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 revised Communication on State aid rules for Important Projects of Common European Interest (IPCEI)
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission announces end of COVID-19 vaccines export mechanism and introduction of new monitoring mechanism
- European Commission issues First Annual Report on the screening of foreign direct investments into the Union
- 13th Asia-Europe Meeting (ASEM) affirms shared commitment to recovery from COVID-19 crisis

Medicines and Medical Devices

- EMA recommends approval of Comirnaty COVID-19 vaccine for children aged 5 to 11
- European Parliament adopts Resolution on a Pharmaceutical Strategy for Europe

Cybersecurity, Privacy & Data Protection

- ENISA publishes Report on Raising Awareness of Cybersecurity
- European Commission adopts EU Digital COVID Certificate equivalence decisions for Singapore and Togo

COMPETITION & STATE AID

State Aid

European Commission publishes revised Communication on State aid rules for Important Projects of Common European Interest (IPCEI) (see here)

On 25 November 2021, the Commission published a revised Communication on State aid rules for Important Projects of Common European Interest (IPCEI).

To recall, the IPCEI rules 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) (*see also Jones Day COVID-19 Update No. 68 of 22 November 2021).*

The revised Communication notes, in particular, the Commission's view that IPCEIs can contribute to a sustainable recovery following serious economic disturbances such as those arising from the COVID-19 pandemic and can reinforce efforts to build the EU's social and economic resilience.

The Commission considers that the existing IPCEI framework has worked well, so the rules maintain their existing scope, while certain targeted changes under the revised Communication seek to reflect experience gained from the application of the 2014 IPCEI Communication and to align the relevant rules with current EU priorities.

In particular, the revised Communication:

- Broadens the European and open nature of IPCEIs by providing that IPCEIs must ordinarily involve at least four Member States and by requiring IPCEIs to be designed in a transparent and inclusive manner. In this respect, all Member States shall be informed of the possible emergence of an IPCEI and given a genuine opportunity to participate.
- Facilitates the participation of small and medium sized enterprises (SMEs) in IPCEIs, in particular by applying certain specificities in assessing the compatibility of aid to SMEs (e.g. the possibility for smaller companies to have a more limited own contribution to projects than otherwise required). The revised Communication also encourages collaborations between larger companies participating in an IPCEI and SMEs.
- Aligns its objectives with current EU priorities. To support the EU's environmental strategies and to accelerate the green transition, for instance, Member States must provide evidence of compliance of notified projects with the "do no significant harm" principle within the meaning of Regulation (EU) 2020/852 on the establishment of a framework to facilitate sustainable investment (Article 17), or other comparable methodologies, such that neither the environmental nor the social objective is significantly harmed.

The revised Communication also confirms the requirement for IPCEIs to deliver significant positive spill-over effects across the EU and also maintains what it considers as strong safeguards to ensure that aid is limited to what is

	necessary and to prevent undue distortions of competition. The revised Communication will apply from 1 January 2022. In this respect, its principles will apply to all notified aid projects for which the Commission is called upon to make a decision on or after 1 January 2022, even for projects notified prior to that date.
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. • €10 million Maltese scheme to support the tourism sector in the context of the coronavirus outbreak. • €700 million French scheme to support hospitality and leisure operators in the context of the coronavirus outbreak. • Latest modification to €16 million Dutch scheme to support the fireworks sector, in particular to increase the compensation factor for the compensation of additional transport costs from 2 to 2.5.

TRADE / EXPORT CONTROLS

European Commission announces end of COVID-19 vaccines export mechanism and introduction of new monitoring mechanism (see here)	On 25 November 2021, the European Commission announced that the COVID-19 vaccines export transparency and authorization mechanism would not be extended upon its expiry on 31 December 2021. To recall, the export authorization mechanism, launched in January 2021, responded to vaccine supply problems and addressed the issue of transparency of vaccine exports outside the European Union (EU) (*see Jones Day COVID-19 Update No. 34 of 3 February 2021*). The mechanism (covering COVID-19 vaccines and the active substances used to manufacture such vaccines) only applied to exports from companies with whom the EU had concluded Advance Purchased Agreements (APAs). Without authorization, such products could not be exported outside the EU. Replacing such export authorization mechanism, as of 1 January 2022, a new monitoring mechanism will seek to ensure the ongoing transparency of exports (*Commission Implementing Regulation (EU) 2021/2071 of 25 November 2021 subjecting certain vaccines and active substances used for the manufacture of such vaccines to export surveillance,* see here). The monitoring mechanism, to be applicable for two years, will provide the Commission with statistical export data, per manufacturer, in view of the timely detection of (i) any indication of lack of compliance with APAs concluded with the Commission and (ii) any other circumstance that could threaten the EU's security of supply, as well as the EU's capacity to pledge and deliver further donations. This monitoring mechanism seeks to enable the Commission, where warranted, to take further action in order to prevent a critical situation from arising due to a shortage of these products.

	Customs authorities of EU Member States shall collect this data, which the Commission will make public at an aggregate level to preserve confidentiality.
European Commission issues First Annual Report on the screening of foreign direct investments into the Union (see here and here)	On 23 November 2021, the European Commission released its First Annual Report on the screening of foreign direct investments (FDI) into the Union, which appraises the first year of implementation of the FDI Screening Regulation (Regulation (EU) 2019/452 of 19 March 2019 establishing a framework for the screening of foreign direct investments into the Union). To recall, the FDI Regulation seeks to address concerns over foreign investors seeking to acquire control or influence in European firms implicating technologies, infrastructure, inputs, or sensitive information critical for more than one Member State or on a project of Union interest. The Regulation sets out a framework for identifying risks related to the acquisition or control of strategic assets that threatens security or public order. It also establishes a cooperation framework between Member States and the Commission, underpinning Member States' FDI assessments and facilitating a Member State's ultimate decision where the FDI is planned or completed. As the COVID-19 crisis uncovered particular vulnerabilities in the EU, including the resilience of the EU's critical industries in areas such as healthcare and medical research, the Commission has emphasized its view that FDI screening can play an important role in dealing with the pandemic. In particular, it called upon Member States without such screening to set up a full-fledged mechanism to enable, for example, the review of transactions posing a risk to EU critical health infrastructures (see *Jones Day Alert, "New European Commission Guidance Calls for Increased Scrutiny of Investments Amid COVID-19 Crisis", March 2020, see here; and Jones Day White Paper "Foreign Direct Investment Screening in Europe and the Middle East", July 2020, see here*). In releasing this First Annual Report on FDI, the Commission notes, in particular: – The Commission screened 265 transactions notified by Member States until end-June 2021 (now up to over 400 foreign investments) since the FDI Regulation entered into force in October 2020; – Of the 265 cases notified, 80% of the cases (212) were closed by the Commission in Phase 1 (i.e. within 15 days), with the remaining 14% cases (36) proceeding to Phase 2 with additional information being requested from the notifying Member State. 6% of the cases remained ongoing at the cut-off date of the Report of 1 July 2021; – Most notifications for screening from Member States concerned the manufacturing, ICT, wholesale and retail sectors; – Among notified FDI cases, the top five countries of origin of investors were companies located in the US, the UK, China, Canada, and the United Arab Emirates; – The Commission issued an opinion in less than 3% out of 265 screened cases, as an opinion is only required based on the circumstances of a case (more specifically, given the investor's risk profile and criticality of an investment target). Such Commission opinions provide recommended mitigating measures that are deemed to be proportionate and specific to the risks and criticality identified. It is ultimately the screening Member State to decide on the transaction

	being screened, including in light of any Commission opinion. According to the Commission's findings, the FDI screening cooperation mechanism works effectively and does not create unnecessary delays for transactions. 18 Member States have now adopted their own screening mechanisms (up from 11 Member States in 2017). The Commission maintains its "*strong expectation*" that all Member States will adopt national screening mechanisms to contribute to safeguarding the collective security and public order of all 27 Member States and the EU. This First Annual Report on FDI was adopted simultaneously with the Annual Report on Dual Use Export Controls (see here). The Commission views export controls, together with FDI screening, as key tools for strategic trade and investment controls in view of ensuring security in the EU. For further information on export controls in the EU, UK, and U.S., see here, *JONES DAY TALKS®: Navigating Sanctions and Export Controls: A Guide for EMEA Businesses*, *March 2021*.
13th Asia-Europe Meeting (ASEM) affirms shared commitment to recovery from COVID-19 crisis (see here)	On 25 and 26 November, the 13th Asia-Europe Meeting (ASEM) took place remotely from Cambodia, where leaders notably reaffirmed their shared partnership and commitment to recovery from the COVID-19 pandemic. The summit marked the 25th year of ASEM, an informal platform for political dialogue and cooperation. With 53 partners, it is the largest international leaders' gathering after United Nations General Assembly and consists of 2 organizational partners (the EU and ASEAN (Association of Nations of the South East Asia)) and 51 partner countries (with 30 in the "European Group" - 27 EU Member States, Norway, Switzerland, and the UK). Ursula von der Leyen (President of the European Commission) and Charles Michel (President of the European Council) represented the EU. The Prime Minister of Slovenia, Janez Janša, represented the rotating EU Council presidency. In addressing the COVID-19 crisis, leaders noted, in particular: – the importance of keeping markets and global supply chains open, stable and accessible; – the need for all countries to have equitable and timely access to quality, safe, effective, affordable and efficacious diagnostics, therapeutics, medicines and vaccines for the COVID-19 response; and – the global response to the pandemic presented an opportunity to accelerate the transitions towards a resilient, digital, low-carbon socio-economic recovery, and towards green, circular and more sustainable economies. Council President Michel also emphasized the increasing importance of the Indo-Pacific region: "*We are already a top investor in this region. And we are also a top development cooperation and trading partner in this region*." In this respect, he referred to the EU's new Indo-Pacific Strategy (adopted in September 2021, see here), which reinforces the EU's strategic focus, presence and actions in the region to contribute to regional stability, security, prosperity and sustainable development.

MEDICINES AND MEDICAL DEVICES

EMA recommends approval of Comirnaty COVID-19 vaccine for children aged 5 to 11 (see here)

On 25 November 2021, the European Medicines Agency (EMA) recommended granting an extension of indication for use of the COVID-19 vaccine Comirnaty (developed by BioNTech and Pfizer) to children aged 5 to 11 *(see also Jones Day COVID-19 Update No. 64 of 18 October 2021).*

The vaccine dose for children aged 5 to 11 will be lower than that for adults and children aged 12 and above. A study of some 1,300 children showed that the immune response to the vaccine given at a lower dose for this younger group is comparable to the response with a higher dose given to 16 to 25 year olds.

European Parliament adopts Resolution on a Pharmaceutical Strategy for Europe (see here)

On 24 November, 2021, the European Parliament (EP) adopted the Resolution on a Pharmaceutical Strategy for Europe.

The Resolution represents the EP's contribution to the Commission's plan to update EU pharmaceutical legislation, as set out in the Commission's long-awaited Pharmaceutical Strategy for Europe published on 25 November 2020. To recall, this Strategy outlines the EU's approach to promoting a strong, competitive and green industry that is responsive to patients and that draws on the potential of the digital transformation era (*see also Jones Day COVID-19 Update No. 28 of 1 December 2020*).

In presenting the Resolution, EP members noted that one of the key lessons learned from the COVID-19 pandemic is the importance of close collaboration at European level, combined with making national health systems more sustainable and resilient. In this respect, the EU must seek to restore the independence of its pharmaceutical supply and reinforce public-private partnerships while ensuring that research priorities are driven by patient and public health needs.

The Resolution creates a framework for future legislative and non-legislative actions with broad-ranging aims that seek to put patients at the center of health policies.

Key recommendations include addressing issues such as the root causes of medicines shortages; ensuring access to safe, affordable and effective pharmaceutical treatments; increasing transparency on prices and public R&D funding; and promoting EU manufacturing and supply resilience.

The Resolution calls on the Commission to undertake a range of actions, such as:

- On authorizations, to consider, in collaboration with EMA, extending the application of rolling reviews used for COVID-19 vaccines to other emergency medicines;
- On clinical trials, to fully implement the Clinical Trials Regulation in order to facilitate the launch of large clinical trials at EU level;
- On transparency, competitivity, and innovation, to make swift progress on initiatives to optimize and modernize the regulatory framework, such as the implementation of electronic product information (ePI), streamlined active pharmaceutical ingredient (API), and improved good manufacturing processes (GMPs);

- On pharmaceutical research, to ensure that EU funding for biomedical research and development is made conditional on the full transparency and traceability of investments and on ensuring supply in all Member States;

- On innovative and new medicines, to create a one-stop shop for developers of Advanced Therapy Medicinal Products (ATMPs) to provide guidance and a forum for communication on their application, in collaboration with EMA;

- On supplementary protection certificates, to evaluate the added value of the Supplementary Protection Certificate (SPC) mechanism in order to prevent delays in access to generic medicines and improve the financial sustainability of healthcare systems, while emphasizing that SPCs should only be allowed in exceptional and justified cases;

- On European health data, to support measures favoring open science in order to accelerate the sharing of data and research results within the scientific community in Europe and globally; in this respect, interconnection and interoperability of high-performance computing infrastructures with European health data area would ensure the availability of large, high quality data sets.

The Commission is expected to propose an update of EU pharmaceutical legislation towards the end of 2022.

CYBERSECURITY, PRIVACY & DATA PROTECTION

ENISA publishes Report on Raising Awareness of Cybersecurity (see here)

On 29 November 2021, the European Union Agency for Cybersecurity (ENISA) issued a Report on Raising Awareness of Cybersecurity.

The Report notes that the COVID-19 pandemic caused a rapid shift to remote working, which increased cybersecurity vulnerabilities and exposed the lack of appropriate guidelines, training and cybersecurity awareness campaigns. As such, businesses were subject to cyber threats and data exposure risks, e.g. where employees connected their work devices to personal equipment or shared corporate devices with family members without authorization to do so.

The Report aims to assist EU Member States in building their cybersecurity capacities by setting out recommendations to raise citizens' awareness of cybersecurity and to better communicate on cybersecurity issues.

The recommendations concern four areas, each laying out good practices, challenges, lessons learnt and suggested further improvement. In particular, ENISA focuses on the following:

(i) Building capacities for cybersecurity awareness, such as through sufficient and consistent funding for public awareness activities;

(ii) Assessing trends and challenges, such as regular analysis of the threat environment;

(iii) Measuring cybersecurity behavior, including through close cooperation with national statistic offices to identify, understand and

	reach target audiences; and (iv) Planning cybersecurity awareness campaigns, such as involving public communications and marketing experts for appropriate message framing. The Report is the main deliverable of the 9th National Cybersecurity Strategies (NCSS) Workshop held on 29 November 2021. This annual event is dedicated to discussing developments and good practices regarding EU Member State cybersecurity strategies.
European Commission adopts EU Digital COVID Certificate equivalence decisions for Singapore and Togo (see here)	On 24 November 2021, the Commission adopted two decisions to ensure that COVID-19 certificates issued by Singapore and Togo are considered equivalent to the EU Digital COVID Certificate (*see also Jones Day COVID-19 Update No. 67 of 15 November 2021 for the latest preceding Commission Equivalence Decisions*). In practice, this means that Singapore and Togo will be connected to the EU's system and that COVID certificates issued by these countries will be accepted in the EU under the same conditions as the EU Digital COVID Certificate. In return, these two countries have accepted EU Digital COVID Certificates for travel to their countries. The European Commissioner for Justice, Didier Reynders, stated that to date: "*…we have 51 countries and territories in five continents that are now connected to the EU Digital COVID Certificate system. I am delighted also that we have the first Southeast Asian country and the first sub-Saharan African country that will be interconnected to the Digital COVID Certificate. With the end of the year holidays approaching, I want to reaffirm to travellers the importance of this tool to underpin the confidence to travel inside and outside the EU.*" The two decisions entered into force on 25 November 2021.

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