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

- Fit for Future Platform pursues simplification of EU law, including Opinion on State aid
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- Fit for Future Platform pursues simplification of EU law, including Opinion on the European Customs Union

Medicines and Medical Devices

- Publication of Regulation on reinforced role for EMA crisis preparedness and management for medicinal products and medicinal devices
- Clinical Trials Regulation enters into application

Cybersecurity, Privacy & Data Protection

- European Commission publishes (i) Communication Establishing a European Declaration on Digital rights and principles for the Digital Decade and (ii) Draft European Declaration on Digital Rights and Principles for the Digital Decade

COMPETITION & STATE AID	
State Aid	
Fit for Future Platform pursues simplification of EU law, including Opinion on State aid (see here and here)	On 28 January 2022, the Fit for Future Platform, a high-level expert group to assist the European Commission with simplifying existing EU laws and reducing administrative burdens for businesses and citizens, held its fourth plenary meeting. The meeting was chaired by Maroš Šefčovič, Vice-President for Interinstitutional Relations and Foresight and Chairman of the Fit for Future Platform, who stated: "*Simplification has become more important than ever, as we seek to kick-start Europe's economy, hit by the pandemic…. We must ensure that EU laws provide the intended benefits for the economy and society, while simplifying existing legislation, reducing burden wherever possible and staying forward-looking*." To recall, the Platform's 2021 work programme targeted a range of sectors, such as State aid, customs, and health, as well as finance, the environment, procurement, transport, and the internal market. The Platform issued 14 Opinions in these areas, which will contribute to the Commission's ongoing work to simplify existing EU laws. The Opinion on State aid focused on revision of the Agricultural Block Exemption Regulation (ABER) and the 2014 Guidelines on State aid to the Agricultural and Forestry Sectors and in Rural Areas. These current rules are applicable until 31 December 2022. According to the Platform's Opinion, the current rules have worked well, but there is scope for procedural simplification and for increasing the effectiveness of certain aid measures (e.g. certain eligibility conditions now deemed as obsolete, causing interpretation difficulties, or unnecessarily burdensome). Suggested actions include to improve the rules' consistency with green policies. In this respect, procedures under the ABER should be simplified in order to facilitate Member States' investments, such as under the RRF* (Recovery and Resilience Facility), and to enable easier disbursement under the RRF. At the plenary meeting, the Platform also announced its 2022 work programme (see here). The issues cover, in particular, the overarching topic of strengthening the interconnectivity between the green and digital transitions, including through simplification. Stakeholders are invited to comment on topics under the work programme until 30 April 2022, for consideration by the Platform in preparing its 2022 opinions. * *To recall, the RRF is 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).* *For further details on the Platform, see below Section on Trade/Export Controls.*
European Commission approves new and	Since the onset of the coronavirus outbreak, the Commission has adopted a significant number of State aid measures under Article 107(2)b, Article

amended Member State measures to support the economy (see here and here)	107(3)b and under the Temporary Framework. The Temporary Framework, adopted in March 2020, is currently applicable until 30 June 2022. • €3.8 billion Italian scheme under Recovery and Resilience Facility to support deployment of Gigabit networks. • Czech scheme, including €8.3 million budget increase, to support travel agencies affected by the coronavirus pandemic. • Renewal of an Italian scheme to support companies active in agriculture, forestry, fishery, aquaculture and related sectors, including €500 million budget increase, in the context of the coronavirus pandemic. • €88 million Polish scheme to support pig sows producers in the context of the coronavirus pandemic. • €10 million Italian scheme to support companies recycling aluminium in the context of the coronavirus pandemic. • €1.7 billion German measure to recapitalise Flughafen Berlin Brandenburg in the context of the coronavirus pandemic.

TRADE / EXPORT CONTROLS

Fit for Future Platform pursues simplification of EU law, including Opinion on the European Customs Union (see here and here)	On 28 January 2022, the Fit for Future Platform, a high-level expert group to assist the European Commission with simplifying existing EU laws and reducing administrative burdens for businesses and citizens, held its fourth plenary meeting, chaired by Maroš Šefčovič, Vice-President for Interinstitutional Relations and Foresight and Chairman of the Fit for Future Platform. To recall, the Platform's 2021 work programme targeted a range of sectors, such as customs, State aid, and health, as well as finance, the environment, procurement, transport, and the internal market. The Platform issued 14 Opinions in these areas, which will contribute to the Commission's ongoing work to simplify existing EU laws. The Opinion on the Union Customs Code (UCC) focused on the ongoing evaluation of the UCC's implementation. Applied since 2016, the UCC is the main EU legislative framework for customs processes and IT systems, serving as a key element of efforts to modernize EU customs. It aims for greater simplicity and uniformity in applying customs rules by streamlining provisions and aims to provide a fully electronic environment by 2025 for the completion of customs formalities by customs authorities and economic operators. The Platform's Opinion's suggested actions include exploring possibilities for flexible implementation of rules in case of crisis. The Opinion notes that during the COVID-19 pandemic, the lack of flexibility of customs rules impeded a swift and uniform response to the crisis in the area of customs. The Opinion indicates that allowing for exceptions, based on *force majeure*, should be considered in the legislation in anticipation of future crises. For example, temporary storage for non-EU goods is ordinarily limited to 90 days. In the Opinion's view, in certain very justified cases (e.g. due to emergency or business need), this time-limit should be allowed to be

extended by customs at the request of the operator.

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For further details on the Platform, see above Section on State aid.

MEDICINES AND MEDICAL DEVICES

Publication of Regulation on reinforced role for EMA crisis preparedness and management for medicinal products and medicinal devices (see here and here)

On 31 January 2022, Regulation (EU) 2022/123 of the European Parliament and of the Council on a reinforced role for the European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices (Regulation) was published in the EU Official Journal (*see also Jones Day COVID-19 Update No. 74 of 24 January 2022*).

The COVID-19 pandemic revealed the urgent need to reinforce the European Union's role towards ensuring cooperation and coordination in effectively managing the availability of medicinal products, medical devices, *in-vitro* diagnostic medical devices and accessories, as well as in developing swift, harmonized medical countermeasures to address public health threats.

As stated by the EMA, the Regulation "… *puts structures and processes established by EMA during the COVID-19 pandemic on a permanent footing, while entrusting several new tasks to the Agency*." The Regulation notably:

- Expands the EMA's mandate to act in case of a cross-border major event (i.e., a public emergency likely to pose a serious risk to public health in relation to medicinal products in more than one Member State). In the context of such event:
  - The Medicine Shortages Steering Group (MSSG) and the Medical Device Shortages Steering Group (MDSSG), established by the Regulation as groups under the EMA, will monitor supply and demand for critical medicinal products and medical devices; mitigate the risk of shortages of critical medicines and medical devices; and coordinate clinical trials.
  - The MSSG will also adopt recommendations on appropriate coordinated actions with regard to the quality, safety and efficacy of medicinal products having the potential to address public health emergencies.
- Imposes information obligations on marketing authorization holders, manufacturers of medical devices, authorized representatives, importers, distributors and Notified Bodies in relation to critical medicinal products and medical devices. Information on critical medicines, in this regard, should be communicated through the newly created European shortages monitoring platform.

The Regulation will apply from 1 March 2022, with the exception of the provisions on monitoring and mitigating shortages of critical medical devices, which will apply from 2 February 2023.

Clinical Trials Regulation enters into application (see here and here)	On 31 January 2022, Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use ("Clinical Trials Regulation", CTR) became fully applicable. The CTR seeks to foster clinical research in the EU and to ease the authorization procedure for clinical trials to be carried out in more than one EU Member State. The COVID-19 pandemic highlighted the urgent need for such coordinated assessments and conclusions on multinational clinical trials. The CTR, in particular, replaces the mechanism of providing multiple submissions of largely identical information, which was applicable under the earlier Directive 2001/20/EC ("Clinical Trials Directive", CTD). Under the CTR, the submission of one clinical trials application dossier is provided to all the Member States concerned through a single submission portal, the "EU Portal." All data and information submitted to the EU Portal will be stored in the "EU Database," which, together with the EU Portal, form the Clinical Trials Information System (CTIS). The technical difficulties of developing the CTIS was one of the main reasons for the delay in application of the CTR. Once the CTIS was declared fully functional, the CTR's date of application was then set (see here and *Jones Day COVID-19 Update No. 58 of 2 August 2021*). As stated by European Commissioner for Health and Food Safety, Stella Kyriakides, "*the Clinical Trials Regulation marks an important and positive step for European patients and brings us closer to a stronger European health Union*." The CTR applies to all clinical trials application submitted from 31 January 2022. It will also apply from 31 January 2025 to clinical trials whose requests for authorization were submitted before 31 January 2022 and where the applicant requested to authorize the study in accordance with the provisions of the CTD. The Implementing Regulation 2022/20 laying down rules for the application of the CTR also entered into application on 31 January 2022 (see here).

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission publishes (i) Communication Establishing a European Declaration on Digital rights and principles for the Digital Decade and (ii) Draft European Declaration on Digital Rights and Principles for the Digital Decade (see here)	On 26 January 2022, the Commission published a (i) Communication Establishing a European Declaration on Digital rights and principles for the Digital Decade and (ii) Draft European Declaration on Digital Rights and Principles for the Digital Decade: (i) The Communication recognizes the COVID-19 pandemic's acceleration of the pace of digital transformation in society and the economy. However, the upsurge of new digital technologies and data has come with a significant rise in undesirable risks, including with regard to privacy and personal data breaches, cybercrime and cyberattacks. The Communication accompanies the proposed draft for a European Declaration on Digital Rights and Principles (see below), which responds, in particular, to the European Parliament's calls to ensure that the European Union's approach to digital transformation is in line with fundamental rights such as data protection and non-discrimination. The Communication seeks to outline the way forward in monitoring measures

and actions taken to put the anticipated Declaration into practice. Such monitoring is in the interests of transparency and supporting policy guidance in possible future legislation in the areas covered by the Declaration's principles.

(ii) The Draft Declaration aims to ensure that EU values and the rights and freedoms of individuals under EU law are respected and reinforced both offline and online. It is intended to serve as a reference point for both public and private actors when developing and deploying new technology and to guide policy makers when defining the European digital transformation.

The Draft Declaration sets out six digital principles: (i) putting people at the center of the digital transformation, (ii) solidarity and inclusion, (iii) freedom of choice, (iv) participation in the digital public space, (v) safety, security and empowerment, and (vi) sustainability.

The Draft Declaration also includes accompanying commitments that aim to complement the legal rights of European citizens in the online environment, such as:

- Ensuring that all Europeans are offered an accessible, secure and trusted digital identity that gives access to a broad range of online services;
- Facilitating and supporting seamless, secure and interoperable access across the European Union to digital health and care services, including health records, designed to meet people's needs;
- Providing the possibility to easily move personal data between different digital services
- Ensuring transparency about the use of algorithms and artificial intelligence, and that people are empowered and informed when interacting with these;
- Ensuring suitable datasets at the basis of algorithmic systems to avoid unlawful discrimination and enable human supervision of outcomes affecting people; and
- Protecting the interests of people, businesses and public institutions against cybercrime, including data breaches and cyberattacks. This includes protecting digital identity from identity theft or manipulation.

The Draft Declaration will now be discussed by the Parliament and Council. Once endorsed, the Declaration will take the form of a joint declaration signed by the Parliament, the Council and the Commission, which are expected to endorse the Draft Declaration by summer 2022.

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