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

- EU adopts new market stabilization measures for wine sector in response to COVID-19 effects
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- *No noteworthy developments for this issue*

Medicines, Medical Devices, and Personal Protective Equipment

- European Parliament approves European Commission's Proposal for a Regulation on certain derogations from GMO rules in the context of COVID-19 clinical trials
- EMA and HMA propose Joint Strategy for 2021-2025
- ICMRA publishes report on Phase 3 clinical trials for COVID-19 vaccines

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

COMPETITION & STATE AID

Competition	
EU adopts new market stabilization measures for wine sector in response to COVID-19 effects (see here)	On 7 July 2020, the European Commission adopted a new package of exceptional measures to support the wine sector, in response to the impact of the COVID-19 crisis. As noted by the Commission, the wine sector is among the agri-food sectors most deeply affected by the pandemic, given the sharp fluctuation in demand and the shuttering of bars and restaurants across the EU. The exceptional measures include a temporary derogation from EU competition rules, which allows operators in the wine sector to self-organize market stabilization measures for a maximum period of 6 months. This will enable operators, for example, to plan joint promotions, to organize storage by private operators, and to commonly plan production.
State Aid	
EU approves new and amended Member State measures to support the economy (see 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: • €9.5 million Swedish scheme to compensate passenger ferries for damages suffered due to the coronavirus outbreak • €20 million Estonian scheme to compensate international ferry operators for damages suffered due to the coronavirus outbreak • €150 million Austrian subordinated loan to compensate Austrian Airlines for damages suffered due to coronavirus outbreak • €250 million Latvian measure to recapitalise airBaltic • Latvian fund to enable €100 million of liquidity and capital support to large enterprises affected by the coronavirus outbreak • Around €2 million Austrian support to coronavirus-relevant research and development projects by Austrian micro biotech companies Apeptico and Panoptes • Cypriot scheme to support newspapers affected by the coronavirus outbreak • Maltese public loan of up to €18.7 million to support bond issue by real estate developer MIH in the context of the coronavirus outbreak • €550 million Czech scheme to support self-employed affected by the coronavirus outbreak

- Latvian guarantee scheme to support mid-sized and large exporting undertakings affected by coronavirus outbreak
- €110 million "umbrella" scheme to support Gibraltar economy in coronavirus outbreak
- €370 million Czech scheme to support enterprises in the primary agricultural sector and in food and feed production affected by coronavirus outbreak
- €6.2 billion Italian grants scheme to support small businesses and self-employed affected by coronavirus outbreak
- €25 million Belgian aid to support the ground handling service provider Aviapartner in the context of coronavirus outbreak
- €23.5 million Hungarian wage subsidy scheme to support the aviation sector in the context of the coronavirus outbreak
- €25 million Dutch subsidized loans scheme to support small and micro companies affected by the coronavirus outbreak
- €222 million Slovenian scheme to support companies affected by the coronavirus outbreak
- €6.35 million Belgian scheme to support the social tourism sector in Flanders
- €58 million Latvian rent compensation scheme to support companies affected by coronavirus outbreak

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Parliament approves European Commission's Proposal for a Regulation on certain derogations from GMO rules in the context of COVID-19 clinical trials (see here)	On 10 July 2020, the European Parliament approved the European Commission's Proposal for a Regulation on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (see here). The Proposal aims at temporarily allowing derogations to specific provisions on genetically modified organisms (GMO) under Directive 2001/18/EC and Directive 2009/41/EC for COVID-19 clinical trials purposes. These derogations apply, *inter alia*, in relation to prior environmental risk assessment and/or consent for the use of GMOs, as well as to rules on packaging and labelling of products containing GMOs. The goal is to facilitate the approval of clinical trials for COVID-19 vaccines and treatments as swiftly as possible. The proposed Regulation is awaiting Council approval to become applicable.
EMA and HMA propose Joint Strategy for 2021-2025 (see here)	On 6 July 2020, the European Medicines Agency (EMA) and the Heads of National Competent Authorities (HMA) launched a two-month public consultation on their proposed Strategy for 2021-2025 (Strategy), which sets challenges, goals, recommendations, and priorities for European medicine

	regulators and national competent authorities (NCAs), in alignment with the European Commission's Pharmaceutical Strategy (see here). The proposed Strategy builds on six main focus areas, namely: • **Availability and accessibility of medicines**. This area addresses both availability issues (shortages) and accessibility (commercialization / downstream decision making), proposing certain solutions, such as the use of electronic product information (ePI). • **Data analytics, digital tools and transformation**. This aims at enabling the use of all available data and tools for generating clinical evidence to promote more efficient regulatory decision-making. Particular attention is given to real world data and to analyzing and processing data for new digital tools. • **Innovation**. This area seeks to support innovators in medicines development for novel borderline products, precision and personalized medicine, authorization of medicinal products based on limited evidence, and the approval of innovative clinical trial designs. • **Antimicrobial resistance and other emerging health threats**. The goal is to encourage the appropriate use of antimicrobials and to impede bacteria resistance to available medicines. The Strategy also plans to discuss the use of platform technologies for exploring alternative approaches to treating infectious diseases. • **Supply chain challenges**. This area seeks to reinforce oversight of supply chain capabilities and product quality. In this regard, Good Distribution Practice (GDP) for veterinary medicinal products are expected to be adopted in 2021, while GDP for human medicinal products may undergo review. • **Sustainability and operational excellence**. The aim is to boost EMA and NCAs scientific and regulatory capacity, funding, governance and digitization. Stakeholders are invited to provide their feedback through a questionnaire (here) by 4 September 2020. The final Strategy is expected to be adopted by the end of 2020.
ICMRA publishes report on Phase 3 clinical trials for COVID-19 vaccines (see here)	On 9 July 2020, the International Coalition of Medicines Regulatory Authorities (ICMRA) published a Report on Phase 3 clinical trials for developers of candidate COVID-19 vaccines (Report). The Report sets out the clinical and preclinical data that indicate that a vaccine is ready for a Phase 3 trial, such as: nonclinical safety studies, nonclinical data from studies in animal models, post-vaccination challenge data, etc. The Report also provides key considerations in designing such trials.

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