



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 ramps up combat against cartels, including reigniting dawn raids
- European Commission adopts Work Programme for 2022
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commissioner for Trade attends G7 Trade Ministerial

Medicines and Medical Devices

- European Commission establishes portfolio of ten COVID-19 therapeutics
- European Parliament adopts Resolution on EU transparency in the development, purchase and distribution of COVID-19 vaccines
- European Commission adopts Work Programme for 2022

Cybersecurity, Privacy & Data Protection

- European Commission adopts Work Programme for 2022

COMPETITION & STATE AID

Competition

European Commission ramps up combat against cartels, including reigniting dawn raids (see [here](#))

On 22 October 2021, Executive Vice-President and Commissioner for Competition Margrethe Vestager highlighted the Commission's commitment to combating cartels during the COVID crisis and in its aftermath.

During the pandemic, the Commission's activity against cartels included decisions issued in the rail cargo, food packaging, financial benchmarks, and ethylene sectors. Commissioner Vestager, however, acknowledged that for nearly two years, the pandemic had slowed certain work, such as dawn raids. These could not be conducted remotely, and it had been impossible in practice to carry out coordinated dawn raids in many countries.

As the pandemic subsides, Commissioner Vestager indicated that the Commission's work is gathering speed in collecting evidence of suspected illicit activities. She referred to the Commission's first international dawn raid in two years, which had occurred the preceding week, and announced that a series of raids would take place in the coming months. Indeed, several days after her remarks, the Commission initiated unannounced inspections on 25 October 2021 at the premises of a pharmaceutical company active in animal health in Belgium in relation to potential infringements of EU antitrust rules against the abuse of a dominant position (see [here](#)).

Commissioner Vestager also referred to other initiatives in the fight against cartels, such as:

- An electronic whistleblowers' tool that enables the Commission to seek information on anticompetitive conduct, while protecting anonymity. Launched in 2017, Commissioner Vestager indicated that this tool has aided in uncovering new cartels, strengthening existing cases, and now handles some one hundred relevant messages each year (see also *Jones Day Commentary, "European Commission Launches Competition Law Anonymous Whistleblower Tool," April 2017, [here](#)*).
- An intelligence unit, created in 2016, uses public information (so-called "open-source intelligence") to find suspect patterns in large volumes of data. This unit has assisted with investigations in over 30 cartel and antitrust cases, and Commissioner Vestager indicated that the unit is expected to play an increasingly key role in the Commission's work.

Commissioner Vestager further indicated that the Commission is heavily investing in the pursuit of cartels, including developing new detection methods and identifying new types of cartels.

European Commission adopts Work Programme for 2022 (see [here](#))

On 19 October 2021, the Commission adopted its Work Programme for 2022 of key initiatives for the coming year and how these will be concretely pursued, particularly towards promoting a greener, more resilient, and digital post-COVID-19 Europe.

The Work Programme contains 42 new initiatives covering the Commission's six main ambitions for 2019-24 (see [here](#)) set out by Commission President

Ursula von der Leyen and following her earlier State of the Union Address 2021 (see also [Jones Day COVID-19 Update No. 61 of 20 September 2021](#)). The Work Programme also takes into account lessons learned from the unprecedented crisis caused by the pandemic.

In the priority area, “A Europe fit for the digital age,” the Work Programme notes the pandemic’s acceleration of the shift to digitalization in Europe and globally. The Commission aspires to realize the EU’s digital transformation by 2030, while emphasizing the necessity of preserving the single market and strong competition policy and enforcement in pursuing a resilient recovery and the twin digital and green transitions. Against this background, the Work Programme indicates that the Commission has initiated a review of competition policy in seeking to ensure the suitability of various instruments.

The Work Programme further notes that while diversified and competitive supply chains supported Europe’s response to the COVID-19 crisis, Europe proved vulnerable in certain sectors due to high dependency on a narrow range of non-EU suppliers, especially for raw materials. This is particularly the case for EU industry confronted by semiconductor shortages. In response, the Work Programme indicates that the Commission will propose a European Chips Act to promote a state-of-the-art European chip ecosystem in view of strengthening innovative capacity and security of supply. The proposed Act would also aim at coordinating EU and national investment along the value chain.

The Work Programme indicates the Commission’s proposal for a European Chips Act is expected in Q2 2022.

For further details on the Work Programme for 2022, please see below Sections on Medicines and Cybersecurity.

State Aid

European Commission approves new and amended Member State measures to support the economy (see [here](#) and [here](#))

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.

- €17.7 million Belgian scheme to further support the tourist accommodation sector in the context of the coronavirus outbreak.
- Latest modification to initial €59 million Lithuanian scheme to support companies active in the agricultural, food, forestry, rural development and fishery sectors, in particular to extend the duration of the scheme until 31 December 2021.
- Latest modification to initial €61 million Lithuanian scheme to support research, development and production of coronavirus-relevant products, in particular to extend the duration of certain measures until 31 December 2021.
- Latest modification to initial €200 million Belgian scheme to support companies in Flanders affected by the coronavirus outbreak, in particular to extend the scope of eligible undertakings to travel agencies and companies active in autocar activities for transporting people.

- Latest modification to initial €255 million Bulgarian guarantee scheme to support SMEs in the coronavirus outbreak, in particular to extend the duration of the scheme until 31 December 2021.

TRADE / EXPORT CONTROLS

European Commissioner for Trade attends G7 Trade Ministerial (see [here](#) and [here](#))

On 22 October 2021, Executive Vice-President and European Commissioner for Trade Valdis Dombrovskis attended the G7 Trade Ministers' meeting, which focused on key issues on the global trade agenda, including global supply chains, market distorting practices, and digital trade.

This G7 Trade Ministerial provides an opportunity to prepare the groundwork for purposeful and attainable outcomes at the forthcoming 12th WTO Ministerial Conference* (MC12) on 30 November to 3 December 2021.

Commissioner Dombrovskis, in particular, announced the Commission's intention to put forward a holistic proposal on how trade can contribute to equitable access to vaccines. He further noted that the EU is actively engaged in advancing WTO negotiations on vaccine access and other key areas.

In this respect, to recall, the WTO's Director-General Dr. Ngozi Okonjo-Iweala expressed her views to the European Parliament on 20 May 2021 that the proposal before the WTO to waive intellectual property rights for COVID-19 vaccines would not suffice to accelerate equitable access to vaccines. She advocated additional measures, such as reducing export restrictions and reinforcing supply chains for vaccines, working with manufacturers to expand production, including in emerging countries with idle capacity, and transferring technology and expertise to produce the vaccines.

The European Parliament subsequently encouraged the EU to engage in a "constructive dialogue" with the WTO for a temporary patent waiver on COVID-19 vaccines in its Report on post-COVID trade strategy of 7 July 2021 (see [here](#)). This Report fed into an ongoing review of EU trade policy, as announced on 18 February 2021 in the Commission's Communication on Trade Policy Review – An Open, Sustainable and Assertive Trade Policy, which sets out Europe's new trade strategy for the coming years, including addressing challenges of the COVID-19 pandemic (see [Jones Day COVID-19 Update No. 37 of 24 February 2021](#)).

** The Ministerial Conference, which is attended by trade ministers and other senior officials from the organization's 164 members, is the highest decision-making body of the WTO.*

MEDICINES AND MEDICAL DEVICES

European Commission establishes portfolio of ten COVID-19 therapeutics (see [here](#))

On 22 October 2021, in the context of the EU Therapeutics Strategy (see [here](#)), the Commission announced a portfolio of ten COVID-19 therapeutics deemed as demonstrating the highest potential impact on the pandemic, i.e. therapeutics in the following product categories for:

- Preventing infection in those exposed to the virus;
- Reducing the need for hospitalization; and

- Preventing hospitalized patients from evolving to critical or dying.

A European expert group selected the ten therapeutics after screening 82 medicine candidates in late stage clinical development based on science-based criteria approved by Member States, taking into account the needs of different patient populations, stages and severity of the disease.

Six of the selected therapeutics are already under rolling review or have applied for marketing authorization to the European Medicines Agency (EMA). The four other candidates received scientific advice from EMA and will start rolling review once sufficient clinical data is collected.

The accompanying FAQs provide further details (see [here](#)).

European Parliament adopts Resolution on EU transparency in the development, purchase and distribution of COVID-19 vaccines (see [here](#) and [here](#))

On 21 October 2021, the European Parliament adopted a Resolution on EU transparency in the development, purchase and distribution of COVID-19 vaccines. In calling for such transparency, the Parliament indicates in particular that this would allow MEPs to more effectively scrutinize EU vaccine policies and would promote public trust in vaccines.

In seeking change, the Resolution points out for example, the “*failures in the procurement process at EU level*” and the European Commission’s “*lack of experience in the negotiation and conclusion*” of agreements to procure vaccines on behalf of the Member States. This resulted in the inability to leverage combined demand from Member States into improved bargaining power with vaccine manufacturers.

The Resolution, in particular, calls for the Commission to:

- Publish the non-redacted versions of the Advanced Purchase Agreements (APAs) entered into with COVID-19 vaccine manufacturers and to disclose, in particular: (a) advance payments made by the Commission, (b) cost sharing between public and private investments, (c) number of doses allocated to each Member State, (d) the price per dose, (e) number and locations of available production sites, (f) liability and compensation regimes, (g) sanctions in the event of breach of contract;
- Provide detailed information on how EU advance payments were used by the concerned pharmaceutical companies;
- Ensure that the contracted manufacturers make the full clinical trial results and protocols of potential COVID-19 vaccines available for evaluation;
- Ensure that the contracted manufacturers publish data from pharmacovigilance reports.

Furthermore, the Resolution calls on the Member States to oppose any efforts by the EU to assume more responsibilities in the area of health policy in general, and states that the perceived failure of the EU’s vaccination strategy and procurement serves as a “warning sign” against the EU’s pursuit of acquiring even more competences.

European Commission adopts Work Programme for

On 19 October 2021, the Commission adopted its Work Programme for 2022 of key initiatives for the coming year and how these will be concretely pursued, particularly towards promoting a greener, more resilient, and digital post-COVID-19 Europe. The Work Programme also takes into account

2022 (see [here](#))

lessons learned from the unprecedented crisis caused by the pandemic.

In the priority area, “Promoting our European way of life,” the Work Programme aspires to a futureproof and crisis-resistant pharmaceuticals system in the broader context of the European Health Union and the Pharmaceutical Strategy for Europe.

The Programme sets out the Commission’s plans, among others, to:

- Propose a framework for a dynamic EU pharmaceutical sector to ensure access to affordable high-quality medicines for all EU citizens, foster innovation and enhance security of supply through digitalization in seeking to provide a simplified and efficient regulatory environment;
- Propose a revision of legislation on medicines for children and rare diseases to tackle shortcomings and ensure that innovative medicines and treatments are readily available; and
- Present a new European care strategy to set out a framework for policy reforms addressing both carers and care receivers, from childcare to long-term care.

For further details on the Work Programme for 2022, please see the Sections on Antitrust (above) and Cybersecurity (below).

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission adopts Work Programme for 2022 (see [here](#))

On 19 October 2021, the Commission adopted its Work Programme for 2022 of key initiatives for the coming year and how these will be concretely pursued, particularly towards promoting a greener, more resilient, and digital post-COVID-19 Europe. The Work Programme also takes into account lessons learned from the unprecedented crisis caused by the pandemic.

In the priority area, “A Europe fit for the digital age,” the Work Programme notes the pandemic’s acceleration of the shift to digitalization in Europe and globally.

The Programme sets out the Commission’s plans, among others, to:

- Propose a European Cyber Resilience Act establishing common cybersecurity standards for products;
- Further reinforce cybersecurity, such as by taking new steps to improve the secure exchange of key information with third countries.
- Build an EU space-based global secure communication system offering EU-wide broadband connectivity and secure independent communications to Member States; and
- Propose an action plan for an accelerated digital transformation of the energy sector ensuring the shift towards renewables, connected mobility, smart buildings, and a more integrated energy system.

Furthermore, in the area of healthcare, the Programme indicates that its initiatives will be supported by the proposal to create a European Health Data Space, with trustworthy governance to ensure data security and data protection. Such initiative aims at promoting access to health data for research on new strategies for prevention, diagnosis, and treatment solutions,

as well as providing individuals with greater control over their health data (see also [Jones Day COVID-19 Update No. 46 of 5 May 2021](#)).

For further details on the Work Programme for 2022, please see above Sections on Antitrust and Medicines.

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