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

- Multilateral Working Group on pharmaceutical mergers launches a joint public consultation
- European Commission receives Recovery and Resilience Plans from 18 Member States
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Parliament and WTO Director-General debate proposed waiver for COVID-19 vaccine patents
- European Commission and Italy co-host first G20 Global Health Summit to address COVID-19 crisis and future pandemics
- Latest Eurostat data – A rise in exports, imports, and intra-euro area trade since March 2020

Medicines and Medical Devices

- European Commission and Italy co-host first G20 Global Health Summit to address COVID-19 crisis and future pandemics
- European Parliament and Council reach agreement on European Commission proposal on Digital COVID-19 Certificate
- European Commission enters into additional agreement with Pfizer/BioNTech for purchase of additional COVID-19 vaccine doses

Cybersecurity, Privacy & Data Protection

- European Parliament and Council reach agreement on European Commission proposal on Digital COVID-19 Certificate

COMPETITION & STATE AID

Competition

Multilateral Working Group on pharmaceutical company mergers launches a joint public consultation (see here)

On 10 May 2021, the Multilateral Pharmaceutical Merger Task Force launched a joint public consultation in the field of pharmaceutical company mergers.

Created in March 2021, the Task Force brings together the European Commission's Directorate General for Competition, the Canadian Competition Bureau, the UK's Competition and Markets Authority, the U.S. Federal Trade Commission ("FTC"), the U.S. Department of Justice and three Offices of Attorneys General (*see also Jones Day COVID-19 Update No. 40 of 17 March 2021*).

The Task Force seeks to assess and update, through concrete and actionable steps, approaches to analyzing the effects of pharmaceutical company mergers. In recent years, the volume of mergers in the pharmaceutical sector has increased, and a number of authorities have argued that closer inquiry is needed to detect those transactions that could lead to elevated drug prices, diminished innovation, or anticompetitive conduct.

The COVID-19 pandemic has also increased pressure on healthcare budgets, and various stakeholders have raised questions about drug pricing, drug supply chain resilience, and other issues.

The public consultation includes questions such as:

- "In pharmaceutical merger review, how should authorities consider the risks or effects of conduct such as price setting practices, reverse payments, and other ways in which pharmaceutical companies respond to or rely on regulatory processes?"

- "What is the full range of a pharmaceutical merger's effects on innovation? What challenges arise when mergers involve proprietary drug discovery and manufacturing platforms?"

The Task Force will receive and make available all submissions through the FTC's portal on www.regulations.gov. The public consultation is open until 25 June 2021. Contributions will serve to inform a public workshop envisaged for later in 2021.

State Aid

European Commission receives Recovery and Resilience Plans from 18 Member States (see here)

As of 26 May 2021, the Commission has received Recovery and Resilience Plans from an additional 4 Member States, for a total of 18 Member States (*see also Jones Day COVID-19 Update No. 46 of 5 May 2021)*.

These Member State plans set out the reforms and public investment projects foreseen for implementation with the support of the Recovery and Resilience Facility (RRF), the key component of NextGenerationEU, the EU's plan for rebounding from the COVID-19 crisis. The RRF will provide up to €672.5 billion to finance reforms and investments (i.e., grants totaling €312.5

	billion and €360 billion in loans). The latest Member State plans request the following total amounts under the RRF: – Croatia (€6.4 billion) – Cyprus (€1.2 billion) – Hungary (€7.2 billion) – Lithuania (€2.2 billion) 14 Member State plans had already requested the following total amounts under the RRF: Austria (€4.5 billion); Belgium (€5.9 billion); Denmark (€1.6 billion); France (€40.9 billion); Germany (€27.9 billion); Greece (€30.5 billion); Italy (€191.5 billion); Latvia (€1.8 billion); Luxembourg (€93 million); Poland (€23.9 billion); Portugal (€16.6 billion), Slovakia (€6.6 billion); Slovenia (€2.5 billion); and Spain (€72 billion). Commission assessment of plans. The Commission will assess the Member State plans within the next two months. The RRF guidelines, notably, make clear that the investment projects included in Member State recovery plans must comply with State aid rules. The Commission published practical guidance for swift treatment of projects under State aid rules, as well as a number of sector-specific templates to help Member States design and prepare the State aid elements of their recovery plans (*Jones Day Commentary, "EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules," March 2021, see here*). In assessing the Member State plans, the Commission will also, in particular, determine whether the plans dedicate at least 37% of expenditure to investments and reforms that pursue climate objectives and 20% to the digital transition. Based on the Commission's proposals, the Council will then have four weeks to approve the Member State plans. The Commission will continue to closely engage with the remaining Member States to deliver robust national recovery plans.
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: • €500 million Greek scheme to support food service companies affected by the coronavirus outbreak • €100 million French aid scheme to mitigate the economic consequences of the cessation of glyphosate use, amplified by the pandemic • €12.5 million Belgian scheme for the passenger transport sector in Wallonia affected by the coronavirus outbreak • €44 million Estonian scheme to support companies active in the tourism and retail sectors in the context of the coronavirus outbreak • €6 million Latvian scheme to support companies in the arts,

entertainment and recreation sectors in the context of the coronavirus outbreak

- €12.835 million Italian aid measure to compensate Alitalia for further damages suffered due to the coronavirus outbreak
- €793 million Greek subsidized loan scheme to support micro, small and medium-sized companies affected by the coronavirus outbreak
- €63.2 million modification of Hungarian scheme to support self-employed individuals in the context of the coronavirus outbreak
- €27.8 million Belgian scheme for companies and self-employed workers in Wallonia indirectly affected by closure decisions in the context of the coronavirus outbreak
- €255 million Belgian scheme to support companies and self-employed people in Wallonia who make a significant part of their turnover with companies affected by closure decisions due to the coronavirus outbreak
- €20 million Italian scheme to support companies managing passenger port terminals in the context of the coronavirus outbreak
- €820,000 Slovenian scheme to support sheep and goat breeders affected by the coronavirus outbreak
- €392,000 Belgian support to compensate Waterloo 1815 Memorial concession holder for damage caused by the coronavirus outbreak
- €90 million Dutch scheme to support SMEs in context of the coronavirus outbreak
- €46 million Romanian scheme to support the activity of cattle breeders affected by the coronavirus outbreak
- Modification of existing German scheme to support rail freight operators and mitigate effects of the coronavirus outbreak on the sector. The modification includes an increase in budget for the year 2021, from €350 million to €567 million
- €5.2 million Danish scheme to support local newspapers affected by the coronavirus outbreak
- €6.8 million Lithuanian scheme to support pig and poultry sectors affected by the coronavirus outbreak
- €8 million Latvian aid measure to support sports centers in the context of the coronavirus outbreak
- €20 million Latvian measure to support shopping centers in context of the coronavirus outbreak

TRADE / EXPORT CONTROLS

European Parliament and WTO Director-General debate	On 20 May 2021, the European Parliament's plenary session debated the proposal to the WTO to waive intellectual property rights for COVID-19 vaccines. The WTO's recently-appointed Director-General Dr Ngozi Okonjo-Iweala joined the session. The proposal for such waiver was initially

proposed waiver for COVID-19 vaccine patents (see here and here)	submitted to the WTO by South Africa and India in Oct. 2020 (see here). Responding to questions from the Parliament's Committee on International Trade ("INTA") on the measures needed to accelerate equitable access to vaccines, Dr Okonjo-Iweala expressed her view that an intellectual property rights ("IPR") waiver for vaccines would not suffice. Dr Okonjo-Iweala advocated further measures, including reducing export restrictions and reinforcing supply chains for vaccines, working with manufacturers to expand production, including in emerging countries with idle capacity such as Indonesia, South Africa, Thailand or Bangladesh, and transferring the necessary technology and expertise to produce the complex vaccines. Earlier, on 19 May 2021, INTA's debate on ensuring global access to shots reflected a lack of consensus among MEPs on a temporary waiver of IPR for COVID-19 vaccines. Some MEPs called on the Commission to support a waiver of IPR for COVID-19 vaccines as essential to speeding up the rollout of shots to low and middle income countries. However, many MEPs argued such waiver would not accelerate the provision of vaccines and would harm innovation. Rather, they advocated for the Commission to push for voluntary licensing alongside knowledge- and technology-sharing, as well as ramping up production facilities in Africa and other regions. During the 7-10 June plenary session, the Parliament will vote on a Resolution on Meeting the Global Covid-19 challenge: effects of waiver of the WTO TRIPS agreement on Covid-19 vaccines, treatment, equipment and increasing production and manufacturing capacity in developing countries.
European Commission and Italy co-host first G20 Global Health Summit to address COVID-19 crisis and future pandemics (see here)	On 21 May 2021, the European Commission and Italy, as chair of the G20, co-hosted the first G20 Global Health Summit. The G20 leaders endorsed a series of actions to accelerate the end of the COVID-19 crisis and to better prepare for future pandemics. The EU, in particular, plans to set forth a proposal before the WTO focusing on: – clarifying and facilitating the use of compulsory licenses in crisis situations such as this pandemic; – supporting the expansion of production; – trade facilitation and limiting export restrictions. As stated by President of the European Commission Ursula von der Leyen: "*This very first G20 summit on health marks the beginning of a new chapter in global health policy. World leaders strongly committed to multilateralism and global cooperation in health. This means, no export bans, keeping global supply chains open and working to extend production capacity everywhere. If we live up to these principles, the world* President of the European Commission Ursula von der Leyen *will be better prepared for pandemics*." *For further details on the G20 Global Health Summit, please see below Section on Medicines*.

Latest Eurostat data – A rise in exports, imports, and intra-euro area trade since March 2020 (see here)	On 18 May 2021, the Commission published the latest Eurostat data on international trade. The first estimate for euro area* exports of goods to the rest of the world in March 2021 was €212.1 billion, an increase of 8.9% compared with March 2020 (€194.7 billion), which reflected the impact of COVID-19 containment measures widely imposed by the Member States. Imports from the rest of the world stood at €196.3 billion in March 2021, a rise of 19.2% compared with March 2020 (€164.7 billion). As a result, the euro area recorded a €15.8 billion surplus in trade in goods with the rest of the world in March 2021, compared with +€29.9 billion in March 2020. Intra-euro area trade, furthermore, rose to €199.0 billion in March 2021, up by 27.5% compared with March 2020. For extra-EU** exports, in March 2021, compared with March 2020, all Member States registered an increase, except Cyprus (-36.3%), Ireland (-20.0%), Lithuania (-6.3%) and Romania (-3.2%). The highest increases were registered in Greece (+54.0%) and Slovakia (+49.8%). Extra-EU imports reflect a similar trend. In March 2021 compared to March 2020, all Member States registered an increase in extra-EU imports, except Cyprus (-36.5%) and Malta (-11.9%). The highest increases occurred in Croatia (+66.3%), Bulgaria and Czechia (both +45.0%). * *The euro area (EA19) includes Belgium, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Austria, Portugal, Slovenia, Slovakia and Finland.* ** *The EU (European Union) includes Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland and Sweden.*

MEDICINES AND MEDICAL DEVICES

European Commission and Italy co-host first G20 Global Health Summit to address COVID-19 crisis and future pandemics (see here)	On 21 May 2021, the European Commission and Italy, as chair of the G20, co-hosted the first G20 Global Health Summit. *For further details on the G20 Global Health Summit, please see above Section on Trade / Export Controls*. The G20 leaders endorsed a series of actions to accelerate the end of the COVID-19 crisis and to better prepare for future pandemics, embodied in the Rome Declaration. The principles agreed under this Declaration seek to strengthen multilateral cooperation and joint action to prevent future global health crises, and present a joint commitment to build a healthier, safer, fairer and more sustainable world. Specifically regarding healthcare, the G20 leaders committed, *inter alia*, to: – Support and further develop existing multilateral health architecture for preparedness, prevention, detection and response having the World Health Organization ("WHO") as leading agency; – Foster the establishment of public and private synergies for

	developing and deploying COVID-19 vaccines, therapeutics, diagnostics and personal protective equipment, as well as enable affordable and timely global access to safe and effective prevention, detection and response tools including non-pharmaceutical measures, clean water, sanitation and hygiene; – Diversify production capacity, address bottlenecks in production, promote data sharing and the use of voluntary licensing agreements of intellectual property, know-how transfers and patent pooling on mutually-agreed terms, as well as support low/middle-income countries to build regional manufacturing capacities and foster digital transformation of their health systems; – Invest in multilateral cooperation in research, development, and innovation and provide adequate funding for such activities; – Invest in resourcing, training and staffing of diagnostic public and animal health laboratories, including genomic sequencing capacity.
European Parliament and Council reach agreement on European Commission proposal on Digital COVID-19 Certificate (see here)	On 20 May 2021, the European Parliament and the Council reached a provisional agreement on the Commission's proposal for a Regulation on the Digital COVID-19 Certificate (previously called the Digital Green Certificate), which is to serve as proof that a person: (i) is vaccinated against COVID-19; (ii) received a negative test result; or (iii) recovered from COVID-19 (see *Jones Day COVID-19 Update No. 41 of 24 March 2021*). The Commission also verified the functioning of the so-called EU Gateway, which allows verification of the Certificates across the Union. In May 2021, successful pilot tests took place with certain Member States. The Gateway is set to go live in June 2021. The European Parliament and Council must now formally adopt the Commission's proposal. The Regulation is expected to become applicable as of 1 July 2021, with a phasing-in period of six weeks for the issuance of certificates for those Member States needing additional time. *For further details on the Digital COVID-19 Certificate, please see below Section on Cybersecurity*.
European Commission enters into a third agreement with Pfizer/BioNTech for purchase of additional COVID-19 vaccine doses (see here)	On 20 May 2021, the Commission entered into an additional agreement with BioNTech and Pfizer for the purchase of the COVID-19 vaccine Comirnaty on behalf of all EU Member States. The agreement provides for the purchase of 900 million doses of vaccines for the years 2021 to 2023 and envisages the option to purchase an additional 900 million doses. Furthermore, the agreement requires the vaccine manufacturing to take place in the EU, and essential components must also be sourced from the Union.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Parliament and Council reach	On 20 May 2021, the European Parliament and the Council reached a provisional agreement on the Commission's proposal for a Regulation on the Digital COVID-19 Certificate (previously called the Digital Green Certificate),

agreement on European Commission proposal on Digital COVID-19 Certificate (see here)	which is to serve as proof that a person: (i) is vaccinated against COVID-19; (ii) received a negative test result; or (iii) recovered from COVID-19 (see *Jones Day COVID-19 Update No. 41 of 24 March 2021*). As concerns data protection, President of the European Commission Ursula von der Leyen emphasized the Commission's view that the EU Digital COVID Certificate "*fully respects citizens' fundamental rights, including protection of personal data*." To recall, 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. The Certificate contains only necessary key information such as name, date of birth, date of issuance, relevant information about vaccine/test/recovery and a unique identifier. Such information cannot be retained by visited countries. For verification purposes, only the validity and authenticity of the Certificate is checked by verifying who issued and signed it. All health data remains with the Member State that issued a Certificate. The EU Gateway, planned for launch in June 2021, will enable verification of all certificate signatures across the EU. The personal data encoded in the certificate will not pass through the Gateway, as this is unnecessary for verifying the digital signature. *For further details on the Digital COVID-19 Certificate, please see above Section on Medicines*.

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