State support, these still faced the risk of going under if State aid rules were tightened before gaining better clarity on the pandemic’s evolution.

The European Commission is currently consulting with Member States on a draft proposal to prolong the State aid Temporary Framework (currently expiring on 31 December 2021) with a progressive phase out to end many support programs by 30 June 2022, as well as an extension of the Framework’s scope with the intended aim of further accelerating economic recovery (see also [Jones Day Update No. 64 of 18 October 2021](#)).

Shortly following Mr. Guersent’s remarks, on 29 October 2021 the Commission approved the extension (until 29 October 2022) and certain amendments to the Polish scheme for public support in the orderly resolution of failing or likely to fail cooperative banks and small commercial banks. The scheme seeks to facilitate the Polish resolution authority’s work, should an actual case and need arise for it, particularly in light of the ongoing COVID-19 pandemic.

Initially approved on 20 December 2016, the scheme had last been amended in December 2020 to exceptionally cover cooperative banks and small commercial banks with total assets of under €5 billion. In this respect, the Commission had accepted a balance sheet threshold that exceeded the €3 billion threshold set in the 2013 Banking Communication. This exception reflected the exceptional circumstances linked to the coronavirus outbreak, the limited portion of the Polish banking market covered by the scheme, and the aid scheme’s safeguards against undue competition distortions.

The Commission noted, in particular, that the segment of small Polish banks (including those with total assets of up to EUR 5 billion) was more likely to be impacted by the COVID-19 crisis, but that such banks also played a central role in Poland in providing banking services to households, micro, small and medium-sized companies. To prevent the disorderly failure of these banks, the Commission considered that extending the scope of the resolution scheme was an important policy tool to mitigate the pandemic’s negative impact on Poland’s financial stability and its wider real economy.

European Commission approves new and amended Member State measures to support the

Since the onset of the coronavirus outbreak, the 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 Temporary Framework, adopted in March 2020, is currently applicable until 31 December 2021.

economy (see [here](#) and [here](#))

- €358 million Romanian scheme to support small and medium-sized enterprises in the context of the coronavirus outbreak.
- €36 million Bulgarian scheme to support the agricultural sector in the context of the coronavirus outbreak.
- €96.9 million Italian scheme to support companies hiring female workers in the context of the coronavirus outbreak.
- Latest modification to initial €60 million French scheme to support companies in the beef cattle sector in the context of the coronavirus outbreak, in particular to extend the period for submitting the aid applications.

TRADE / EXPORT CONTROLS

European Commission publishes first Report on Implementation and Enforcement of EU Trade Agreements (see [here](#))

On 27 October 2021, the Commission published its first annual Report on Implementation and Enforcement of EU Trade Agreements. This document outlines the Commission's full range of actions deployed in 2020 and the first half of 2021.

The Report was produced under the direction of Denis Redonnet, who was appointed on 24 July 2020 as the Deputy Director-General in the European Commission's Directorate-General for Trade (DG TRADE), which encompasses the new role of Chief Trade Enforcement Officer (CTEO). The CTEO oversees and directs activities in implementing and enforcing EU Trade Agreements, under the guidance of the Executive Vice President and European Commissioner for Trade, Valdis Dombrovskis.

The Report notes, in particular, that the COVID-19 pandemic severely impacted trade in 2020, including leading to supply chain disruptions, decrease in demand, and a significant decline in both overall and preferential trade (although preferential trade fared slightly better). In particular:

- Trade with the 67 EU preferential partners fell by 9.1%. Notable exceptions included, for example, an increase in exports of chemicals (largely driven by a 10% rise in pharmaceutical exports under the concerned agreements).
- Trade with the EU's non-preferential partners fell by 11.1%, and trade with the rest of the world dropped by 10.5%.

Among the 67 trading partners covered in the Report, Switzerland remained the EU's top trading partner, with 21.5% of trade, followed by Turkey (11.3%), Japan (9.4%), Norway (7.8%) and South Korea (7.7%). Together, these five partners accounted for over half of EU preferential trade (57.7%).

New trade barriers also emerged in 2020 among the EU's trading partners, including those with preferential trade agreements with the EU, which reflected an increase in protectionist tendencies as accentuated by the COVID-19 pandemic. In terms of the sectors most affected last year, 43% of barriers were in the agriculture and fisheries sector.

Still, in 2020, the Commission also fully or partially removed 33 barriers in 22 partner countries. The Commission relies on various instruments to solve and prevent barriers, often resolving problems within the some 200 committees and working groups under EU trade agreements. These allow the EU and its

partners to discuss issues related to implementation and to find solutions. Through committee work, for example, in 2020 Egypt removed quantitative restrictions for imports of seed potatoes and restrictive requirements for feta cheese.

The Report further indicates that in 2020, companies in the EU could export an additional €5.4 billion due to the elimination of 130 barriers between 2014 and 2019, notably those affecting EU exports in goods.

Further details on the Report are available in Key Facts ([here](#)) and the Commission Staff Working Document accompanying the Report ([here](#)).

European Commission publishes EU Aid for Trade – Progress Report 2021 (see [here](#))

On 29 October 2021, the Commission released its EU Aid for Trade – Progress Report 2021. The Report illustrates the EU's contribution to the global Aid for Trade initiative and is based on responses to a questionnaire completed this year by 98 EU Delegations around the world, as well as on OECD data on Aid for Trade volumes.

The EU's Aid for Trade strategy was adopted in 2007 in response to the Aid for Trade (Aft) initiative launched by the World Trade Organization in 2005. It encourages developing countries to recognize the role that trade can play in their sustainable development.

The Report highlights the pandemic's severe impact on trade. EU27 imports from developing countries declined by almost EUR 100 billion (-16%) from EUR 621.6 billion to EUR 522.9 billion between 2019 and 2020.

To counter the impact of COVID-19 on its partner developing countries, Team Europe (i.e. the European Union and its Member States, as well as the European Investment Bank and the European Bank for Reconstruction and Development) reacted swiftly. This included mobilizing EUR 46 billion between April 2020 and April 2021 to help the EU's partner countries mitigate the pandemic's socio-economic impact. These commitments include both additional new funding as well as adjusting ongoing funding to tackle the impacts of the crisis.

The Team Europe approach that emerged in 2020 is viewed by the Commission as a successful response to the effects of the COVID-19 pandemic. Building on this approach, the EU is preparing some 150 Team Europe Initiatives to address sustainable development challenges and to further support the aim of rapid, fair and green recovery from the pandemic.

MEDICINES AND MEDICAL DEVICES

European Council publishes G20 Rome Leaders' Declaration (see [here](#))

On 30 and 31 October 2021, the Presidents of the European Council and European Commission represented the European Union during the G20 Summit hosted by the Italian presidency in Rome. The meeting closed with the adoption of a G20 Rome Leaders' Declaration, as published by the European Council.

The Declaration endorsed a series of commitments to overcome the global health and economic crisis stemming from the COVID-19 pandemic. With respect to global health, the G20 leaders plan, in particular to:

- Advance efforts to ensure timely, equitable and universal access to safe and affordable vaccines, therapeutics and diagnostics;
- Establish a G20 Joint Finance-Health Task Force to enhance dialogue and global cooperation on issues relating to pandemic prevention, preparedness and response; and
- Pursue a “One Health approach” enhancing global surveillance, early detection, warning systems and risks emerging from the human-animal-environment interface.

As a compass for collective action, the leaders also referred to the Rome Declaration issued at the first G20 Global Health Summit on 21 May 2021. (see [Jones Day COVID-19 Update No. 48 of 26 May 2021](#)).

For further details on the G20 Rome Leaders’ Declaration, please see the below Section on Cybersecurity.

EMA reviews certain potential medical conditions and COVID-19 vaccines (see [here](#))

On 29 October 2021, the European Medicines Agency’s (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) commented on assessments of certain medical conditions and COVID-19 vaccines:

- Following PRAC’s previous recommendation to list certain conditions (myocarditis and pericarditis, inflammatory heart conditions) as side effects in the product information of the vaccines Comirnaty and Spikevax (previously COVID-19 vaccine Moderna), PRAC has now requested the companies marketing these vaccines to conduct an in-depth review of all published data on the association between the vaccines and these conditions.
- PRAC concluded there is currently insufficient evidence to link multisystem inflammatory syndrome (MIS) and COVID-19 vaccines, and an update of the product information is not warranted. It encourages healthcare professionals to report all cases of MIS occurring after vaccination, and PRAC will continue to monitor reports of the condition.
- PRAC commenced evaluating data to assess a potential causal relationship between capillary leak syndrome and the COVID-19 vaccine Spikevax. Six cases of the disorder were reported in the EudraVigilance database (a centralized European database of suspected adverse reactions to medicines that are authorized or being studied in clinical trials in the European Economic Area (EEA)).

European Parliament and Council reach provisional agreement on proposed Regulation on a Reinforced Role for the EMA in Crisis Preparedness and Management (see

On 28 October 2021, the European Parliament (EP) and Council announced reaching a Provisional Agreement on the proposed Regulation on a Reinforced Role for the European Medicines Agency in Crisis Preparedness and Management for Medicinal Products and Medical Devices.

Reinforcing the EMA’s role is one component of the EU’s response to the COVID-19 pandemic and pursuit of constructing a European Health Union to improve Europe’s ability to respond to cross-border health threats and emergencies (see also [Jones Day COVID-19 Update No. 27 of 18 November 2020](#)).

According to statements by the EP and Council, the Provisional Agreement

[here](#) and [here](#))

sets out clarifications and additional transparency obligations to the initial Proposal, and in particular:

- Defines when an event should be regarded as “major” (i.e. likely to pose a serious risk to public health in relation to medicinal products) and how such event is recognized (i.e. following a positive opinion from the Medicines Shortage Steering Group), in view of triggering actions such as adopting a list of critical medicinal products;
- Shields against conflicts of interest by prohibiting members of the two “shortage steering groups” (for medicines and medical devices respectively) from having interests in related industry sectors that could affect their impartiality. These steering groups will meet regularly and when required, in preparation of or during a public health emergency;
- Requires EMA to set up and manage a “European Shortage Monitoring Platform” (i.e. a platform facilitating the collection of information on shortages, supply and demand of medicinal products);
- Requires transparency tools, including:
 - Providing publicly-available summaries of proceedings and recommendations of shortage steering group meetings;
 - Establishing a public webpage by EMA with information on shortages of clinical medicines and medical devices;
 - Making publicly-available in the EU clinical trial register, during a public health emergency, the study protocol and summary of results of clinical trials conducted in the EU by its sponsors; and
 - Publication by EMA of product information with details of conditions of use and clinical data received when a medicinal product is granted marketing authorization.
- Strengthens data protection provisions by ensuring that transfers of personal data in the context of the new EMA mandate will be subject to EU data protection rules, including GDPR.

The actual Provisional Agreement between the European Parliament and Council is not publicly available. The Agreement is part of inter-institutional negotiations, facilitating the formal adoption of the proposed Regulation.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Council publishes G20 Rome Leaders’ Declaration (see [here](#))

On 30 and 31 October 2021, the Presidents of the European Council and European Commission represented the European Union during the G20 Summit hosted by the Italian presidency in Rome. The meeting closed with the adoption of a G20 Rome Leaders’ Declaration, as published by the European Council.

The G20 leaders endorsed a series of commitments to overcome the global health and economic crisis stemming from the COVID-19 pandemic, while addressing cybersecurity and data protection concerns, such as by:

- Restarting international travel by use of vaccination certificates and interoperable mutually recognized digital applications, while continuing to protect public health and ensuring privacy and data protection;
- Strengthening bilateral and multilateral cooperation to secure information and communications technology, addressing vulnerabilities and threats, and combating cybercrime;
- Identifying commonalities, complementarities and elements of convergence between existing regulatory approaches and instruments enabling data to flow with trust, in order to foster future interoperability; and
- Pursuing further work on the design of digital identity tools.

The leaders also invited their Digital Ministers to further discuss the digital economy.

For further details on the G20 Rome Leaders' Declaration, please see the above Section on Medicines.

President of EU General Court rejects interim measure to suspend application of Regulation on EU Digital COVID-19 Certificates (available in French, see [here](#))

On 29 October 2021, the President of the EU General Court rejected the application for interim relief to suspend application of the Regulation on EU Digital COVID-19 Certificates* in Case T-527/21 R.

The EU Digital COVID-19 Certificate aims to facilitate the free movement of citizens within the Member States during the pandemic and to progressively lift COVID restrictions by Member States (see [Jones Day COVID-19 Update No. 41 of 24 March 2021](#)).

On 30 August 2021, a group of EU citizens brought an action before the General Court requesting the annulment of the Regulation. On 31 August 2021, the applicants applied for interim relief suspending the provisions of the Regulation on the issuance, verification (at a country-level and cross-borders) and acceptance of the COVID-19 Certificates. The applicants argued that the Regulation infringed the Charter of Fundamental Rights of the European Union, and in particular, violated:

- The right to non-discrimination between vaccinated and non-vaccinated persons; and
- The right to lead a normal social life.

The President dismissed the application due to the absence of evidence establishing the urgency of the requested interim relief.

The final judgment of the Court will be issued at a later stage. The rejection of the interim measures does not prejudice the outcome of the main action.

** Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic*

**ENISA publishes
2021 Threat
Landscape Report
(see [here](#))**

On 27 October 2021, the European Union Agency for Cybersecurity (ENISA) published the 9th edition of the annual ENISA Threat Landscape Report covering the period of April 2020 to July 2021. The Report describes the status of cybersecurity threats by identifying primary threats, threat actors, attack techniques, and relevant mitigation measures.

The Report emphasizes the impact of the COVID-19 pandemic on the cybersecurity threat landscape. In particular, the lasting shift to a hybrid office model has increased the attack surface, resulting in a number of cyber-attacks targeting organizations and companies through home offices.

The Report identified cybersecurity trends specifically driven by the COVID-19 pandemic, such as:

- Cyber espionage by state-sponsored actors to seek data related to recovery and vaccine developments efforts, infection rates, country-level responses and treatments. Consequently, healthcare, pharmaceutical and medical research sectors have been heavily targeted;
- Email attacks developed through social engineering crimes (i.e. cybercriminals seeking financial gain by exploiting people's interests, concerns, and fears through COVID-19 related phishing lures);
- Disinformation attacks boosted dramatically, with social media as the most critical vector for such attacks;
- Data breaches in the health care sector due to the shift towards the remote provisioning of health care services during the pandemic; and
- Non-malicious incidents, as the COVID-19 pandemic became a multiplier for human errors, system misconfigurations, and data breaches arising, in particular, from the forced migration to the cloud during the pandemic.

The Report also sets out proposed high-level mitigation measures in light of the identified threats, attack techniques, and trends. These mitigation measures address areas such as preventing and responding to ransomware, malware, cryptomining, e-mail and data-related attacks, as well as non-malicious threats.

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