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 adopts Communication on a Competition Policy Fit for New Challenges
- European Commission adopts sixth amendment of State aid Temporary Framework
- European Commission approves amendments to €25 billion Pan-European Guarantee Fund
- European Commission approves new and amended Member State measures to support the economy

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- European Commission publishes 3rd Raw Materials Scoreboard

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- EMA reviews data on COVID-19 treatment, molnupiravir, to support decisions on early use by national authorities
- EMA evaluates application for marketing authorization for COVID-19 medicine Xevudy
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- EMA reviews data on COVID-19 treatment, Paxlovid, to support decisions on early use by national authorities

Cybersecurity, Privacy & Data Protection

- European Commission issues Communication on a Competition Policy Fit for New Challenges
- Council of Europe adopts Second Additional Protocol to the Convention on Cybercrime on Enhanced Cooperation and the Disclosure of Evidence

COMPETITION & STATE AID

European Commission adopts Communication on a Competition Policy Fit for New Challenges (see here)

On 18 November 2021, the European Commission adopted a Communication on a Competition Policy Fit for New Challenges, focusing on supporting Europe's recovery, the green and digital transitions, and a resilient Single Market.

The Communication argues that competition policy was key to the EU's crisis response toolbox in swiftly acting against the COVID-19 outbreak, including notably:

- The State Aid Temporary Framework, adopted March 2020 (see here) to support the economy in the context of the pandemic by enabling the rapid adoption of certain aid measures by Member States; and
- The Antitrust Temporary Framework (adopted April 2020, see here), which sought to provide guidance and legal certainty to companies, e.g. when cooperating to sustain supply chains amidst border closures or to tackle shortages of medicines, medical equipment, or bottlenecks in vaccine production. Based on the COVID-19 evolution, the Commission may review the Antitrust Temporary Framework, which will remain applicable until the Commission withdraws it (once it considers that the underlying exceptional circumstances are no longer present).

The Communication addresses, in particular:

(i) The progressive phase-out of crisis measures under the above-referred State aid Temporary Framework, as accompanied by new measures to ramp up private investment (*see below for further details*); and

(ii) The comprehensive current review of competition policy and enforcement in light of the EU's ambitions to achieve a green and digital transition in a resilient Single Market. This spans over 20 sets of competition rules and guidelines, across all competition instruments (merger, antitrust and State aid control). Among these:

- The rules on pan-European Important Projects of Common European Interest (IPCEI) seek to enable Member States and industry to jointly invest in ambitious pan-European projects in a transparent and inclusive manner, where the market alone appears unable to deliver and particularly where the risks are deemed as too large for a single Member State or company to assume. The Commission is particularly focusing on projects responding to key green and digital priorities (e.g. hydrogen, cloud, health and microelectronics).

  The Commission views the current IPCEI framework as working well, so the rules will maintain their existing scope, while making certain targeted changes. In this respect, the announced IPCEI State aid Communication (expected by end-2021) will aim at, e.g. further facilitating the participation of small and medium-sized enterprises and clarifying criteria to pool national and EU resources.

- To build resilience in the EU semiconductors sector, State aid rules seek to provide various possibilities to address current acute global shortages, including the following initiatives:

  - Preparing a second IPCEI concerning semiconductors, following the first IPCEI approved by the Commission on 18 December 2018;
  - Streamlining State aid rules under a recent amendment to the GBER

	(General Block Exemption Regulation), applicable to national funding for projects or financial instruments falling under Horizon Europe (EU's central research and innovation funding programme) and InvestEU (to mobilize public and private investment to meet EU-policy objectives). The amendment, applicable since 1 August 2021, intends to foster synergies between national and EU-funding policies to enhance the EU's competitiveness, including in the field of semiconductors. • Potential support aimed at addressing perceived funding gaps, in view of creating European first-of-a-kind facilities in the semiconductor ecosystem. The forthcoming European Chips Act, expected in the first half of 2022, would aim at strengthening innovation, production capacity, as well as security of supply through a framework for international cooperation and partnership. The proposed Act would also aim at coordinating EU and national investment along the value chain. Other measures set out in the Communication also reflect Europe's ambitions for a green and digital transition, e.g. the forthcoming Climate, Environmental Protection and Energy Aid Guidelines; and updating the Commission's 1997 Market Definition Notice (by Q1 2023), taking into account significant developments of the past twenty years, in particular digitalization and new ways of offering goods and services. *For further details on the Communication, see below Section on Cybersecurity*.
European Commission adopts sixth amendment of State aid Temporary Framework (see here)	On 18 November 2021, the Commission adopted the sixth amendment of the State aid Temporary Framework, adopted by the Commission in March 2020 to facilitate targeted support by Member States to businesses during the coronavirus crisis. This latest amendment has two objectives: First, the progressive phase-out of crisis measures of the Temporary Framework, with a limited 6-month prolongation of existing measures until 30 June 2022. This extension reflects feedback received from the majority of Member States. Second, boosting targeted support to companies most impacted by the crisis by adding the following two new measures to the Temporary Framework, which will be of longer duration than the above-referred crisis measures: – Enabling Member States to create direct incentives for private investments (until 31 December 2022). This seeks to spur companies to start filling the investment gap left by the crisis. Member States can use this tool, in particular, to accelerate the green and digital transitions by enabling support for any investments that Member States consider to be important to accelerate economic recovery (e.g. investments in equipment to improve the circular economy, such as through recycling). – Introducing a solvency support measure aimed at easing access to equity finance for smaller companies (until 31 December 2023). This measure enables Member States to leverage private funds and make them available for investments in SMEs, including start-ups, and small mid-caps. For example, Member States could provide guarantees to investment funds, in view of reducing risks to attract

	private investors. Other targeted adjustments to the Temporary Framework include, e.g. extending the adjusted list of non-marketable risk countries, in the context of the short-term export credit insurance (STEC), for an additional 3 months (from 31 December 2021 to 31 March 2022) (see also *Jones Day COVID-19 Update No. 61 of 21 September 2021*). Since the Temporary Framework's inception, the Commission has adopted over 670 decisions and approved over €3.1 trillion of State aid in all 27 Member States. The Communication notes that these decisions were adopted in record time, due to special adoption procedures and close coordination between the Commission and Member States.
European Commission approves amendments to €25 billion Pan-European Guarantee Fund (see here)	On 22 November 2021, the Commission approved amendments to the €25 billion Pan-European Guarantee Fund to support companies affected by the coronavirus outbreak, deeming these amendments as compatible with EU State aid rules. To recall, the Commission approved the Fund's establishment on 14 December 2020, finding it compatible with State aid rules (*see also Jones Day COVID-19 Update No. 31 of 13 January 2021*). The Fund, operating under the European Investment Bank ("EIB", the EU's long-term lending institution owned by the Member States), primarily focuses on supporting small and medium-sized enterprises by providing guarantees on debt and equity instruments. By mobilizing extra finance from the private sector, the Fund aims to generate up to €200 billion for the economy. The present amendments to the Fund seek to respond to the sustained COVID crisis and include: (i) increasing the financing ceilings and maximum maturities of certain guaranteed products; (ii) allowing banks to include loans and other financing options under the Fund's guarantee until 30 June 2022 and to further prolong the maturity of such loans in justified circumstances; and (iii) a new basket bonds product aimed at addressing the specific financing needs of SMEs and mid-caps. All Member States have the option to participate in the Fund. Participating countries provide guarantees proportional to their share in the EIB or other institutions. The EGF Contributors' Committee, made up from representatives of these Member States, decides on the availability of guarantees. Thus far, 22 Member States participate in the Fund (i.e. Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Lithuania, Luxemburg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain and Sweden). Among the Fund's latest operations, on 16 November 2021, the EIB announced that the Fund will back the EIB's grant to ELKARGI (Spain's leading guarantee company by volume of guarantees granted) of a counter-guarantee of up to €75 million. This will allow ELKARGI to channel over €110 million in finance to Spanish mid-caps, and particularly those impacted by the COVID-19 pandemic (see here).
European Commission approves new and amended Member	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.

State measures to support the economy (see here and here)	The Temporary Framework, adopted in March 2020, is currently applicable until 31 December 2021. • €210 million Belgian scheme to support travel organizers in the context of the coronavirus outbreak. • €20.5 million Bulgarian scheme to support bus and coach operators in the context of the coronavirus outbreak. • €22.7 million Croatian scheme to support the primary agricultural sector in the context of the coronavirus outbreak. • €140 million Italian scheme to support companies in the context of the coronavirus outbreak. • €1.4 million Romanian scheme to support the sport sector in the municipality of Miercurea-Ciuc in the context of the coronavirus outbreak. • Latest modification to initial €20 million Italian scheme to support companies providing road passenger transport services, in particular to increase the budget by €5 million.

TRADE / EXPORT CONTROLS

European Commission publishes 3rd Raw Materials Scoreboard (see here)	On 17 November 2021, the European Commission presented the 3rd Raw Materials Scoreboard, which sets out an in-depth analysis of Europe's raw material supply chains (focusing on metals, wood and industrial minerals), their competitiveness, and trade flows. The Scoreboard provides input to the EU's policy efforts during a time of acute disruptions to global raw material supply chains, including as a result of the COVID-19 pandemic, which exposed global dependencies of the EU economy. These dependencies included not only medical supplies, but also the import of raw materials and technologies (e.g. semiconductor chips), as mines around the world closed, and logistics and production halted. Such circumstances have brought renewed attention to vulnerabilities in value chains relevant to the EU's security and its twin green and digital objectives, which will need large amounts of raw materials for climate-neutral energy generation and storage, e-mobility and digital infrastructure. Among the findings, the Scoreboard highlights that Europe has high levels of dependency on other regions for certain raw material production, whereas domestic production of raw materials and the circular use of raw materials can generate opportunities and employment in the EU. On the issue of import reliance, in particular, the Scoreboard notes that many of the raw materials for which the EU faces supply challenges are those employed in the technologies that enable green growth, such as solar photovoltaics, batteries, electric vehicle motors, wind turbines and fuel cells. The pandemic's supply chain disruptions may further increase the risk to supply. Towards addressing import reliance, the Scoreboard notes that the Commission's 2020 Critical Raw Materials Action Plan (see here) proposed a strategy to increase EU security of supply by diversifying international and

	domestic sourcing and by promoting supply of secondary raw materials from European sources. The Scoreboard's findings will support, in particular, implementation of this Action Plan.
MEDICINES AND MEDICAL DEVICES	
EMA reviews data on COVID-19 treatment, molnupiravir, to support decisions on early use by national authorities (see here)	On 8 November 2021, the European Medicines Agency (EMA) announced its decision to review data on the use of molnupiravir, a COVID-19 treatment, in view of determining whether to issue a recommendation to national authorities on use of the medicine prior to a formal marketing authorization. Such recommendation, which would be issued in a short timeframe, would facilitate early use of the medicine, such as in emergency use settings. Molnupiravir is an oral antiviral medicine to treat COVID-19 developed by Merck Sharp & Dohme and Ridgeback Biotherapeutics that reduces the ability of SARS CoV 2 to multiply in the body. As agreed by the EMA and the Heads of Medicines Agencies (i.e., the network of European Economic Area National Agencies competent for medicinal products), this review responds to the need for additional guidance on COVID-19 treatments in light of rising rates of infection and deaths due to COVID-19 across the EU. The review will take place in parallel with a rolling review of the data on quality, efficacy and safety. A rolling review (i.e., a regulatory tool enabling the EMA to review clinical data as soon as they become available) will enable applying for marketing authorization once sufficient data is collected.
EMA evaluates application for marketing authorization for COVID-19 medicine Xevudy (see here)	On 18 November 2021, EMA announced the start of evaluating the application for marketing authorization for the COVID-19 medicine Xevudy (sotrovimab) submitted by GlaxoSmithKline Trading Services Limited ("Applicant"). Xevudy is a monoclonal antibody intended to treat adults and adolescents with COVID-19 who do not require supplemental oxygen therapy and who are at increased risk of progressing to severe COVID-19. It is developed by the Applicant and Vir Biotechnology. EMA will assess the medicine under a shortened timeline and could issue an opinion within two months, as it has already reviewed certain data during a rolling review.
EMA evaluates application for conditional marketing authorization for COVID-19 vaccine Nuvaxovid (see here)	On 17 November 2021, the EMA announced that it would review the application for conditional marketing authorization for Nuvavox's COVID-19 vaccine, Nuvaxovid. The EMA will assess whether it can recommend granting such conditional market authorization, which can only be granted for medicines that address unmet medical needs and is based on less comprehensive data compared to normal marketing authorizations. Additionally, the available data must indicate that the benefits of the vaccine in protecting against COVID-19 outweigh its risks and that the Nuvavox will be able to provide comprehensive clinical data in the future.

	The EMA will assess the vaccine under an accelerated timeline, as the EMA has already reviewed a substantial portion of the data during a rolling review.
EMA reviews data on COVID-19 treatment, Paxlovid, to support decisions on early use by national authorities (see here)	On 19 November 2021, the EMA announced its decision to review data on the use of COVID-19 treatment Paxlovid, developed by Pfizer, in view of determining whether to issue a recommendation to national authorities on use of the medicine prior to a formal marketing authorization. Such EU-wide recommendation, issued in a short timeframe, would aim to facilitate national authorities in taking evidence-based decisions on the early use of the medicine, such as in emergency use settings. The review takes place in parallel with a more comprehensive rolling review, preceding a possible application for marketing authorization. Paxlovid is an oral antiviral medicine that aims to reduce the need for hospitalization in patients with COVID-19 by, among other things, blocking the activity of the enzyme required to multiply the virus.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission issues Communication on a Competition Policy Fit for New Challenges (see here)	On 18 November 2021, the European Commission issued a Communication on a Competition Policy Fit for New Challenges, focusing on supporting Europe's recovery, the green and digital transitions, and a resilient Single Market. The Communication argues that competition policy was key to the EU's crisis response toolbox in swiftly responding to the COVID outbreak. As Europe draw lessons from the pandemic, and in light of its digital ambitions and cybersecurity and data protection concerns, the Communication addresses how competition policy and enforcement can remain fit for purpose and how new instruments can tackle these challenges. The Communication notes the importance of data as a key element for the innovative potential of companies. As such, it explains that competition enforcement complements the Commission's regulatory actions in levelling the playing field between so-called digital "gatekeepers" and smaller companies, as well as in promoting data sharing. Furthermore, the Commission's enforcement practice has recognized the relevance of privacy as parameter of competition and has accepted commitments to ensure that, among others, this competitive dimension is preserved (e.g. Commission's decision of 6 December 2016 in Case M.8124 - Microsoft/LinkedIn). The Communication notes, in particular, that under the proposed Digital Markets Act: – The Commission could receive information from digital "gatekeepers" (defined by the Commission as large online platforms with a significant impact on the internal market and active in multiple EU countries) about their acquisitions, which increases the knowledge of the Commission about the transactions and the business rationale, and which in turn could aid the Commission to determine whether the transactions might negatively affect competition; – The Act would work in tandem with competition enforcement by setting out *ex ante* rules applicable to those deemed as "gatekeepers"

	in pursuing its goal of ensuring contestable and fair digital markets, which would be enforced *ex post* by the competition rules; Additionally, the Communication indicates that compliance with competition rules must be predictable in order to enable companies to know what type of data they can share with competitors, suppliers or customers and therefore to enable increased data sharing, as foreseen by the Commission's initiatives on data, such as the proposed Data Governance Act and the upcoming Data Act. In response, the ongoing revision of the Horizontal Guidelines will provide updated guidance on data sharing, in view of allowing companies to take the most out of data without undermining competition and enabling the envisaged Data Governance Act and Data Act to fulfil their full potential in that aspect. *For further details on the Communication, see above Section on Competition.*
Council of Europe adopts Second Additional Protocol to the Convention on Cybercrime on Enhanced Cooperation and the Disclosure of Evidence (see here)	On 17 November 2021, the Council of Europe adopted the Second Additional Protocol to the Convention on Cybercrime on Enhanced Cooperation and the Disclosure of Electronic Evidence ("Protocol") on behalf of the European Union. The Protocol supplements the Convention on Cybercrime ("Budapest Convention") of 2001, which the Council of Europe views as the most relevant international agreement on cybercrime and electronic evidence. The Protocol aims to further enhance cooperation on cybercrime, in particular, by offering criminal justice authorities the ability to collect evidence in electronic form for specific criminal investigations or proceedings related to computer systems and data, while safeguarding the use of sensitive data. Provisions include, in particular, procedures to: – allow authorities to request information on domain name registration from service providers; – use video conference technology to take testimony and statements from a witness or expert, while safeguarding, in particular, appropriate levels of security and authentication; and – appropriately handle certain types of sensitive data that may be needed, in particular, as evidence in a criminal investigation or proceeding, but which must be protected from the risk of unwarranted prejudicial impact to the concerned individual arising from the use of such data, for example, by: • preventing unlawful discrimination based on, for example, the use of evidence revealing race, religion or gender orientation. • prohibiting decisions based only on the automated processing of personal data where this produces a significant adverse effect impacting an individual's interests (e.g. issuing an arrest, warrant or denying bail or parole, unless such decision making is authorized under domestic law and subject to appropriate safeguards, which must include the possibility to obtain human intervention to assess the decision). Additionally, the Explanatory Report to the Protocol recognizes that information and communication technology has evolved, and that the exploitation of technology for criminal purposes has increased since the Budapest Convention was opened for signature in 2001. It also recognizes that many parties to the Budapest Convention now consider cybercrime as a serious threat to human rights, the rule of law and the functioning of

democratic societies. For instance, during the COVID-19 pandemic, many cyber-attacks targeted hospitals and medical facilities responsible for developing COVID-19 vaccines, and domain names were misused to promote fake vaccines and treatments.

The adoption of the Protocol took place during the Octopus Conference on Cooperation against Cybercrime to mark the 20th anniversary of the Budapest Convention (see here). The event gathered some 1200 cybercrime experts from some 120 countries, representing the public and private sectors and international and non-governmental organizations, to share cybercrime related experience.

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