



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 approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission reports slight increase in EU27 agri-food trade despite coronavirus and Brexit challenges

Medicines, Medical Devices, and Personal Protective Equipment

- Public hearing at European Parliament on COVID-19 vaccines
- European Commission signs contracts with Sanofi-GSK for the supply of COVID-19 vaccine
- European Medicines Agency issues a positive opinion on use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation
- European Parliament urges Member States to harmonize COVID-19-related health measures
- European Parliament to tackle pharmaceutical pollution
- European Parliament aims at tackling shortages of medicinal products and boosting EU manufacturing capacity
- European Commission President von der Leyen presents State of the Union Address at European Parliament Plenary
- European Medicines Agency restores publication of clinical trial data for COVID-19 related medicinal products
- European Medicines Agency publishes publication the Big Data Steering Group work plan for 2020-2021
- European Commission concludes exploratory talks with a sixth COVID-19 vaccine manufacturer
- EFPIA statement on the European Regulatory Network Strategy to 2025

- European Parliament meeting on European Commission's COVID-19 vaccine negotiations

Cybersecurity, Privacy & Data Protection

- European Commission introduces proposal for a Council Regulation on establishing the European High Performance Computing Joint Undertaking

COMPETITION & STATE AID

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.

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

- €1.46 billion UK scheme to distribute free medical grade personal protective equipment in the context of coronavirus outbreak
- €1.5 million Maltese direct grant scheme to support land farmers in the context of the coronavirus outbreak
- €7.4 million Romanian scheme to support companies active in the bovine breeding sector in the context of the coronavirus outbreak
- €305 million Czech scheme to support self-employed affected by the coronavirus outbreak
- €120 million Austrian scheme to support companies in Lower Austria affected by the coronavirus outbreak
- €1 million Lithuanian scheme to support tour operators repatriating travellers in context of the coronavirus outbreak
- €44 billion Italian recapitalisation scheme to support large companies affected by the coronavirus outbreak
- Modified Austrian liquidity assistance scheme to support companies affected by the coronavirus outbreak
- €193 million Polish scheme to support companies operating in the tourism and cultural sector affected by the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Commission reports slight increase in EU27 agri-food trade despite coronavirus and Brexit challenges (see [here](#))

On 10 September 2020, the European Commission released its new trade monitoring report for January-May 2020. The report indicates that despite the impact of the coronavirus pandemic and Brexit challenges, EU27 agri-trade slightly increased as compared to the same period in 2019, such that:

- The total value of EU27 agri-food exports rose by 2%, reaching €75.8 billion;
- The value of imports increased by nearly 1%, reaching €52.7 billion; and
- The EU enjoyed an agri-food trade surplus of €23.1 billion, reflecting an increase of 5%.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

Public hearing at European Parliament on COVID-19 vaccines (see here)	<p>On 22 September 2020, the European Parliament hosted a public hearing on addressing the challenges of access to safe COVID-19 vaccines.</p> <p>The discussion focused on clinical trials and expediting the manufacturing and distribution of COVID-19 vaccines across the EU.</p> <p>Participants included members of the Committees on Environment, Public Health and Food Safety (ENVI) and on Industry, Research and Energy (ITRE), as well as researchers, representatives of pharmaceutical companies, and members of the European Medicines Agency (EMA).</p>
European Commission signs contracts with Sanofi-GSK for the supply of COVID-19 vaccine (see here)	<p>On 18 September 2020, the European Commission entered into an agreement with Sanofi-GSK for the purchase of up to 300 million doses of a COVID-19 vaccine.</p> <p>This is the second agreement executed by the Commission, following its earlier agreement with AstraZeneca (see <i>Jones Day COVID-19 Update No. 20 of 1 Sept 2020</i>).</p>
European Medicines Agency issues a positive opinion on use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation (see here)	<p>On 18 September 2020, the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA) issued a favorable opinion on dexamethasone as a treatment option for patients who require oxygen therapy (Opinion).</p> <p>The Opinion follows the publication of a study reflecting positive data for dexamethasone when used for treating patients with COVID-19 requiring supplemental oxygen or mechanical ventilation.</p> <p>Marketing authorization holders (MAHs) of dexamethasone medicinal products can submit a variation of the marketing authorization (MA) to the competent authority to extend the MA's scope according to the therapeutic indications as provided in the Opinion.</p>
European Parliament urges Member States to harmonize COVID-19-related health measures (see here)	<p>On 17 September 2020, a Resolution of the European Parliament urged Member States to:</p> <ul style="list-style-type: none">– adopt common definitions for positive cases, deaths and recovery from COVID-19 infection;– mutually recognize test results and cut related waiting times;– establish a common quarantine period;– coordinate travel restrictions as needed, in line with the Commission's proposal (see <i>Jones Day COVID-19 Update No. 21 of 8 September 2020</i>);– coordinate the proper functioning of the Schengen area, by excluding internal border controls and contingency plans. <p>The Resolution further proposed that the Commission develop a harmonized passenger locator form and emphasized the importance of encouraging the use of tracing apps. National tracking systems are expected to be interoperable by October 2020.</p>

<p>European Parliament to tackle pharmaceutical pollution (see here)</p>	<p>On 17 September 2020, the Parliament adopted a Resolution calling for new measures to tackle pharmaceutical pollution, addressing changes spanning from the design and production stages to end-of-pipe controls (e.g. improved wastewater treatment).</p> <p>The Resolution refers to the Commission’s Communication on “<i>European Union Strategic Approach to Pharmaceuticals in the Environment</i>” (here), which provided a list of possible actions towards the “green design” of medicinal products.</p>
<p>European Parliament aims at tackling shortages of medicinal products and boosting EU manufacturing capacity (see here)</p>	<p>On 17 September 2020, the Parliament adopted a Resolution calling for self-sufficiency for medicinal products and medical equipment to ensure the continuous supply of products and availability of treatments.</p> <p>In particular, the Parliament called on:</p> <ul style="list-style-type: none"> – the Commission to (i) boost measures for ensuring safety, availability and accessibility of medicinal products, as well as to adopt measures for reinforcing manufacturing of pharmaceuticals within the Union and screening foreign direct investment in pharmaceutical manufacturing plants, towards encouraging non-EU companies to invest in Europe; (ii) adopt a proposal for a directive setting minimum standards for quality healthcare systems; and (iii) create a European contingency reserve of medicines of strategic importance to minimize shortages, and review rules on packaging in order to ease circulation of medicine among Member States; – Member States to share best practices in stock management and create coordinated health strategies, including further use of joint EU procurement of medicines.
<p>European Commission President von der Leyen presents State of the Union Address at European Parliament Plenary (see here)</p>	<p>On 16 September 2020, Commission President Ursula von der Leyen’s speech on the State of the Union presented the Commission’s planned actions and goals.</p> <p>The President focused, <i>inter alia</i>, on the importance of strengthening crisis preparedness and cross-border health threat management. Thus, the Commission intends to:</p> <ul style="list-style-type: none"> – reinforce and empower the EMA and the European Center for Disease Prevention and Control (ECDC); – build an EU agency similar to the US Biomedical Advanced Research and Development Authority (BARDA) to support capacity and readiness to fight cross-border threats and emergencies.
<p>European Medicines Agency restores publication of clinical trial data for COVID-19 related medicinal products (see here)</p>	<p>On 16 September 2020, the EMA announced that, as part of its exceptional transparency measures applicable during the pandemic, it will require sponsors to publish clinical trial data for COVID-19 medicines and vaccines immediately after the granting of an MA.</p> <p>For non-COVID-19 related medicinal products, the publication of clinical trial data has long been suspended due to disruptions following the relocation of the EMA’s headquarters from London to Amsterdam.</p>
<p>European Medicines Agency publishes</p>	<p>On 14 September 2020, the EMA and the Heads of Medicines Agency (HMA) published the Work Plan for 2020-2021 for the Big Data Steering Group, established in February 2020.</p>

<p>publication the Big Data Steering Group work plan for 2020-2021 (see here)</p>	<p>The Work Plan provides an overview of the scope of EMA/HMA activities through early 2022.</p> <p>It presents ten recommendations aimed at promoting the evolution towards data-driven regulation through smart working and collaboration with stakeholders.</p>
<p>European Commission concludes exploratory talks with a sixth COVID-19 vaccine manufacturer (see here)</p>	<p>On 9 September 2020, the European Commission concluded exploratory talks with BioNTech-Pfizer for the purchase of a potential COVID-19 vaccine.</p> <p>Under the draft agreement, once this medicinal product is granted a marketing authorization, Member States may purchase 200 million vaccine doses, with the option of an additional 100 million doses.</p> <p>The Commission has already concluded explanatory talks with other four marketing authorization holders (MAHs) of potential COVID-19 vaccines and also entered into its first advance purchase agreement scheme (APA) with AstraZeneca (see <i>Jones Day COVID-19 Update No. 20 of 1 Sept 2020</i>).</p>
<p>EFPIA statement on the European Regulatory Network Strategy to 2025 (see here)</p>	<p>On 8 September 2020, the European Federation of Pharmaceutical Industries and Associations (EFPIA) released a statement expressing its full support of the “<i>European Medicines Agencies Network Strategy through 2025</i>” (see <i>Jones Day COVID-19 Update No. 16 of 10 July 2020</i>).</p> <p>This Strategy sets out the most relevant regulatory issues within the pharmaceutical sector for European medicine regulators and national competent authorities (NCAs), such as technological innovation, supply chain challenges and antimicrobial resistance.</p> <p>The EFPIA’s statement proposes to:</p> <ul style="list-style-type: none"> – Escalate work on innovative clinical trials; – Redesign a more iterative, flexible, integrated product support mechanism; – Implement a real world evidence (RWE) pilot programme; and – Develop and implement an overarching EU strategy to enable digital transformation.
<p>European Parliament meeting on European Commission’s COVID-19 vaccine negotiations (see here)</p>	<p>On 7 September 2020, the Deputy Director-General of DG Health and Food Safety, Sandra Gallina, participated in the Committee on Environment, Public Health and Food Safety (ENVI) meeting, discussing the EU Vaccines Strategy and APAs (see <i>Jones Day COVID-19 Update No. 13 of 19 June 2020</i>).</p> <p>According to Gallina, certain vaccines may be ready for distribution by the end of 2020, to be provided to Member States based on population size.</p> <p>Furthermore, it was clarified that while vaccination criteria are within the remit of Member States, a Blue Guide should be issued on such criteria at the European Union level.</p>

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission introduces proposal for a Council Regulation on establishing the European High Performance Computing Joint Undertaking (see [here](#))

On September 18, 2020, the European Commission published a proposal for a Council Regulation on establishing the European High Performance Computing Joint Undertaking ("Proposal").

The "Joint Undertaking" comprises a legal and financial framework, pooling resources from 32 EU countries and private entities, with the aim of developing High Performance Computing at an EU level.

The Proposal seeks to build Europe's leading role in supercomputing and quantum computing, including fostering innovative healthcare and personalized medicine.

As concerns the COVID-19 crisis, the Proposal indicates that supercomputing plays a key role in tackling this and any future pandemic, since supercomputing serves to:

- Accelerate the identification and production of treatments;
- Predict the virus' spread;
- Help plan the distribution of medical supplies and resources; and
- Simulate post-epidemic exit measures.

The Proposal further states that supercomputers under the Joint Undertaking should be operated and used in compliance with GDPR and the ePrivacy Directive.

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