COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 73 | 17 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

- Commission publishes Competition Policy – 2021 at a glance
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Investment Bank releases Investment Report 2021/2022

Medicines and Medical Devices

- EMA recommendations to update product information on COVID-19 Vaccines Janssen and Vaxzevria
- EMA launches initiative on Accelerating Clinical Trials in the EU
- EMA announces regulators discussion on global regulatory response to COVID-19 Omicron variant
- EMA publishes findings on continuous monitoring of data on effectiveness of vaccines against COVID-19
- Commission adopts the Implementing Regulation on the rules and procedures for cooperation of Member States in safety assessment of clinical trials

Cybersecurity, Privacy & Data Protection

- European Data Protection Supervisor issues decision on complaint against the European Parliament on data protection obligations regarding its COVID testing website

COMPETITION & STATE AID

Competition

Commission publishes Competition Policy – 2021 at a glance (see here)

On 22 December 2021, the European Commission published its Competition Policy – 2021 at a glance.

This infographic reported, in particular, the following:

- In State aid, over 675 COVID-19 related decisions (out of over 1000 State aid decisions);
- 14 Phase II mergers cases;
- 11 cartel decisions;
- Total fines of €1.7 billion.

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.

- €100 million Flemish scheme to support companies affected by the coronavirus pandemic.
- €60 million Austrian wage subsidy scheme to support seasonal businesses affected by the coronavirus pandemic.
- €15.3 million Bulgarian scheme to support the tourism sector in the context of the coronavirus pandemic.
- €9 million Slovak scheme to support bus companies in the context of the coronavirus pandemic.

TRADE / EXPORT CONTROLS

European Investment Bank releases Investment Report 2021/2022 (see here)

On 12 January 2022, the European Investment Bank (EIB) released its Investment Report 2021/2022 – Recovery as a springboard for change.

The Report seeks to closely examine investment in the EU, as well as the COVID-19 crisis' impact on individuals, businesses, and countries in the EU. The Report also looks ahead at how recovery can serve to propel transformation through investment in digitalization and climate change.

As concerns trade-related issues, the EIB expects that COVID-19 will have a persistent impact on trade and notes the following, in particular:

Supply chains: The pandemic's global shock resulted in the reshuffling of

supply sources, and businesses were often forced to change their products and services. Additionally, with supply disruptions and bottlenecks, companies are re-evaluating their supply chains. According to the Report, trade data provide an initial confirmation of diversifying global value chains. However, evidence of shortening of supply chains and of repatriating manufacturing is less clear.

Uneven Member State recovery: Exports and imports in 2021 rebounded as compared to 2020. Imports from outside the EU increased by 16.7%, and by 1.1% vs. 2019. Exports to outside the EU grew by 13.8% compared with the same period of 2020 and declined 0.2% vs. 2019. However, this overall trend masked significant variances within the EU. Notably, diverging trends are emerging for exports of goods and services:

- Some countries had the capacity to seize the opportunities brought by the recovery, particularly those with a strong manufacturing base and whose exporters could respond to the shock caused by the pandemic (e.g. Belgium, the Netherlands, Sweden, Italy, Poland, the Czech Republic and Slovakia).

- Other countries experienced a deterioration in trade. For example, Cyprus, Malta, Luxembourg are small, open economies that suffered from the general disruption to trade. Negative trends were also shaped by challenges in specific sectors, such as aeronautics in France.

While the Report expects that most trade differences among EU Member States are likely crisis-related and will not persist in the long term, it also believes that the pandemic and the digital and green transition are unleashing or accelerating structural shifts in demand for certain sectors, in addition to changes in global value chains. For instance, the pandemic triggered rising demand for IT products, and even when the health situation normalizes, the EIB expects that increased trade in IT products will likely endure.

As Europe emerges from the pandemic, EIB Chief Economist Debora Revoltella emphasized: "*This is the time to start focusing on the future. Investment needs are huge, to adapt to the new normal and reap the benefits of the green and digital transition. Public and private investment have to complement each other. This calls for continued policy focus on public investment and increased efforts to catalyse private investment*."

MEDICINES AND MEDICAL DEVICES

EMA recommendations to update product information on COVID-19 Vaccines Janssen and Vaxzevria (see here)

On 14 January 2022, the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) – the committee responsible for assessing and monitoring the safety of human medicines – recommended modifications to the product information, both for (i) the COVID-19 Vaccine Janssen and (ii) Vaxzevria (previously known as COVID-19 Vaccine AstraZeneca), to include a warning to raise awareness among healthcare professionals and people receiving the vaccines of reports of very rare cases of transverse myelitis ("TM", a rare neurological condition) following vaccination.

After a review of the available information on globally reported cases, the PRAC concluded that a causal relationship between these two vaccines and TM is at least a reasonable possibility. However, the benefit-risk profile of both

	vaccines remains unchanged. Additionally, the PRAC recommended updating product information for Vaxzevria on the very rare cases of thrombosis with thrombocytopenia ("TTS", a blood-clotting condition) that occurred following vaccination. After a review of cumulative data, the PRAC highlighted that the majority of suspected TTS events were reported worldwide after the administration of the first dose. Fewer events were observed after the second dose.
EMA launches initiative on Accelerating Clinical Trials in the EU (see here and here)	On 13 January 2022, the EMA announced the launch of the initiative on Accelerating Clinical Trials in the EU (ACT EU), including an accompanying Strategy Paper. The purpose is to strengthen the EU as a hub for clinical research, enhance the development of high quality and effective medicines and better streamline clinical research in the European health system. ACT EU will be co-led by the European Commission, the Heads of Medicines Agencies (HMA), and the EMA. The Strategy Paper notes that the COVID-19 pandemic demonstrated a relative absence of EU-wide impactful multi-state clinical trials, as well as the continued registration of a preponderance of small single Member State studies. In this respect, diverging Member State regulatory requirements complicate the submission of multi-state trial applications, leading to costly trials and slower trial authorizations that could negatively affect research responsiveness. This might in part explain a fall in the inclusion of trial results generated in the EU, as reflected in an analysis of centralized marketing authorization applications. Recognizing the need for improvements, and combined with the application of the Clinical Trials Regulation ("CTR", Regulation (EU) No. 536/2014) on 31 January 2022, the European Medicines Regulatory Network Strategy to 2025 and European Commission Pharmaceutical Strategy for Europe (see here and here) put forward recommendations to foster innovation in clinical trials. In view of delivering on these recommendations, the Strategy Paper identifies ten key priorities for 2022-2023, including, for instance: • Development and publication of key methodologies guidance, e.g., on artificial intelligence and/or machine learning impacted clinical trials; decentralized clinical trials; and the interface between the In Vitro Diagnostic Medical Devices Regulation and the CTR; • Implementation of the Good Clinical Practice modernization; • Reinforcement of coordination between scientific advice on clinical trial approval and clinical trial design; and • Delivery of a clinical trials training curriculum, including modules on drug development and regulatory science with links to universities and SMEs, serving as an educational ecosystem. Public communications and stakeholder outreach on ACT EU are also slated to be initiated.
EMA announces regulators discussion on global regulatory	On 13 January 2022, the EMA announced a discussion of regulators worldwide on the global regulatory response to the COVID-19 Omicron variant during a workshop by the International Coalition of Medicines Regulatory Authorities (ICMRA), chaired by EMA and the US Food and Drug

response to COVID-19 Omicron variant (see here)	Administration.* The goal of the workshop discussion was two-fold: (i) Review available evidence on the effectiveness of approved COVID-19 vaccines against the Omicron variant; and (ii) Reach alignment on key regulatory requirements to support the development of a possible adapted vaccine. According to the EMA, while most available data suggest that the approved COVID-19 vaccines are losing effectiveness in protecting against infection and mild disease, the vaccines continue to provide high protection against developing severe disease and the need for hospitalization linked to the Omicron variant. The EMA also referred to broad agreement that clinical data are needed for approving a new updated vaccine. EMA's Executive Director and chair of ICMRA, Emer Cooke, stated: *"Today is not only about the regulatory response to Omicron but is also part of setting the scene for a more strategic discussion about what types of vaccines might be needed in the long-term to adequately manage COVID-19. These decisions are not for regulators alone. Collaboration is needed across all the actors in this space, including public health decision-makers at national, regional and global level. In that context, we need to emphasize the importance of the collaboration with WHO to take a decision on strain updates".* More details on the discussion are expected to be shared in the coming days. * *Note: The ICMRA's international regulatory workshops enable in-depth discussions and agreements on common approaches on important topics. Participants include delegates representing 28 medicines regulatory authorities globally and experts from the World Health Organization and the European Commission. The workshops aim to achieve alignment between regulators, in particular, to expedite and streamline global development and authorization of new or modified COVID-19 vaccines against emerging coronavirus variants.*
EMA publishes findings on continuous monitoring of data on effectiveness of vaccines against COVID-19 (see here)	On 11 January 2022, EMA published findings from its continuous monitoring of data on the effectiveness of vaccines against COVID-19, including disease caused by the rapidly-spreading Omicron variant. Based on data from studies from European countries, the United Kingdom, and South Africa, the EMA findings include, e.g.: • The Omicron variant appears to be more infectious than other variants; • The Omicron variant brings a lower risk of hospitalization, i.e., the risk is currently estimated to be between a third and half of the risk with the Delta variant; and • Vaccine effectiveness against symptomatic disease is lower for the Omicron variant than for other variants and tends to wane over time. However, vaccination continues to provide a high level of protection against severe disease and hospitalization linked to the Omicron variant. The latest evidence also suggests that people who have had a booster dose are better protected than those who have only

	received their primary course. EMA will continue to review data on vaccine effectiveness and severity of the disease caused by the Omicron variant. These assessments may serve to guide future vaccination strategies advanced by experts in Member States.
Commission adopts the Implementing Regulation on the rules and procedures for cooperation of Member States in safety assessment of clinical trials (see here)	On 7 January 2022, the European Commission adopted Implementing Regulation 2022/20 laying down rules for the application of the above-referred CTR (Implementing Regulation). The COVID-19 pandemic highlighted the importance of assessing the safety information of medicinal products (e.g., concerning their adverse effects) arising from clinical trials. Through a coordinated Member State assessment of this information, the highest safety standards for participants in the trial should be ensured. Additionally, knowledge of the potential risks of medicinal products should be improved before these are placed on the market. Under the CTR, the overall responsibility for ensuring participants' safety lies with the sponsor of the clinical trial. This is further reinforced by additional oversight from the Member States, including through their cooperation in evaluating the safety of the investigational medicinal products. The Implementing Regulation now establishes the rules for Member State cooperation in assessing information and reports submitted under the CTR. In particular, the rules concern: • Selection of a safety assessing Member State, (i.e., the Member State responsible for, among other things, assessing the safety reports; the preparation and submission of general recommendations on the safety of the active substance to the other Member States concerned; and the provision of assistance on safety matters related to the active substance when requested by a Member State); • Screening and assessment of suspected unexpected serious adverse reactions and annual safety reports; • Submission of recommendations on corrective measures and other risk mitigating actions for safety oversight from the safety assessing Member State to the reporting and other concerned Member States; • Coordination between the Member States in implementing corrective measures and risk mitigating actions, and • Cooperation between safety assessing Member States, reporting Member States and Member States concerned in clinical trials using the same active substance. The Implementing Regulation will apply from 31 January 2022, the same date of applicability of the CTR.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Data Protection Supervisor issues decision on	On 5 January 2022, the European Data Protection Supervisor (EDPS) issued a decision in complaint case 2020-1013 initiated by Members of the Parliament (MEPs) in October 2020 against the European Parliament in relation to its data protection obligations on an internal COVID testing website.

complaint against the European Parliament on data protection obligations regarding its COVID testing website (see here)	The website enabled MEPs to register online for COVID-19 PCR testing within the Parliament's premises. The Parliament had contracted with a private provider to provide both the testing and website. A complementary complaint against the Parliament, which repeated and expanded on the original complaint, was subsequently filed on behalf of the concerned MEPs by the non-profit European Center for Digital Rights (nyob) in January 2021. The EDPS confirmed that the Parliament violated its data protection obligations under Regulation (EU) 2018/1725 on data protection obligations for the EU institutions and bodies when they process personal data and develop new policies (Regulation). In particular, the EDPS found: • The Parliament (acting as controller) delegated the setting up and functioning of the website to the test provider (acting as processor), thereby giving the test provider operational independence and discretion, while being aware that such tasks were not within the test provider's primary field of expertise and without obtaining sufficient guarantees that the test provider could implement appropriate measures to carry out these tasks in line with the Regulation; • The data protection Notice on the website was not fully compliant with the data protection principles of transparency and accountability and the data subjects' right to information. In particular, the Notice erred in: – copying a notice from another testing center, which was inaccurate in that it referred to a legal basis that the Parliament could not reply upon; – not referring to the processor; and – not sufficiently mentioning the duration, or the factors explaining the duration of storing the personal data; • Personal data was transferred to the U.S. through the use of "Stripe" and "Google Analytics" cookies, but the Parliament failed to provide information regarding the measures implemented to ensure an essentially equivalent level of protection of the personal data, as required by the CJEU Schrems II case; • The website's cookie banner violated the requirements of valid consent and did not provide transparent information; and • In violation of the data subjects' right of access, the Parliament failed to provide data subjects with relevant information regarding the personal data transferred and the safeguards in place. In the present case, the EDPS was not in a position to impose an administrative fine on the Parliament under the terms of the Regulation, but it issued a reprimand and ordered the Parliament to update its Notice within one month.

LAWYER CONTACTS

Kaarli H. Eichhorn
Partner, Antitrust & Competition Law; Government Regulation; Technology
Brussels
keichhorn@jonesday.com
+32.2.645.14.41

Cristiana Spontoni
Partner, Health Care & Life Sciences; Government Regulation
Brussels
cspontoni@jonesday.com
+32.2.645.14.48

Dr. Jörg Hladjk
Partner, Cybersecurity, Privacy & Data Protection; Government Regulation; Technology
Brussels
jhladjk@jonesday.com
+32.2.645.15.30

Rick van 't Hullenaar
Partner, Government Regulation; Investigations & White Collar Defense
Amsterdam
rvanthullenaar@jonesday.com
+31.20.305.4223