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

- Commissioner McGuinness addresses EU's bank crisis management and deposit insurance framework, including COVID-19 crisis and State aid concerns
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Parliament discusses Study on post COVID-19 value chains
- European Commission participates in Aid-for-Trade event on trade impacts of COVID-19 pandemic
- European Commission publishes list of Member State authorities overseeing authorization mechanism for vaccine exports

Medicines and Medical Devices

- European Parliament meets with Head of DG SANTE and EMA's Executive Director on COVID-19 vaccine agreements and approval status
- EMA holding third public meeting on COVID-19 vaccines
- EMA concludes that the AstraZeneca vaccine is safe
- European Commission proposes Regulation for a Digital Green Certificate for COVID-19

Cybersecurity, Privacy & Data Protection

- European Commission proposes Regulation for a Digital Green Certificate for COVID-19, including treatment of personal data

COMPETITION & STATE AID

State Aid

Commissioner McGuinness addresses EU's bank crisis management and deposit insurance framework, including COVID-19 crisis and State aid concerns (see here)

On 18 March 2021, the European Commissioner for Financial services, financial stability and Capital Markets Union, Mairead McGuinness, spoke at the conference on Strengthening the EU's Bank Crisis Management and Deposit Insurance Framework.

She recalled the major program of reforms a decade ago of the EU financial system, following multiple bank failures. This laid down the basis for the Banking Union, which remains unfinished.

Commissioner McGuinness noted that the COVID-19 crisis and massive economic repercussions are another reminder of the importance of a robust crisis management framework.

She noted, in particular, that the Single Resolution framework can serve as an effective tool, by ensuring the orderly resolution of failing banks with minimal costs for taxpayers and the economy. Still, the Single Resolution mechanism can be improved and strengthened to better protect depositors. In this respect, the review of the crisis management and deposit insurance framework ("CMDI") is relevant.

Commissioner McGuinness commented on improving the CMDI framework and related challenges, such as:

- developing proportionate and consistent solutions to effectively manage the failure of all categories of banks;
- addressing situations whereby similar sources of funding may be attached to different conditions if they qualify as State aid, which raises complexities, since this largely depends on the circumstances of the case; and
- addressing the fact that deposit guarantee schemes remain national and that depositors benefit from different levels and types of guarantees depending on their location.

The Commission's proposed CMDI review aims to improve the existing framework to achieve consistent and proportionate solutions, and to avoid undesirable incentives to rely on varying national-level solutions.

Commissioner McGuinness stated the importance of the forthcoming Euro Summit in June 2021, where a work plan is expected to be outlined on all outstanding elements needed to complete the Banking Union, which remains a priority for the Commission.

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:

- €3 million Latvian scheme to support cultural institutions affected by the coronavirus outbreak

- €350 million Finnish support to Finavia in the context of the coronavirus outbreak
- €1 million Luxembourgish scheme to support pig farmers affected by the coronavirus outbreak
- €4 million Slovenian scheme to support apple growers affected by the coronavirus outbreak
- €25 million French program designed to support the horticulture sector during the coronavirus pandemic
- €45 million Irish scheme to support companies active in the beef sector in the context of the coronavirus outbreak
- €3 million Latvian scheme to support small farmers affected by the coronavirus outbreak
- French scheme with a budget between €140 and €700 million to compensate ski lifts operators for damages suffered due to the coronavirus outbreak
- €3 million Czech scheme to support tour operators affected by the coronavirus outbreak
- €3.7 million Slovenian scheme to support the wine production sector affected by the coronavirus outbreak
- €38.5 million Danish scheme to support companies active in culture sector and small non-professional sporting activities affected by the coronavirus
- €21 million Greek scheme to support operators of tourist buses and trains affected by the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Parliament discusses Study on post COVID-19 value chains (see here)

On 17-18 March 2021, the INTA (European Parliament Committee on International Trade) met to address various COVID-19 related topics, including a presentation of the Study on "Post Covid-19 value chains: options for reshoring production back to Europe in a globalised economy."

The Study, commissioned by Directorate General for External Policies of the Union, discusses economic and political justifications for reshoring with respect to security of supply concerns and the debate on the EU's strategic autonomy.

Notably, the reshoring of production has become a topical issue in the recent EU policy debate, in light of supply shortages of medical products during the COVID-19 pandemic and geopolitical rivalry between the US and China.

The Study recognizes the importance of a more proactive policy approach to mitigating security of supply concerns and to promoting strategic autonomy in the EU. The Study, however, indicates that reshoring should be primarily focused on specific critical sectors and products facing acute supply bottlenecks, in particular, for pharmaceuticals and medical products.

	Beyond reshoring, the Study notes that other instruments are available to promote the security of supply of critical products and building greater strategic autonomy for Europe, such as: - stockpiling policies as a complement to reshoring; - using EU trade policy to promote nearshoring by EU-based companies, particularly for products where supply security concerns could be addressed by developing a more regionally diversified supply chain and where production conditions in neighboring countries are favorable (e.g., by encouraging regulatory approximation by trade partners in the Eastern and Southern neighborhood, such as Algeria, Egypt, Jordan, Lebanon, Morocco, etc.).
European Commission participates in Aid-for-Trade event on trade impacts of COVID-19 pandemic (see here)	On 25 March 2021, the European Commission is participating in the conference on "A New Direction for Aid for Trade: Promoting an Inclusive and Green Pandemic Recovery." This so-called Aid-for-Trade Stocktaking event focuses on the trade impacts of the COVID-19 crisis and innovative policies and practical solutions for COVID-19 recovery. Aid-for-Trade is a multi-stakeholder initiative, led by the WTO, which seeks to mobilize resources to address the trade-related needs and supply-side constraints identified by developing countries and least-developed countries. The objective is to enable these countries play a more active role in world trade. The conference, in particular, focuses on developing and least developed countries' trade needs arising from the pandemic and mobilizing financing for a continued, sustained response that supports recovery and resilience. Keynote speakers include Ngozi Okonjo-Iweala, the newly-appointed Director-General of the World Trade Organization (WTO). Other speakers include Cécile Billaux, European Commission, Head of Unit for Micro-Economic Analysis, Investment Climate, Private Sector, Trade and Employment, Directorate-General for International Partnerships. The event is hosted by the European Union, Canada, and the International Trade Centre (ITC, a joint agency of the United Nations and the WTO, is the only multilateral agency fully dedicated to supporting the internationalization of SMEs. Its joint mandate combines a focus on expanding trade opportunities with the aim of fostering sustainable development).
European Commission publishes list of Member State authorities overseeing authorization mechanism for vaccine exports (see here)	On 17 March 2021, the European Commission published the list of Member State authorities competent for overseeing the transparency and authorization mechanism for COVID-19 vaccine exports. To recall, the vaccine export mechanism, covering exports outside the EU of COVID-19 vaccines subject to Advance Purchase Agreements ("APAs"), was recently extended from 12 March 2021 to 30 June 2021. This extension responds to continuing delays in vaccine deliveries to the EU (*see Jones Day COVID-19 Update No. 40 of 17 March 2021)*.

MEDICINES AND MEDICAL DEVICES

European Parliament meets with Head of DG SANTE and EMA's Executive Director on COVID-19 vaccine agreements and approval status (see here)	On 23 March 2021, the European Commission Director-General for Health and Food Safety ("SANTE"), Sandra Gallina, updated European Parliament's Budgetary Control Committee ("CONT") on the Advanced Purchase Agreements ("APAs") that the European Commission entered into with eight COVID-19 vaccine manufacturers. Commissioner Gallina aimed to clarify several primary issues, such as the effectiveness of APA implementation, the quantity of vaccine supplies, and whether pharmaceutical companies are complying with APA terms and deadlines. On the same day, the European Medicines Agency's ("EMA") Executive Director, Emer Cooke, updated the European Parliament's Environment, Public Health and Food Safety ("ENVI") Committee on the status of COVID-19 vaccine approvals. On 22 March 2021, Members of the European Parliament were also updated on the state of play of COVID-19 variants by representatives of the EMA, the European Centre for Disease Prevention and Control ("ECDC"), and the World Health Organization ("WHO") (see here).
EMA holding third public meeting on COVID-19 vaccines (see here)	On 26 March 2021, the EMA will hold a third public meeting on the continued assessment, approval and safety monitoring of COVID-19 vaccines. The event will provide, *inter alia*, an update on approved vaccines and those under assessment; post-authorization activities, including emerging safety data since EU authorization of the first COVID-19 vaccines and ongoing work to address new variants; information on publishing clinical data related to COVID-19 vaccines; and the vaccines' expected impact on society. This meeting is part of EMA's commitment to transparency regarding its work with COVID-19 vaccines, and EMA will continue to provide the public with regular updates.
EMA concludes that AstraZeneca vaccine is safe (see here)	On 18 March 2021, the EMA's Pharmacovigilance Risk Assessment Committee ("PRAC") concluded that the benefits of the AstraZeneca COVID-19 vaccine outweigh any potential risks of side effects, including thromboembolic events and that there is no evidence of issues related to specific batches or to particular manufacturing sites. In particular, the PRAC noted that the rate of clotting events is not higher in vaccine recipients than in the general population. However, a small subset of events is currently under review, involving a rare and unusual combination of low blood platelets and clotting. Member States that paused the administration of the AstraZeneca's vaccine must make their own decisions on re-starting the vaccination based on the PRAC's conclusions. The EMA will continue close safety monitoring of reports of blood clotting disorders, and further studies are planned in order to provide more laboratory data and real-world evidence. EMA will communicate further on developments as appropriate.

European Commission proposes Regulation for a Digital Green Certificate for COVID-19 (see here)	On 17 March 2021, the Commission adopted a proposal for Regulation for a Digital Green Certificate ("Certificate"), in view of facilitating free movement during the current pandemic within the European Union, with the possibility of including Iceland, Liechtenstein, Norway and Switzerland in the mechanism. The Certificate will serve as proof that a person: (i) is vaccinated against COVID-19; (ii) received a negative test result; or (iii) recovered from COVID-19. The Certificate should be issued to EU citizens and their family members, regardless of their nationality. It should also include non-EU nationals who reside in the EU and visitors who have the right to travel to other Member States. Additionally, in particular, for Member States that accept proof of vaccination to waive certain public health restrictions such as testing or quarantine, they would be required to grant the same rights to individuals holding a Certificate. The Certificate would be made available in digital or paper format and include a QR code to ensure its security and authenticity. The Commission also plans to build an EU virtual gateway to ensure verification of the Certificate across the EU. The Commission's proposal will now undergo discussion and adoption by the Parliament and the Council, anticipated for this summer. *For further details on the Certificate, see below Section on Cybersecurity*.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission proposes Regulation for a Digital Green Certificate for COVID-19, including treatment of personal data (see here)	On 17 March 2021, the Commission adopted a proposal ("Proposal") for a Regulation for a Digital Green Certificate ("Certificate"), in view of facilitating free movement during the current pandemic within the European Union (*for further details, see above section on Medicines and Medical Devices above*). As personal data will be processed in the context of the Certificate, the Certificate is subject to GDPR, as well as "*clear rules, conditions and robust safeguards"* that Member States must implement. Annex 1 of the Proposal sets out a list of the categories of personal data to be processed in relation to the Certificate as concerns vaccination, testing, and recovery (e.g., full name, date of birth, disease targeted/recovered from, Member State of vaccination/testing, etc.). The transmission and exchange of personal data across EU countries is also provided for in the Proposal, to confirm and verify the holder's vaccination, testing or recovery status. The Proposal notably reflects key data protection principles, such as the principle of data minimization, since it requires limiting the processing of personal data to the minimum necessary. Moreover, due to the sensitivity of the personal data processed (i.e., medical data), a very high level of data protection must be ensured. In this respect, for instance, the Proposal advises against establishing and maintaining a database at an EU level, but rather to decentralize the verification of digitally signed interoperable certificates.

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