COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 74 | 24 January 2022

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 approves new and amended Member State measures to support the economy

Trade / Export Controls

- *No noteworthy developments for this issue*

Medicines and Medical Devices

- EMA publishes COVID-19 vaccines safety update
- European Parliament endorses agreement with Council on reinforced role for EMA crisis preparedness and management for medicinal products and medicinal devices
- Ministers of Health of EU Member States and EU Commissioner for Health and Food Safety discuss Resilience of Health Systems to Support Cooperation on a European Scale

Cybersecurity, Privacy & Data Protection

- Council of the European Union adopts Recommendation on a coordinated approach to facilitate safe free movement during COVID-19 pandemic
- ENISA publishes reports on security of digital identification

COMPETITION & STATE AID

State Aid

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 30 June 2022.

- Italian "umbrella" scheme to support companies affected by the coronavirus pandemic, including an overall budget increase of €2.5 billion (from €12.5 billion to €15 billion). The scheme is a re-introduction of a measure already approved by the Commission on 21 May 2020.
- Six Dutch schemes (a re-introduction of measures already approved by the Commission), as well as the amendment of one scheme to support companies affected by the coronavirus pandemic, including a budget increase of €475 million, bringing the total budget for the measure to about €2.37 billion.
- Amendment to Irish scheme to support commercial venues, producers and promoters of live performances affected by the coronavirus pandemic, including an overall budget increase of €45 million.
- €3.07 million Bulgarian scheme to support tour operators in the context of the coronavirus pandemic.
- Three Portuguese schemes to support companies in Azores in the context of the coronavirus pandemic, including a €8.7 million wage subsidy scheme that replaces three regional aid measures previously approved by the Commission.
- €2 million Cypriot scheme to support tour operators affected by the coronavirus pandemic.
- €12 billion German umbrella scheme to compensate companies for damages suffered due to coronavirus outbreak.
- Renewal of an Italian scheme to support companies active in agriculture, forestry, fishery, aquaculture and related sectors, including a €500 million budget increase, in the context of the coronavirus pandemic.
- Czech scheme, including an €8.3 million budget increase, to support travel agencies affected by the coronavirus pandemic.

MEDICINES AND MEDICAL DEVICES

EMA publishes COVID-19

On 20 January 2022, the European Medicines Agency (EMA) published a safety update for vaccines granted with marketing authorization in the

vaccines safety update (see here and here)	European Union, including COVID-19 vaccines Comirnaty (BioNTech), COVID-19 Vaccine Janssen, Vaxzevria (AstraZeneca), and Nuvaxovid (Novavax CZ)). The EMA reported on modifications to be made to the concerned vaccines' product information, as well as ongoing assessments of the vaccines, in light of evaluations by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). For COVID-19 Vaccine Janssen and Vaxzevria, transverse myelitis ("TM", a rare neurological condition) will be included in product information as a side effect of "unknown frequency." Also for COVID-19 Vaccine Janssen and Vaxzevria, product information will be updated on the very rare side effect of thrombosis with thrombocytopenia syndrome ("TTS", a blood-clotting condition). This includes removing the statement on the higher prevalence of women in TSS cases in the case of COVID-19 Vaccine Janssen (since the sex imbalance seems smaller than previously observed). For Vaxzevria, the information update reflects that the majority of TTS cases were reported after the first dose (rather than the second). Furthermore, the EMA indicated the absence of adverse effects from use of Comirnaty during pregnancy, as well as the ongoing assessment of reports of capillary leak syndrome (CSL) in persons vaccinated with Comirnaty. As concerns Nuvaxovid, the EMA reported that since its marketing authorization in the EU on 20 December 2021, it has yet to be used in the EU/EEA. The EMA will review and communicate all relevant new information that may emerge worldwide.
European Parliament endorses agreement with Council on reinforced role for EMA crisis preparedness and management for medicinal products and medicinal devices (see here and here)	On 20 January 2022, the European Parliament endorsed the agreement reached with the Council of the European Union (see here) on the European Commission Proposal for a Regulation on a reinforced role for the European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices (Regulation) (see here). The COVID-19 pandemic has demonstrated the need to strengthen the European Union's role towards ensuring cooperation and coordination in managing the availability of medicinal products and medical devices to address public health threats at an early stage. The Regulation aims to expand the mandate of the EMA to act in case of a major event (i.e., likely to pose a serious risk to public health in relation to medicinal products in more than one Member State) or public health emergency at EU level. In the context of such event, the EMA would facilitate an EU-level coordinated response by monitoring and mitigating the risk of shortages of critical medicines and medical devices, providing advice, and coordinating clinical trials. Under the agreement reached, the EMA would additionally set up and manage the European shortages monitoring platform, capable of processing information on supply and demand of critical medicinal products during a major event or public health emergency and, outside those situations, to allow reporting shortages likely to lead to public health emergencies or major events. The EMA's web portal would also establish a public webpage with information on actual shortages of medicines and medical devices considered critical during the major event or public health emergency.

	The agreement must now be endorsed by the Council, to be followed by publication of the agreement in the EU Official Journal and application as of 1 March 2022.
Ministers of Health of EU Member States and EU Commissioner for Health and Food Safety discuss Resilience of Health Systems to Support Cooperation on a European Scale (see here)	On 18 January 2022, Ministers of Health of the EU Member States and EU Commissioner for Health and Food Safety, Stella Kyriakides, met in a high level conference on the Resilience of Health Systems to Support Cooperation on a European Scale. Discussions highlighted that COVID-19 had demonstrated the need to increase resilience of the health systems of Member States and to strengthen coordination at EU level. Ideas put forward during in the meeting included, for example, setting up cooperation mechanisms to transfer patients between Member States or to provide training on critical care medicine. In this respect, there is interest in the proposal to create a voluntary European cooperation instrument under a "European hospital label" for health facilities and establishments, facilitating a network-based approach and coordinated action.

CYBERSECURITY, PRIVACY & DATA PROTECTION

Council of the European Union adopts Recommendation on a coordinated approach to facilitate safe free movement during COVID-19 pandemic (see here)	On 25 January 2022, the Council adopted Council Recommendation on a coordinated approach to facilitate safe free movement during the COVID-19 pandemic. This replaces Recommendation (EU) 2020/1475 of 13 October 2020. The Recommendation establishes a "person-based" approach, such that COVID-19 travel measures should be applied at the personal level instead of the regional level. This means that travelers holding a valid EU Digital COVID Certificate should not be subject to additional restrictions to free movement, such as the requirement to undergo quarantine. Additionally, given the important role of contact tracing, the Recommendation indicates that Member States could consider requiring persons to submit Passenger Locator Forms (PLF) in accordance with data protection requirements when travelling to their country by collective transport modes, with pre-assigned seats or cabins. In this respect, Member States could make use of the common European Digital Passenger Locator Form and join the PLF Exchange Platform, established on the basis of Commission Implementing Decision (EU) 2021/858 (see here), to strengthen cross-border contact tracing capabilities for all transport modes. The Recommendation will enter into force on 1 February 2022, the same day as the Delegated Regulation amending the acceptance period of vaccination certificates in the EU Digital COVID Certificate to 270 days (*see Jones Day COVID-19 Update No. 72 of 10 January 2022*).
ENISA publishes reports on security of digital identification (see here and here)	On 20 January 2022, the European Union Agency for Cybersecurity (ENISA) published two reports, described below, addressing the security of digital identification. Digital identification serves to provide proof of identity for citizens or organizations in order to access online services or perform online transactions, particularly on a cross-border basis.

ENISA notes that the COVID-19 pandemic underlined the importance of well-regulated and reliable remote identification processes for public and private sector organizations.

The two ENISA Reports, as set out below, aim to further support the objective of Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation) (see here) in securing electronic identification and authentication in cross-border online services offered within Member States:

(1) The Report on "Digital Identity: Leveraging the SSI Concept to Build Trust" assesses the current global and European Self-Sovereign Identity (SSI) landscape and governance of a digital identity framework, and considers the risks associated with SSI technologies. SSI technologies give an identity holder greater control over how and to what degree their identity is represented and disclosed to other parties relying on the identity information, and in particular over the personal information revealed to those other parties. The Report, in particular, highlights the following:

- During the pandemic, maintaining continuity in social life, businesses and administration has accelerated the need for a decentralized electronic identity, i.e. the ability of an identity holder to have multiple "decentralized identifiers" issued for different activities and to separate out the attributes associated with an identifier in "verifiable credentials". In this respect:
  - Decentralized digital identities, for instance, can be used to support pseudonyms for privacy of identity;
  - The ability to hold multiple authentication keys in a wallet with separate identity documents from different controllers enables the user to cryptographically separate transactions to maintain privacy by avoiding links between the separate transactions;
- Key security measures, such as data minimization, consent and choice by the user and accuracy and quality of the data must be considered in the SSI architecture.
- Audit and oversight over decentralized identifiers issuers must be considered.

(2) The Report on "Remote Identity Proofing: Attacks & Countermeasures" addresses remote identity proofing, i.e., the process whereby an online user proves that he or she is the owner of a claimed identity. The proofing process typically occurs over a webcam or a mobile device, where users show their faces and produce their identity cards or passports. These systems, however, can be circumvented.

The Report lists remote identity proofing methods and identifies different types of attacks. In addition, the Report analyzes how a secure standardized environment can mitigate the risks of circumvention, including applicable countermeasures for such attacks, such as:

- Checking the metadata of remote identity verification sessions, such as geolocation, IP, timestamps, and VPN usage, which enables detecting fraud patterns;
- Use of an electronic identity document equipped with an NFC chip (i.e., a chip containing the document data encrypted and digitally signed by the issuing state), which provides the highest level of

guarantee using a government-issued ID;

- Verification that an identity document is not lost, stolen or expired by consulting national and international databases when access to such databases is available;

- Employing software systems used to perform Presentation Attack Detection (PAD) that make use of artificial intelligence and machine learning to understand whether images were captured from a living human being. The video-based solutions commonly provide more data for analysis and therefore provide a higher assurance of identity and fraud mitigation;

Furthermore, ENISA notes that the European Commission has proposed to amend the eIDAS Regulation by creating a European Digital Identity Wallet, i.e., a personal digital wallet aiming to allow citizens to digitally identify themselves, store and manage identity data and official documents in electronic format (see here). The Commission has noted the urgency of this revision following the outbreak of the COVID-19 pandemic and the sudden need for accessing and using all types of public and private services online.

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