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

- Launch of Multilateral Working Group of leading competition authorities to assess the effects of mergers in the pharmaceutical sector, including drug pricing
- European Parliament issues Study on Non-performing Loans ("NPLs"), including addressing EU State aid rules and potential surge in NPLs due to COVID-19 crisis
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission extends export authorization mechanism for COVID-19 vaccines until 30 June 2021
- European Parliament INTA Committee meeting to discuss COVID-19 related topics

Medicines and Medical Devices

- EMA to review administration of AstraZeneca's COVID-19 vaccine and potential related thromboembolic events
- European Commission grants conditional marketing authorization to Janssen's single-dose COVID-19 vaccine
- EMA starts rolling review of Eli Lilly antibodies for treatment of COVID-19

Cybersecurity, Privacy & Data Protection

- European Commission issues Outline on a Trust Framework for Interoperability of health certificates

COMPETITION & STATE AID

Competition

Launch of Multilateral Working Group of leading competition authorities to assess the effects of mergers in the pharmaceutical sector, including drug pricing (see here)

On 16 March 2021, a Multilateral Working Group was launched to assess the effects of mergers in the pharmaceutical sector, bringing together the European Commission's Directorate General for Competition, the U.S. Federal Trade Commission, the Canadian Competition Bureau, the UK's Competition and Markets Authority, the U.S. Department of Justice and three Offices of Attorneys General.

Welcoming this joint initiative, Executive Vice-President and Competition Commission Margrethe Vestager stated: "*Over the past years the European Commission has taken new initiatives in scrutinising global pharmaceutical mergers to ensure effective competition in the sector. We have contributed to fair prices for vital medicines and we have protected the development of new, life saving drugs*."

COVID-19 pandemic, in particular, has increased pressure on healthcare budgets, and a number of stakeholders have raised questions about drug pricing and other issues.

In recent years, the volume of mergers in the pharmaceutical sector has also increased, and the authorities argue that close inquiry is needed to detect transactions that could lead to elevated drug prices, diminished innovation, or anticompetitive conduct.

The Multilateral Working Group will build on the expertise of the competition authorities, as well as other stakeholders with relevant experience, with the stated aim to ensure the most effective enforcement in what they view as critical markets.

State Aid

European Parliament issues Study on Non-performing Loans ("NPLs"), including addressing EU State aid rules and potential surge in NPLs due to COVID-19 crisis (see here)

On 9 March 2021, the European Parliament released a Study on "Non-performing loans - new risks and policies?", which addresses the policy implications of a potential wave of NPLs due to the COVID-19 pandemic, including the role of State aid.

To recall, NPLs are loans subject to late repayment (i.e. 90 days past due) or unlikely to be repaid by the borrower. The Study assesses potential scenarios and draws lessons from previous crises for effective NPL treatment.

In the aftermath of the 2007-2009 global financial crisis and the 2010-2012 euro zone debt crises, the Study notes that asset management companies ("AMCs") proved effective in managing large portfolios of NPLs burdening national banking systems. At least 12 EU Member States (including the UK) took this route.

The Study indicates that AMCs using public or bank funds to remove bad assets from bank books appear to provide a superior approach to tackling accumulations of NPLs, as compared with decentralized management of distressed loans at the level of individual banks. As the COVID-19 pandemic is expected to trigger a significant surge in NPLs, this may require some Member States to once again cleanse their bank balances with publicly supported AMCs.

	The Study further notes that third parties are unlikely to be willing to pay a price for NPLs that reflects their real economic value. The use of publicly supported AMCs can overcome this market failure and more broadly impact financial stability, economy and society. However, the use of AMCs raises difficulties in the EU, particularly given the restrictions placed on public support by the State aid regime. The Study advises that existing efforts of the European Commission and others to promote effective and efficient AMCs should be complemented by a revision of the existing State aid regime. In particular, the Study indicates that the criteria for the estimation of the real economic value should be specified, which should be based on a responsible winding down of NPLs, whereby the remaining minimum income for households and long-term viability of businesses are taken into account. Also on the topic of increased numbers of NPLs and State aid, the European Commission earlier issued a Communication on tackling non-performing loans in the aftermath of the COVID-19 pandemic, including the use of State aid measures (*see Jones Day COVID-19 Update No. 30 of 7 January 2021*).
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: • €200 million Cypriot schemes to support companies and self-employed affected by the coronavirus outbreak • €2 billion French scheme to support uncovered fixed costs of companies affected by the coronavirus outbreak • €60 million Greek scheme to support micro, small and medium-sized enterprises affected by the coronavirus outbreak • €511 million Italian scheme to compensate commercial rail passenger operators for damages suffered due to the coronavirus outbreak • €16.3 million Swedish subsidized loan scheme to support air traffic control services affected by the coronavirus outbreak • €511 million Italian scheme to compensate commercial rail passenger operators for damages suffered due to the coronavirus outbreak • €1.1 billion Polish scheme to further support companies affected by the coronavirus outbreak • €10 million Belgian scheme to support organizers of festivals in the Flemish and Brussels Regions in context of the coronavirus outbreak • €350 million Finnish support to compensate Finnair for damages suffered due to the coronavirus outbreak • €1.5 million Slovenian scheme to support holders of ancillary activities at farms in the context of the coronavirus outbreak • €15.8 million Estonian schemes to support farmers affected by the coronavirus outbreak

	• €3 billion Dutch scheme to support companies affected by the coronavirus outbreak • €63 million Italian aid scheme to support trade fairs sector affected by the coronavirus outbreak • €1 million Italian scheme to support organizers of international sport events in context of the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Commission extends export authorization mechanism for COVID-19 vaccines until 30 June 2021 (see here)	On 12 March 2021, the European Commission extended the transparency and authorization mechanism for COVID-19 vaccine exports from 12 March 2021 to 30 June 2021. This extension, which responds to ongoing delays in vaccine deliveries to the EU, was adopted under a new Implementing Regulation (EU) 2021/442 on making the exportation of certain products subject to the production of an export authorization ("new Implementing Regulation"). To recall, on 30 January 2021, the Commission adopted the first Implementing Regulation (EU) 2021/111 establishing an export authorization mechanism for exports outside the EU of COVID-19 vaccines subject to Advance Purchase Agreements ("APAs") (*see Jones Day COVID-19 Update No. 34 of 3 February 2021)*). The new Implementing Regulation, in particular, simplifies the authorization procedure by permitting the grouping, in one single request, of exports to different final recipients in the same country. It also adds clarity by identifying the customs codes for the active substances covered by the authorization mechanism. The Commission reiterated that the vaccine export authorization mechanism is entirely consistent with the EU's international commitments under the WTO and the G20. The Commission also earlier published FAQs providing non-legally binding clarifications to exporters and Member States authorities on the application of export requirements for COVID-19 vaccine (see here and *Jones Day COVID-19 Update No. 36 of 17 February 2021*).
European Parliament INTA Committee meeting to discuss COVID-19 related topics (see here)	On 17-18 March 2021, the INTA (European Parliament Committee on International Trade) is meeting to address various COVID-19 related topics, including a hearing on "Trade related aspects and implications of Covid-19". The hearing's panel of speakers features Marion Jansen, OECD Director - Trade and Agriculture Directorate, as well as members of the academic and research communities. The panel discussion aims to build on INTA's reflection process on the role of trade as an instrument for sustainable recovery and open strategic autonomy. Topic highlights include resilient, fair and sustainable supply chains and multilateralism vs. unilateralism during the pandemic. The INTA meeting also includes a presentation on "Post Covid-19 value chains: options for reshoring production back to Europe in a globalised economy".

MEDICINES AND MEDICAL DEVICES

EMA to review administration of AstraZeneca's COVID-19 vaccine and potential related thromboembolic events (see here)	On 11 March 2021, the European Medicines Agency ("EMA") issued a statement on the safety profiles relevant to the AstraZeneca COVID-19 vaccine. In particular, it noted that certain Member State competent authorities have paused their vaccination campaign with regard to the AstraZeneca's vaccine on the ground of potential thromboembolic events linked to its administration, following reports of blood clots in people who received the vaccine. The EMA Pharmacovigilance Risk Assessment Committee ("PRAC") – *i.e.*, the body responsible for assessing post-marketing risk management aspects of medicinal products for human use – informed that "*there is currently no indication that vaccination has caused these conditions*" and that the vaccine's benefits continue to outweigh its risks. Therefore, the EMA stated that the vaccine can continue to be administered to patients. The PRAC is currently investigating the thromboembolic events. It stated that at this time, the number of thromboembolic events in vaccinated people is no higher than the number occurring in the general population. As of 10 March 2021, 30 cases of such events had been reported among nearly 5 million people vaccinated with COVID-19 Vaccine AstraZeneca in the European Economic Area. Once completing its review, PRAC will issue any recommendations necessary to minimize risks and safeguard patients' health.
European Commission grants conditional marketing authorization to Janssen's single-dose COVID-19 vaccine (see here)	On 11 March 2021, the Commission granted a conditional marketing authorization ("CMA") for the single-dose COVID-19 vaccine developed by Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. This is the fourth COVID-19 vaccine granted with a CMA in the EU. The CMA was granted on the basis of the EMA's favorable opinion issued in relation to the vaccine's prevention of COVID-19 in people from 18 years of age. The data submitted by Janssen to the EMA show a 67% reduction in the number of symptomatic COVID-19 cases after 2 weeks in people who received the vaccine (116 cases out of 19,630 people) compared with people given a placebo (348 of 19,691 people) (see here). Welcoming this fourth vaccine, the President of the European Commission, Ursula von der Leyen, stated: "*The Janssen vaccine … will help us enhance the vaccination campaign in the second quarter of 2021. It only requires a single dose, which takes us another step closer to achieving our collective goal of vaccinating 70% of the adult population by the end of summer.*"
EMA starts rolling review of Eli Lilly antibodies for treatment of COVID-19 (see here)	On 11 March 2021, the EMA started a rolling review of data on the two antibodies developed by Eli Lilly ("bamlanivimab" and "etesevimab") for their use in combination for the treatment of COVID-19. The review will also concern bamlanivimab used alone. Bamlanivimab and etesevimab are both monoclonal antibodies with activity against COVID-19. A monoclonal antibody is a type of protein designed to attach to a specific structure (i.e., an antigen). Bamlanivimab and etesevimab are designed to attach to the spike protein of SARS-CoV-2, thereby impeding the virus from entering the body's cells.

	The EMA's decision to start the review is based on positive preliminary results from two clinical trials related to the efficacy of the these two antibodies to treat COVID-19 when combined and when bamlanivimab is used alone. The EMA will continue the review until enough evidence is available to support the filing of a marketing authorization application.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission issues Outline on a Trust Framework for Interoperability of health certificates (see here)	On 12 March 2021, the eHealth Network of the European Commission published an Outline on a Trust Framework for Interoperability of vaccination certificates ("Trust Framework"). The eHealth Network, established under the aegis of the European Commission, is a voluntary network that provides a platform for Member States' competent authorities dealing with eHealth issues. The Outline on the Trust Framework follows the Guidelines of the European Commission on the proof of vaccination for medical purposes – basic interoperability elements ("Guidelines"), published on 27 January 2021 (*see Jones Day COVID-19 Update No. 34 of 3 February 2021*). Under the three pillars of the Guidelines, the Trust Framework aims at establishing the certificates' authenticity, integrity, and validity. The Outline on the Trust Framework provides a basis for discussion between EU Member States on the implementation of interoperable certificates in EU Member States. In particular, the Trust Framework highlights the rules, policies, protocols, formats and standards required to ensure the authenticity and integrity of COVID-19 health certificates. Since certain processing operations undertaken in the context of the Trust Framework will cover personal data (e.g., issuance and verification of certificates), the EU GDPR will apply. In particular, organizations issuing and verifying vaccination certificates will act as data controllers and will therefore be subject to data protection requirements (e.g., determining a legal basis for processing, implementing appropriate security measures, informing data subjects, etc.).

LAWYER CONTACTS

Renato Antonini
Partner, Government Regulation; Antitrust & Competition Law
Brussels
rantonini@jonesday.com
+32.2.645.14.19

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

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

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