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

- European Commission approves new and amended Member State measures to support the economy
- European Commission approves further schemes under State aid Temporary Crisis Framework in context of Russia's invasion of Ukraine

Trade / Export Controls

- European Commission creates new EU Energy Platform Task Force to secure alternative supplies
- Commission welcomes provisional agreement on proposed Regulation establishing EU Single Window Environment for Customs

Medicines and Medical Devices

- In Vitro Diagnostic Medical Devices Regulation enters into application
- Commission publishes Independent Expert Report: COVID-19 Therapeutics Innovation Booster

Cybersecurity, Privacy & Data Protection

- European Commission publishes Q&A on proposed Digital Services Act
- Commission welcomes provisional agreement on proposed NIS2 Directive
- EDPB publishes 2021 Annual Report on Enhancing the depth and breadth of Data Protection
- ENISA publishes report on pseudonymization techniques for health data

COMPETITION & STATE AID	
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. • €223 million Flemish scheme to support companies and public entities in the context of the coronavirus pandemic and Brexit • €45.4 million Croatian scheme to support the civil aviation sector affected by the coronavirus pandemic • €9.5 million Italian scheme to preserve employment levels in the context of the coronavirus pandemic • €677 million Italian investment support scheme towards a sustainable recovery in the context of the coronavirus pandemic • Re-introduction of Swedish scheme, including €2.55 million budget increase, to support air traffic control services affected by the coronavirus pandemic • €300 million Romanian scheme to support agri-food entities in the context of the coronavirus pandemic • €33.4 million Latvian measure to recapitalize airBaltic in the context of the coronavirus pandemic • €11.6 million Latvian aid measure to compensate airBaltic for the damage suffered due to the coronavirus pandemic • €8 million Portuguese scheme to support companies in Azores in the context of the coronavirus pandemic • €890,000 Cypriot scheme to support cheesemakers in the context of the coronavirus pandemic • Re-introduction of a Slovenian scheme, including €150 million budget increase, to support companies affected by the coronavirus pandemic and the development of coronavirus-relevant products
European Commission approves further schemes under State aid Temporary Crisis Framework in context of Russia's invasion of Ukraine (see	In the second half of May 2022, the Commission approved additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine. These are among the initial schemes approved under this Crisis Framework, adopted by the Commission on 23 March 2022, which sets out the criteria for Member States to support businesses in the context of Russia's invasion of Ukraine and its serious disruption to the EU economy (see *Jones Day COVID-19 Update No. 80 of 25 March 2022*).

here)	To recall, in adopting this Crisis Framework, the Commission noted that the conflict had significantly impacted the energy market, and steep rises in energy prices had affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The conflict also disrupted supply chains for both EU imports from Ukraine (in particular, cereals and vegetable oils) and EU exports to Ukraine. The latest schemes under the Crisis Framework include: – €500 million Luxembourgish loan guarantee scheme to provide liquidity support to companies of all sizes and sectors active in Luxembourg, with the exception of the financial sector, in the context of Russia's invasion of Ukraine – €16 million Finnish scheme to support farmers in context of Russia's invasion of Ukraine – €30 million Maltese scheme to support the importation, manufacturing and wholesale of grains in context of Russia's invasion of Ukraine – €1.2 billion Italian scheme to support agricultural, forestry, fishery and aquaculture sectors in context of Russia's invasion of Ukraine – €25 million French aid scheme to support companies in the fishing sector in the context of Russia's invasion of Ukraine Notably, the Crisis Framework complements the various possibilities for Member States to design measures in line with existing EU State aid rules. For instance, State aid measures under the Crisis Framework may be cumulated with aid granted under the COVID-19 Temporary Framework (*see Jones Day COVID-19 Update No. 68 of 22 November 2021*), provided that their respective cumulation rules are respected. The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2022. During its period of application, the Commission will keep the Framework under review in light of developments regarding the energy markets, other input markets, and the general economic situation. Prior to the Crisis Framework's end date, and in view of maintaining legal certainty, the Commission will assess whether it should be prolonged.

TRADE / EXPORT CONTROLS

European Commission creates new EU Energy Platform Task Force to secure alternative supplies (**see here**)	On 25 May 2022, the Commission announced the new EU Energy Platform Task Force to support the EU Energy Platform (*see also Jones Day COVID-19 Update No. 82 of 15 April 2022*) and implementation of the REPowerEU Plan's goal of supply diversification and making Europe independent from Russian fossil fuels well before 2030.* To recall, the EU Energy Platform is a voluntary coordination mechanism to secure the supply of gas, LNG (Liquefied Natural Gas), and hydrogen. As stated in the REPowerEU Plan, adopted on 18 May 2022 (see here), the Commission seeks to develop a "joint purchasing mechanism" to negotiate and contract gas purchases on behalf of participating Member States. The Commission describes such joint purchasing mechanism as replicating the ambition of the common COVID vaccine purchasing program. The Task Force, established within the Directorate-General for Energy, will

	tackle objectives set out in the REPowerEU Plan. In particular, the Task Force will work towards demand aggregation, coordination of capacity and negotiation of energy supplies, as well as providing support for the Regional Task Forces of Member States and neighboring countries. The Task Force will also manage outreach to international partners. The Task Force commenced work on 1 June 2022. * *Following Russia's invasion of Ukraine, European energy companies notably face unprecedented uncertainty, and the potential reduction or cessation of Russian gas imports would invariably impact all market segments in Continental Europe. For a discussion on such impact on European gas markets and potential legal arguments in response to continued contractual performance if imports are reduced or stopped, see the Jones Day White Paper on The War in Ukraine: Downstream Ripple Effects on the European Gas Market, May 2022.*
Commission welcomes provisional agreement on proposed Regulation establishing EU Single Window Environment for Customs (see here and here)	On 19 May 2022, the Commission welcomed the provisional agreement of the Council and the European Parliament on the proposed Regulation establishing the EU Single Window Environment for Customs to streamline digital customs cooperation between customs and partner competent authorities. The aim is to make international trade easier, shorten customs clearance times and lighten administrative burdens for traders, as well as reduce the risk of fraud. To recall, this initiative is part of the Commission's efforts to improve and simplify the management of EU customs and to reinforce responsiveness to crises like the COVID-19 pandemic. The Commission further notes that the EU's unprecedented sanctions against Russia have highlighted the importance of agile and robust customs and non-customs processes. Most notably, the Single Window will enable businesses to complete all border formalities in one electronic step in an individual Member State. This is expected to lead to faster clearance, for example, of essential medical products, including expedited verification that goods comply with EU requirements and prevention against the entry of counterfeit or unsafe medical goods. The provisional agreement between the co-legislators also strengthens the Commission's original proposal, recognizing in particular the non-fiscal responsibilities of customs authorities. The Single Window is amongst the steps taken towards fulfilling the EU's ambitious legislative reform program to prepare the Customs Union for challenges of the future. The Commission will set forth a package of proposals to modernize the Customs Union by end-2022, following recent recommendations for a more modern and efficient Customs Union of the EU's Wise Persons' Group on the future of Customs (*see also Jones Day COVID-19 Update No. 81 of 5 April 2022*). Following its formal adoption by the European Parliament and the Council, the Single Window's intergovernmental component will come into effect by 2025, with the business-to-government scheme becoming accessible at a later stage.

MEDICINES AND MEDICAL DEVICES

In Vitro Diagnostic Medical Devices Regulation enters into application (see here)

On 26 May 2022, the In Vitro Diagnostic Medical Devices Regulation ("IVDR")* became applicable.

The IVDR lays down rules concerning the "placing on the market", "making available on the market", or "putting into service" in vitro diagnostic medical devices for human use ("IVDs") and accessories for IVDs. IVDs are medical devices intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, for the purpose of providing information on a person's health (e.g., COVID-19 test, self-tests for pregnancy, as well as tests performed in clinical laboratories).

The IVDR replaces the In Vitro Diagnostic Medical Devices Directive** ("Directive") in view of substantial technological and scientific progress over the last 20 years.

In particular, the IVDR:

- Extends the scope of in vitro diagnostic medical devices that will be under the control of notified bodies (i.e. independent conformity assessment bodies). The IVDR will cover some 80% of in vitro diagnostic medical devices, up from about 8% of all in vitro diagnostics on the market under the Directive. For example, the IVDR applies to companion diagnostics, i.e., devices essential to the safe and effective use of a corresponding medicinal product to identify patients most likely to benefit from, or to be at increased risk of serious adverse reactions as a result of treatment with that corresponding medicinal product;

- Introduces a new risk-based device classification system, ranging from class A (lowest risk) to class D (highest risk). IVD classification is determined by its intended purpose and takes into consideration the risk to the individual and the risk to public health;

- Increases the requirements for clinical evidence and conformity assessment, with more detailed and stricter rules on the evaluation of device performance, greater involvement of notified bodies, and stricter criteria for designating notified bodies;

- Strengthens transparency and information for patients by making information public in the European database of medical devices (EUDAMED);

- Enhances traceability by introducing a unique device identifier (UDI) for IVDs; and

- Enhances vigilance and market surveillance, such that manufacturers must collect data about the performance of devices once available on the market, and EU countries will closely coordinate their vigilance and market surveillance activities.

The IVDR is now immediately applicable to:

  - New devices placed on the EU market from 26 May 2022, regardless of their risk class; and

- Lowest-risk devices (class A non-sterile), such as laboratory instruments.

Additionally, the IVDR's transitional period (which began on 25 May 2017 when the IVDR came into force) was amended under Regulation (EU) 2022/112 to allow for the IVDR's progressive roll-out with the length of the transition periods depending on the risk class of the device. The amended transitional period responded to the COVID-19 crisis, which diverted resources away from meeting the substantial changes introduced by the IVDR in time for the date of application on 26 May 2022:

- Certain devices with valid certificates issued under the Directive may continue to be placed on the market until 26 May 2024 and made available until 26 May 2025.

- Additional transitional periods apply to IVDs that must undergo a conformity assessment involving notified bodies for the first time under the IVDR, differentiating between risk classes:

  - for class D (high risk devices), the transition period runs until May 2025,
  - for class C devices, until May 2026
  - for class B and A sterile (lower risk devices), until May 2027.

On 25 May 2022, the Commission also published a Q&A providing further information on the IVDR (see here).

** Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.*

*** Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.*

Commission publishes Independent Expert Report: COVID-19 Therapeutics Innovation Booster (see here)

On 23 May 2022, the Commission released the Independent Expert Report of the COVID-19 therapeutics sub-group: COVID-19 Therapeutics Innovation Booster ("Report").

The Report aims to facilitate the identification of promising research projects and technologies, their stages of development, as well as to provide guidance to researchers and innovators on optimally focusing investment in order to accelerate innovation.

The Report is a key action of the EU Strategy on COVID-19 Therapeutics (*See Jones Day COVID-19 Update No. 47 of 12 May 2021).* To recall, this EU Strategy aims to build a broad portfolio of COVID-19 therapeutics. It covers the full lifecycle of medicines from research, development, selection of promising candidates, fast regulatory approval, manufacturing and deployment to final use.

In particular, the Report:

- Identifies the need to collect high quality "real world" data to inform public health policies on treatments management and vaccinations. Collaboration is essential to accumulate data and to generate evidence that can be used for decision-making and to avoid duplication;

	• Recognizes the need to further explore the uncertainties surrounding "long COVID", including better classification of the syndrome, deeper knowledge of the pathogenesis of the different conditions, further exploration of whether long COVID has similarities to other post-infectious syndromes are needed, and defining predictive factors for the occurrence of the different forms of long COVID; • Suggests recommendations for clinical trials for potential future pandemics, such as creating structures and partnerships to facilitate prioritization of clinical research, simplifying clinical trial delivery, developing digital testing models, and establishing procedures for data collection and sharing; • Lists horizon scanning for the most promising and credible medicinal products to avoid duplication, including horizon scanning for potential medicinal products that are in different clinical phases of development, as well as clinical trial registers; and • Emphasizes the value of creating a Trans-European Platform for cross validation of promising compounds, creating a network of independent laboratories in Member States that specialize in preclinical drug development, testing, and toxicity verification. Furthermore, the Report lists seven selection criteria for the most promising and credible medicinal products, including the soundness of the scientific approach and technology used, the stage of development, the suitability of the product for the particular healthcare setting, and the intention to engage at an early stage with EMA/HTA (Health Technical Assessment) bodies to obtain scientific advice. The Therapeutic Innovation Booster will contribute to the Health Emergency Preparedness and Response Authority's (HERA) activities, and in particular, HERA's planned interactive mapping platform for promising therapeutics.
Commissioners Kyriakides and Urpilainen issue statement announcing launch of work on a new EU Global Health Strategy (see here)	On 19 May 2022, at the G7 Development and Health Ministerial, Commissioner for Health and Food Safety, Stella Kyriakides, and Commissioner for International Partnerships, Jutta Urpilainen, issued a statement announcing the launch of work on a new EU Global Health Strategy. The statement communicates that the COVID-19 pandemic has demonstrated the intolerable human cost and heavy economic impact of the weakness of our global health architecture. The pandemic also reversed decades of progress in global health and deepened inequalities. Accordingly, lessons must be learned, and Sustainable Development Goals must be put back on track. Based on the new Global Health Strategy, the Commissioners stated: *"We must improve health systems so that they can more effectively prevent and respond to global health threats as well as tackle all infectious and non-communicable diseases. We must address inequalities and advance towards universal health coverage. We must have strong strategic health partnerships with other regions in the world. We must reinforce local health manufacturing capacities, in Africa and beyond."* The Commissioners called on all stakeholders to join in developing and implementing the new EU Global Health Strategy.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission publishes Q&A on proposed Digital Services Act (see here)

On 20 May 2022, the European Commission published a Q&A on the proposed Regulation on a Single Market for Digital Services ("DSA", see here).

The DSA, proposed by the Commission on 15 December 2020, is one of the measures taken as part of the EU Recovery Plan to lead Europe out of the COVID-19 crisis (*see Jones Day COVID-19 Update No. 10 of 29 May 2020*).

The proposed DSA introduces rules and obligations on digital services that act as intermediaries in their role of connecting consumers with goods, services and content (i.e., online marketplaces, internet service providers, cloud services, messaging, social networks). Among other things, the proposed DSA introduces new mechanisms to counter illegal content online, rules to trace sellers on online marketplaces, and crisis response mechanisms in case of serious threat in public health and security emergencies.

The Q&A provides general guidance on the proposed DSA's impact, once adopted, on currently applicable legislation and on users, businesses and Member States. For instance:

- Users will benefit from a safer online experience. Online platforms must comply with mandatory procedures to remove illegal goods, trace their traders, identify their business users, and clarify who is selling the product or offering the service. In addition, users may report illegal content and products easily and effectively, and they will receive more information about advertisements published on online platforms, and may seek compensation from providers of intermediary services for any damage or loss suffered by an infringement of the DSA;

- Businesses will benefit from a modern, clear and transparent framework in view of assuring that rights are respected and obligations are enforced. Compliance costs will also be lowered, since businesses will no longer face 27 different regimes in the EU; and

- Each Member State will need to appoint a national Digital Services Coordinator, responsible for monitoring compliance with the DSA together with the Commission. The Commission will have the same supervisory powers as under current antitrust rules and will be responsible for supervising online platforms with over 45 million users.

The proposed DSA is now subject to formal approval by the Council and the European Parliament. When adopted, the DSA rules will start applying in two steps:

- The DSA will be directly applicable across the EU, 15 months after entry into force, or from 1 January 2024, whichever is later.

- Once designated by the Commission, providers of very large platforms and very large online search engines (to be directly supervised by the Commission) must comply with the DSA at an earlier date, i.e. four months after their designation.

Commission welcomes

On 13 May 2022, the Commission welcomed the provisional agreement of the European Parliament and Council on the proposed Directive on measures for

provisional agreement on proposed NIS2 Directive (see here)	a high common level of cybersecurity across the Union, repealing Directive 2016/1148 ("NIS2 Directive") (see *Jones Day COVID-19 Update No. 84 of 17 May 2022*). To recall, during the COVID-19 pandemic, growing security threats emerged demonstrating the vulnerability of increasingly interdependent societies. The proposed NIS2 Directive thus aims to strengthen the resilience and incident response capacities of public and private entities, competent authorities and the EU as a whole. In particular, the Commission notes that the proposed NIS2 Directive now more broadly covers: • Medium and large entities from more critical sectors (e.g. providers of public electronic communications services, digital services, waste water and waste management, manufacturing of critical products, postal and courier services and certain public administration bodies, both at central and regional level). • The healthcare sector (e.g. including medical device manufacturers, given the increasing security threats that arose during the COVID-19 pandemic). The Commission Vice-President for Promoting our European Way of Life Margaritis Schinas stated: *"By agreeing on these further strengthened rules, we are delivering on our commitment to enhance our cybersecurity standards in the EU. Today, the EU shows its clear determination to champion preparedness and resilience against cyber threats, which target our economies, our democracies and peace".* The proposed NIS2 Directive, which is not yet publicly available, is now subject to approval by the Council and the European Parliament. Once published in the Official Journal, Member States will have 21 months to transpose the Directive into national law.
EDPB publishes 2021 Annual Report on Enhancing the depth and breadth of Data Protection (see here)	On 12 May 2022, the European Data Protection Board ("EDPB") published the 2021 Annual Report on Enhancing the depth and breadth of Data Protection. The EDPB is an independent European body, established by the General Data Protection Regulation (GDPR), which seeks to ensure the consistent application of data protection rules across the European Economic Area (EEA). The Report highlights developments in 2021, such as: • The EDPB's legislative consultation activities, which included a Joint Opinion 04/2021, issued together with the European Data Protection Supervisor (EDPS), on the then-Proposal for a Regulation on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery (EU Digital COVID Certificate) during the COVID-19 pandemic. The Joint Opinion, in particular, considered it essential to ensure that the Proposal would be consistent and not conflict with application of the GDPR, including compliance with the principles of necessity and proportionality; and • Activities carried out by National Supervisory Authorities ("SA"),

	including on issues related to COVID-19. For example, in 2021, the Litigation Chamber of the Belgian SA found no infringement pertaining to the setting up of smart cameras by the controller Westtoer at the Belgian coast to measure the number of visitors during the summer months due to the risks associated with COVID-19. However, the Litigation Chamber reprimanded the controller and ordered to bring certain elements into compliance (such as consent for the use of cookies on Westtoer's website, its register of processing activities, and its privacy policy). The Report also contains the EDPB's Strategy for 2021-2023, which consists of four main pillars: (i) Advancing harmonization and facilitating compliance; (ii) Supporting effective enforcement and efficient cooperation between SAs; (iii) A fundamental rights approach to new technologies; and (iv) The global dimension.
ENISA publishes report on pseudonymization techniques for health data (see here)	On 24 March 2022, the European Union Agency for Cybersecurity ("ENISA") published a report on deploying pseudonymization techniques in the health sector and how pseudonymization can be used in practice to protect health data during processing. There is a recent abundance of new sources of health data occurring as a result of the widespread use of electronic health records, health applications, and wearable devices. The expanding processing of digitized medical data also increases cybersecurity, data protection, and data breach risks. Protecting health-related data is a high priority due to their sensitive nature and their impact on data subjects. Pseudonymization aims at protecting personal data by hiding the identity of individuals in a dataset, such as by replacing one or more personal identifiers with the so-called pseudonyms, and by appropriately protecting the link between the pseudonyms and the initial identifiers. The report summarizes the most common pseudonymization techniques, demonstrates the added value of pseudonymization in the healthcare domain, and highlights the importance of defining the goals and objectives of pseudonymization for each processing operation.

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

Lucie Fournier *(Associate),* ***Cecelia Kye*** *(Consultant), and* ***Justine Naessens*** *(Associate) in the Brussels Office contributed to this Update.*