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 publishes proposed Regulation on foreign subsidies distorting the internal market
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission publishes proposed Regulation on foreign subsidies distorting the internal market
- European Commission releases Communication on New Industrial Strategy
- EU-India Leaders' Meeting discusses investing in EU-India Strategic Partnership
- European Parliament to debate on IP waiver for COVID vaccines and vote on report on post-COVID trade

Medicines and Medical Devices

- WHO and ICRMA issue Joint Statement on clinical data transparency
- European Medicines Agency starts rolling review of the GlaxoSmithKline COVID-19 vaccine
- European Commission adopts EU Strategy on COVID-19 therapeutics

Cybersecurity, Privacy & Data Protection

- WHO and ICRMA issue Joint Statement on clinical data transparency

COMPETITION & STATE AID

European Commission publishes proposed Regulation on foreign subsidies distorting the internal market (see here)

On 5 May 2021, the Commission published a proposed Regulation on foreign subsidies distorting the internal market. This novel instrument would afford the Commission with extensive new powers to counteract alleged distortive effects of foreign subsidies in the EU Single Market (*Jones Day Alert, "European Commission publishes proposal to counter foreign subsidies distorting the Single Market," May 2021, see here*).

The Commission argues in its proposal that the COVID economic crisis is leading to higher levels of subsidization worldwide. The Commission's Impact Assessment on the proposed Regulation (see here) claims that the problem of distortive foreign subsidies is becoming more pressing in the context of acquisitions, public procurement and other market situations.

The Impact Assessment, in particular, contends that a wave of acquisitions may also come in the wake of the deflated value of certain EU companies as a result of the COVID crisis. Some non-EU companies are also reported as considering diversifying or localizing parts of their supply chains due to the disruptions to the global production chains.

The proposed Regulation seeks to address possible distortions that fall outside the current EU State aid, merger control and antitrust framework. As concerns competition and State aid rules, at present, there are no specific EU provisions to address the potentially distortive effects of foreign subsidies on the internal market. The Commission believes that there are challenges to finding a multilateral solution to subsidies within a reasonable and are therefore moving forward with this proposal.

The proposed Regulation combines elements from EU rules on merger control, State aid, trade defense, and public procurement. It proposes three tools, i.e.:

- **Mandatory merger notification system**. In mergers and acquisitions facilitated by foreign subsidies, the acquirer would need to submit a prior notification to the Commission when:
  - The EU turnover of the EU company to be acquired, or of at least one of the EU merging parties, is at least €500 million; and
  - the foreign subsidy amounts to at least €50 million.
- **Public procurement.** In public procurement procedures, bidders would be required to disclose any foreign subsidies received by submitting a prior notification to the contracting authority when:
  - the estimated value of the procurement is at least €250 million; and
  - any foreign subsidies have been received three years prior to the notification.
- **Ex officio review of foreign subsidies**. A general tool is proposed to review foreign subsidies that would allow the Commission to investigate any market situation, including mergers and acquisitions or public procurement procedures not meeting the thresholds under the above two tools. The Commission could start such an investigation on its own initiative and would have the power to request ad hoc notifications.

The European Parliament and the Member States will now review the Commission's proposal in view of adopting a final text of the Regulation.

The proposed Regulation is also open to comments 5 July 2021.

	For further details on the proposed Regulation, see below Section on Trade / Export Controls.
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: • increase in budget of €213 million for Italian scheme to support trade fairs sector affected by the coronavirus outbreak • second modification of Belgian scheme to support companies in Flanders affected by the coronavirus outbreak – the modification includes a budget increase from 440 million to €634 million • €13 million Latvian scheme to support pig farmers affected by the coronavirus outbreak • €3.6 million Slovenian scheme to support pig breeders affected by the coronavirus outbreak • €8.8 million Estonian scheme to support organizers of cultural events in context of the coronavirus outbreak • €22 million Portuguese scheme to support micro, small and medium-sized enterprises in the region of Madeira in context of the coronavirus outbreak • €47 million per month Danish scheme to compensate companies for damages suffered due to the coronavirus outbreak • €1.9 billion Czech scheme to support companies in the context of the coronavirus outbreak • €11.6 million Czech scheme to support travel agencies in the context of coronavirus outbreak
TRADE / EXPORT CONTROLS	
European Commission publishes proposed Regulation on foreign subsidies distorting the internal market (see here)	On 5 May 2021, the Commission published a proposed Regulation on foreign subsidies distorting the internal market. This novel instrument would afford the Commission with extensive new powers to counteract alleged distortive effects of foreign subsidies in the EU Single Market (*Jones Day Alert, "European Commission publishes proposal to counter foreign subsidies distorting the Single Market," May 2021, see here*). The proposal combines elements from EU rules on trade defense, merger control, State aid, and public procurement. *For further details on the proposed Regulation, see above Section on Competition & State Aid.* As concerns trade, the Commission's Impact Assessment on the proposed Regulation (see here) highlights that the EU is the world's largest trading block, accounting for 16.4% of overall global trade, with trade in goods and services amounting to nearly EUR 6 trillion in 2019. The EU is also the world's leading provider and destination of foreign direct investment (FDI) with outward stocks at close to EUR 9 trillion and inward stocks at some EUR 7 trillion in 2019.

	The Commission emphasizes that openness to trade and investment is an important building block of the resilience of the economy and will contribute to the recovery from the COVID-19 crisis. However, it also notes that EU rules on trade defence instruments (as well as competition and public procurement) do not apply to foreign subsidies that afford their recipients with an unfair advantage when acquiring EU companies, participating in public procurements in the EU, or engaging in other commercial activities in the EU. For example, the Impact Assessment indicates: – Although subsidized steel imports can be addressed in trade defence investigations, subsidized steel companies increasingly seek to circumvent those rules (only applicable to trade in goods) via greenfield investments and acquisitions. – Trade in services is not covered by the existing EU trade defence instruments. Services are therefore viewed as more vulnerable to possible distortions caused by subsidies. And despite the pandemic, some estimates continue to support that international trade in services could rise by 31% between 2019 and 2025. The proposed tools under the Regulation would close these and other regulatory gaps by complementing (not overlapping with) existing rules. The proposed Regulation, for example, would cover the provision of services in the Single Market, as it would cover foreign subsidies to undertakings engaging in an economic activity in the EU. The Commission will also seek to ensure the proposed Regulation's compatibility with the EU's international obligations. It states that if international trade rules change in the future, the legal framework could also require modification to ensure continued coherence.
European Commission releases Communication on New Industrial Strategy (see here)	On 5 May 2021, the Commission published its Communication on Updating the 2020 New Industrial Strategy: Building a Stronger Single Market for Europe's Recovery, in view of ensuring that Europe's industrial goals take full account of the new circumstances following the COVID-19 crisis and supports the transition to a more sustainable, digital, resilient and globally competitive economy. The Communication notes that one of the pandemic's key lessons is the need for greater clarity concerning Europe's current and potential future strategic dependencies. This will serve as a basis for facts-based policy measures to address strategic dependencies while preserving the open, competitive and trade-based EU economy. Also, while the EU will continue to favor international cooperation and dialogue, it stands ready to combat unfair practices and foreign subsidies that undermine the Single Market's level-playing field. In mapping Europe's strategic dependencies and capacities, the Commission conducted a "bottom-up analysis" based on trade data that provides initial insights on relevant issues (see here). The analysis identifies 137 products out of 5,200 products imported into the EU (representing 6% of the EU's total import value of goods) in sensitive sectors with high EU-dependency – primarily in energy intensive industries (such as raw materials) and healthcare (e.g. active pharmaceutical ingredients), as well as other products relevant to supporting the green and digital transformation. About half of imports for these dependent products originate in China, followed by Vietnam and Brazil.

	The Communication presents a toolbox to reduce and prevent strategic dependencies, including certain key measures, such as: – Exploring international partnerships and cooperation to address strategic dependencies (Starting in 2021) – Launch of alliances on processors and semiconductor technologies, on industrial data, edge and cloud (Q2 2021) – Reinforced action on SME supply chain disruptions and vulnerabilities (Q4 2021) – Adopting a standardization strategy (Q3 2021). Commenting on the release of the new Industrial Strategy, Commissioner Thierry Breton, responsible for the Internal Market, stated: "*The real industrial revolution is starting now – provided we…set the right framework conditions*."
EU-India Leaders' Meeting discusses investing in EU-India Strategic Partnership (see here)	On 8 May 2021, in view of further advancing the EU-India Strategic Partnership, the EU (represented by Ursula von der Leyen, President of the European Commission; Charles Michel, President of the European Council; and all members of the European Council) met with Indian Prime Minister Modi. The EU and India, the world's two largest democracies, represent a combined market of 1.8 billion people with a combined GDP of €16.5 trillion per year. The leaders agreed, in particular, to enhance the EU-India trade and investment relationship in view of reaping its full potential and to contribute to inclusive and sustainable economic growth and recovery from the COVID-19 pandemic. It was agreed, for example, to establish a joint working group on resilient supply chains, building on experience gained from the COVID-19 pandemic. This EU-India Leaders' Meeting was preceded by two earlier preparatory meetings of the EU-India High-Level Dialogue on Trade Investment (*see Jones Day COVID-19 Update No. 35 of 10 February 2021)*. This High-Level Dialogue has now been tasked, in particular, with ensuring progress on market access issues and overseeing negotiations, as well as advancing cooperation on regulatory aspects and resilient value chains.
European Parliament to debate on IP waiver for COVID vaccines and vote on report on post-COVID trade (**see here**)	On 25 May 2021, the INTA (European Parliament Committee on International Trade) INTA and the Commission will discuss the request for a waiver from certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the prevention, containment and treatment of COVID-19 within the wider framework of increasing production capacity for vaccines. Following the US decision to support such waiver, discussions at the World Trade Organization have gained momentum in relation to the request by a number of countries to waive intellectual property protections under TRIPS for COVID-19 vaccines. Thus far, the EU has rejected the waiver. Additionally, during this INTA meeting, the Committee will vote on the own-initiative report on the trade related aspects and implications of COVID-19. This report is the Committee's main input to the Commission's ongoing Trade Policy Review (*see Jones Day COVID-19 Update No. 43 of 7 April 2021)*.

MEDICINES AND MEDICAL DEVICES

WHO and ICRMA issue Joint Statement on clinical data transparency (see here)	On 7 May 2021, a Joint Statement on promoting wider access to clinical data for new medicines and vaccines was issued by the World Health Organization (WHO) and the International Coalition of Medicines Regulatory Authorities (ICMRA) – which includes, among others, the European Medicines Agency (EMA), the UK Medicines & Healthcare products Regulatory Agency (MHRA), and the US Food and Drug Administration (FDA). The Joint Statement notes that the COVID-19 pandemic highlighted the urgent need for information and data, including to support researchers and industry in developing vaccines and therapeutics; to assist regulators and health authorities in their decision-making; to guide healthcare professionals in their treatment decisions; and to strengthen public confidence in the vaccines and therapeutics offered. The Joint Statement indicated, in particular, that clinical data should be published at the time of finalization of the regulatory review, regardless of whether the decision is positive or negative. This would contribute to weighing the benefits and risks for a certain therapy and increase public trust. Furthermore, the Joint Statement notes that publishing negative trials could streamline the development process by avoiding unnecessary replication of failed studies. The Joint Statement considers that consistent public access to data supporting approvals and rejections of medicines reviewed by regulators is long overdue, despite existing initiatives, such as those from the European Medicines Agency. Reiterating that the COVID-19 pandemic has revealed that access to data is vital to public trust, the ICMRA and WHO urge the pharmaceutical industry to rapidly commit, and ahead of legal changes, to provide voluntary unrestricted access to trial results data for the benefit of public health. *For further details on the Strategy, see below Section on Cybersecurity, Privacy & Data Protection.*
European Medicines Agency starts rolling review of the GlaxoSmithKline COVID-19 vaccine (see here)	On 7 May 2021, the EMA started the rolling review of sotrovimab (also known as “VIR-7831” and “GSK4182136”), a monoclonal antibody developed by GlaxoSmithKline and Vir Biotechnology, Inc. for the treatment of COVID-19, based on positive results from laboratory and animal studies and an ongoing clinical trial. The rolling review procedure enables the EMA to review data as they become available from ongoing studies, in view of shortening the timeline for the approval of a medicinal product while ensuring compliance with the common standards for effectiveness, safety and quality. During the rolling review, and throughout the pandemic, EMA and its scientific committees are supported by the COVID-19 EMA pandemic task force (COVID-ETF). This group gathers experts from across the European medicines regulatory network to advise on developing, authorizing, and monitoring the safety of medicines and vaccines for COVID-19 and to facilitate swift and coordinated regulatory action.

European Commission adopts EU Strategy on COVID-19 therapeutics (see here)	On 6 May 2021, the Commission adopted a Communication on EU Strategy on COVID-19 Therapeutics. This Strategy complements the Vaccine Strategy (*see Jones Day COVID-19 Update No. 13 of 19 June 2020*) and lays the groundwork for a "*strategic approach to developing, manufacturing and procuring safe and effective COVID-19 therapeutics*". The Strategy sets out a number of objectives, including to: – Boost research and development of medicinal products for the treatment of COVID-19 by setting up a platform which, in bringing together EMA, national authorities and industry players, will seek to identify promising research projects and technologies in view of providing "*guidance on where to best focus investments*"; – Identify and support the development of 10 promising medicinal products in the fight against COVID-19 and create an interactive mapping platform available for Member States to analyze their "*development phases, production capacities and supply chains including possible bottlenecks*"; – Promote and fund the development of large scale clinical trials for COVID-19 treatments; – Map and secure pharmaceutical supply chains, as well as fund a €40 million preparatory action to support flexible manufacturing and access for COVID-19 therapeutics under the *"EU Fab project, which will set up a network of 'ever-warm' production capacities for vaccine and therapeutics manufacturing at EU level*"; – Organize new matchmaking events for supply chain actors, towards resolving manufacturing bottlenecks, and support cooperation between undertakings; – Review the regulatory framework in coordination with the EMA to ensure a more rapid and flexible regulatory approval process for medicinal products; – Act as a joint procurement contractor for the purchase of COVID-19 therapeutics and/or create mechanisms of advance purchase agreements (APAs) similar to those already established for vaccines (*see Jones Day COVID-19 Update No. 13 of 19 June 2020*).

CYBERSECURITY, PRIVACY & DATA PROTECTION

WHO and ICRMA issue Joint Statement on clinical data transparency (see here)	On 7 May 2021, a Joint Statement on promoting wider access to clinical data for new medicines and vaccines was issued by the World Health Organization (WHO) and the International Coalition of Medicines Regulatory Authorities (ICMRA) – which includes, among others, the European Medicines Agency (EMA), the UK Medicines & Healthcare products Regulatory Agency (MHRA), and the US Food and Drug Administration (FDA). *For further details on the Strategy, see above Section on Medicines.* Noting that the COVID-19 pandemic highlighted the urgent need for information and data, the WHO and ICMRA advocate the publication of

clinical trial reports "*without redaction of confidential information for reasons of overriding public health interest*".

Instead, only personal data and individual patient data should be redacted. The Strategy notes that, in any event, aggregated data are unlikely to lead to re-identification of personal data, and anonymization processes can be applied.

The Strategy contends that such transparency will first benefit public trust. By opening their decisions to public scrutiny, regulators are demonstrating confidence in their work.

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