
# EU EMERGENCY RESPONSE UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

No. 102 | 3 May 2023

This regular alert covers key regulatory developments related to EU emergency responses, including in particular, to COVID-19, Russia's war of aggression on against Ukraine, and cyber threats. It does not purport to provide an exhaustive overview of developments.

*This regular update expands from the previous COVID-19 Key EU Developments – Policy & Regulatory Updates (last issue No. 99).*

## LATEST KEY DEVELOPMENTS

### Competition & State Aid

- European Commission adopts merger simplification package
- European Commission publishes State aid Scoreboard 2022
- European Commission approves French measure to support new €7.4 billion microchips plant
- European Commission approves further schemes under new Temporary Crisis and Transition Framework to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies
- European Commission approves further schemes to compensate for damage due to COVID-19 crisis

### Trade / Export Controls

- European Commission and Council of the European Union announce anti-corruption package
- Council of the European Union expands sanctions against Iran and proposed 11th package of sanctions underway

### Medicines and Medical Devices

- European Commission publishes proposed reform of EU pharmaceutical legislation
- EDPS publishes Annual Report 2022

### Cybersecurity, Privacy & Data Protection

- EDPS publishes Annual Report 2022
- EU Digital Markets Act now applicable

- European Commission designates first set of very large online platforms and search engines under DSA

## COMPETITION & STATE AID

### Competition

**European Commission adopts merger simplification package (see here)**

On 20 April 2023, the Commission adopted a package of three measures in view of further simplifying procedures for reviewing concentrations under the EU Merger Regulation: (1) a revised Merger Implementing Regulation (Implementing Regulation); (2) a Notice on Simplified Procedure (Notice); and (3) a Communication on the transmission of documents (Communication).

In announcing the package, Executive Vice-President and Competition Commissioner Margrethe Vestager stated:

> "*Reducing administrative burden is a Commission-wide priority. The 2023 Merger simplification package adopted today widens the scope of our simplified procedure to review unproblematic mergers. The new rules also make the notification process significantly easier for the parties to the benefit not only of companies and advisors but also of the Commission, which will be able to focus its resources on the most complex cases.*"

The primary changes of the 2023 merger simplification package aimed at streamlining merger review include, among others:

For the simplified procedure:

- Broadening and/or clarifying cases that can be reviewed under the simplified procedure, e.g.:
  - The Notice identifies two new categories of cases that can benefit from simplified treatment. These comprise cases where under all plausible market definitions:
    - The individual or combined upstream market share of the merging parties is below 30% and their combined purchasing share is below 30%; and
    - The individual or combined upstream and downstream market shares of the merging parties are below 50%, the market concentration index (HHI delta) is below 150, and the company with the smallest market share is the same in the upstream and downstream markets.
- Facilitating the review of simplified cases. The Implementing Regulation introduces a new notification form (so-called "tick-the-box" Short Form CO) for simplified cases, which includes primarily multiple-choice questions/tables and streamlined questions on the jurisdictional and substantive assessment of cases.

For the non-simplified procedure:

- The Implementing Regulation reduces and clarifies the information requirements in the notification form for these cases (Form CO, Annex I of Implementing Regulation), such as by:
  - Clarifying information on possibilities for waivers from certain information requirements, which codifies existing practice;

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| | – Eliminating certain previous information requirements concerning "Cooperative Agreements", "Trade between Member States and imports from outside the EEA", and "Trade associations".<br><br>On transmitting documents to the Commission, the new Communication introduces electronic notifications by default, and notably:<br><br>• Following exceptional measures taken due to the COVID-19 pandemic, the Commission has been temporarily accepting, and in fact encouraging, notifications in digital format since May 2020. Based on this experience and to promote the Commission's digital transformation, it is appropriate to establish permanent rules on digital transmissions of documents in the context of EU merger control.<br>• Technical specifications are provided for the signature of documents submitted electronically (where a signature is required). In this respect, documents submitted electronically must be signed using at least one Qualified Electronic Signature (QES) complying with the requirements set out in the eIDAS Regulation (Regulation (EU) No 910/2014).<br>• A fall-back mechanism allows for transmitting documents to the Commission's Directorate General for Competition by post or by hand delivery (e.g., in exceptional circumstances, for example, where transmissions exceed 10 gigabytes in size; or where required electronic delivery or signing is technically not possible).<br><br>Further details on the main changes are provided in an Explanatory Note accompanying the revised rules and Q&A.<br><br>The new rules under the merger simplification package will be applicable as of 1 September 2023. |
| **State Aid** | |
| **European Commission publishes State aid Scoreboard 2022 (see here)** | On 24 April 2023, the Commission released the State aid Scoreboard 2022.* The Scoreboard is the Commission's benchmarking instrument for State aid, launched in July 2001 in view of providing a transparent and publicly accessible source of information on the Commission's State aid control activities and the overall State aid situation in the Member States.<br><br>Timeframe covered. The 2022 Scoreboard is based on State aid expenditure made by Member States in 2021 and provides updates of State aid expenditure in the previous years. Thus, the 2022 Scoreboard does not cover State aid expenditure under the Temporary Crisis Framework to support the economy in the context of Russia's invasion of Ukraine, adopted on 23 March 2022 (as replaced by the Temporary Crisis and Transition Framework for State Aid on 9 March 2023).<br><br>Sustained impact of pandemic. The Scoreboard highlights that Member States continued to disburse "*massive amounts*" of State aid to mitigate the COVID-19 pandemic's profound economic effects. In 2021, the 27 Member States spent approximately €335 billion under State aid measures for all objectives (or some 2.3% of their combined 2021 GDP), excluding aid to railways and Services of General Economic Interest (SGEI). |

The Scoreboard further observes that in 2021, Member States appeared to reduce their spending capacity for non-COVID crisis objectives. Compared to 2020, State aid expenditure in 2021 by Member States decreased by -1.9% (i.e. €6.17 billion) after adjusting for inflation. However, the expenditure related to the COVID-19 crisis increased by 4.7% in constant prices (i.e. €8.6 billion), and support for other measures decreased by 1.7% (i.e. €2.43 billion). More specifically:

- Total expenditure for COVID-19 measures in 2021 amounted to €190.65 billion (approx.. 57% of total spending). In this respect, notably:
  - Member States with the largest share of COVID-19 related State aid expenditure relative to their 2021 national GDP were Malta (2.48%) and Greece (2.46%), followed by Austria (2.1%), Slovenia (2%), Latvia and Slovakia (each around 1.9% of GDP), and by Germany (1.8%).
  - Member States with the smallest share of COVID-19 related State aid in relative terms were Sweden (0.21%) and Belgium (0.22%), followed by Estonia and Ireland (0.4% each).
  - Despite significant spending dispersion across Member States, the Commission's view is that temporary State aid measures adopted in the COVID-19 crisis were proportionate and necessary to the economic damage suffered during the crisis. The Commission also found no evidence of Member States granting an excessively larger amount compared to the others.
- Total non-COVID related public support measures in 2021 amounted to €143.89 billion (approx. 43% of total spending), and in this respect:
  - In line with previous years, in 2021, Member States spent by far the most on environmental protection and energy savings (non-crisis-related) policy objectives (€69 billion). Research and development, including innovation, became the second objective in 2021 on which Member States spent the most (€18.77 billion, an increase of €6.48 billion compared to 2020), overtaking regional development (€14.21 billion, a decrease of €2.19 billion compared to 2020).
  - In an ongoing trend, Member States are increasingly using the General Block Exemption Regulation (GBER), which provides scope for implementing, without prior approval by the Commission, certain measures deemed as having limited impact on the internal market, as well as other sectoral block exemptions (i.e. Agricultural Block Exemption Regulation (ABER) and Fishery Block Exemption Regulation (FIBER)). In 2021, Member States implemented 2,365 new GBER, 296 new ABER, and 29 new FIBER measures, together representing 83% of all new State aid measures in 2021.

State aid expenditure data gathered by DG Competition is available on its data repository webpage hosted by EUROSTAT (see here).

* For the State aid Scoreboard 2021, see *Jones Day COVID-19 Update No. 86 of 8 September 2022*.

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| **European Commission approves French measure to support new €7.4 billion microchips plant (see here)** | On 28 April 2023, the Commission approved a French aid measure to support STMicroelectronics (ST) and GlobalFoundries (GF) in the construction and operation of a new microchips manufacturing facility in Crolles, France, a project worth some €7.4 billion (ST-GF Project).<br><br>The Commission's assessment was based on Article 107(3)(c) TFEU (which enables Member States to grant aid to facilitate the development of certain economic activities subject to certain conditions) and on the principles set out in the European Chips Act Communication.<br><br>To recall, the Chips Act Communication is part of the Commission's package of measures released in February 2022 (see here) aimed at ensuring the EU's security of supply and technological leadership in the field of semiconductors. The package includes the forthcoming EU Chips Act to establish a framework of measures for strengthening Europe's semiconductor ecosystem (*see also Jones Day EU Emergency Response Update No. 101 of 19 April 2023; and Jones Day Commentary, EU Chips Act: The EU's Push for Semiconductor Autonomy, March 2022*).<br><br>The French aid measure, comprised of direct grants, is intended to reinforce Europe's security of supply, resilience and digital sovereignty in semiconductor technologies, in line with the objectives of the European Chips Act Communication and Europe's digital and green transition.<br><br>According to the Commission's assessment, in particular, the ST-GF Project is a first-of-a-kind facility in Europe. The project is focused on FD-SOI (Fully Depleted Silicon On Insulator), a technology developed in Europe that is anticipated to enable large-scale production of energy-efficient and secure chips.<br><br>The ST-GF Project builds, among others, on technologies developed as part of the Important Project of Common European Interest (IPCEI) for research and innovation in microelectronics, which the Commission approved on 18 December 2018 (see here).*<br><br>The ST-GF Project is planned to be operating at full capacity by 2027. The plant is expected to produce per year 620,000 wafers of 300 mm diameter based on technologies and production processes not yet present in Europe.<br><br>Approval of this French aid measure is the Commission's second decision based on the principles set out in the Chips Act Communication. On 5 October 2022, the Commission approved, under EU State aid rules, an Italian measure to support STMicroelectronics in constructing a plant in the semiconductor value chain in Catania, Sicily (*see Jones Day COVID-19 Update No. 89 of 14 October 2022*).<br><br>* *To recall, the IPCEI rules seek to enable Member States and industry to jointly invest in ambitious pan-European projects in a transparent and inclusive manner, where the market alone appears unable to deliver and particularly where the risks are deemed as too large for a single Member State or company to assume. On 25 November 2021, the Commission published a revised Communication on State aid rules for Important Projects of Common European Interest (IPCEI) (see Jones Day COVID-19 Update No. 69 of 29 November 2021).* |
| **European Commission** | The Commission approved additional measures under the new State aid Temporary Crisis and Transition Framework (new TCTF) to support the |

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| **approves further schemes under new Temporary Crisis and Transition Framework to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies (see here)** | economy in the context of Russia's invasion of Ukraine and in sectors key to accelerating the green transition and reducing fuel dependencies (applied as from 9 March 2023, *see also Jones Day COVID-19 Update No. 99 of 17 March 2023*).<br><br>Among the most recently approved State aid schemes under the new TCTF (until 5 May 2023):<br><br>– €435.4 million (PLN 2 billion) Polish scheme to support the wheat production sector in the context of Russia's war against Ukraine, as approved under the new TCTF.<br><br>– €137 million Portuguese scheme to support primary agricultural producers in the context of Russia's war against Ukraine, as approved under the new TCTF.<br><br>– €2.6 billion (SEK 29 billion) Swedish scheme to support companies active in southern Sweden in the context of Russia's war against Ukraine, as approved under the new TCTF.<br><br>– Prolongation and amendments of a Spanish and Portuguese measure aimed at reducing the wholesale electricity prices in the Iberian market by lowering the input costs of fossil fuel-fired power stations.<br><br>The amended measure was approved under Article 107(3)(b) TFEU, recognizing that the Spanish and Portuguese economies are still experiencing a serious disturbance, and the general principles set out in the new TCTF to support the economy in the context of Russia's invasion of Ukraine, which the Commission applied by analogy. |
| **European Commission approves further schemes to compensate for damage due to COVID-19 crisis (see here and here)** | The Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b, and the State aid COVID Temporary Crisis Framework adopted in March 2020 under Article 107(3)b TFEU. With certain exceptions, the Temporary Crisis Framework applied until 30 June 2022.*<br><br>Among the latest schemes (up to 5 May 2023):<br><br>• €34 million Dutch measure to support organizers of top-level sports events and competitions to be in line with EU State aid rules. The measure aims at compensating organizers of such events for the damage suffered between 13 November 2021 and 17 January 2022 due to the restrictions imposed by the Netherlands to limit the spread of the coronavirus.<br><br>The Commission assessed the measure under Article 107(2)(b) TFEU, which enables the Commission to approve State aid measures granted by Member States to compensate specific companies or sectors for the damage directly caused by exceptional occurrences, such as the coronavirus outbreak.<br><br>** Exceptions notably include the possibility for Member States to (i) create direct incentives for private investments as a stimulus to overcome an investment gap accumulated in the economy due to the crisis (until 31 December 2023) and (ii) provide solvency support measures (until 31 December 2023) aimed at easing access to equity finance for smaller companies.*<br><br>*The Temporary Framework also provides for a flexible transition, under clear safeguards, in particular for the conversion and restructuring options of debt* |

*instruments (e.g., loans and guarantees) into other forms of aid, such as direct grants, until 30 June 2023.*

## TRADE / EXPORT CONTROLS

**European Commission and Council of the European Union announce anti-corruption package (see here and here)**

On 3-4 May 2023, the European Commission and Council of the European Union announced a multi-pronged package to ramp up the fight against corruption. According to conservative estimates, corruption costs the EU economy some €120 billion annually.

In highlighting the need for this initiative, the Council observed:

> *"The COVID-19 pandemic has strained resources and reaffirmed the importance of effective oversight of public spending. Russia's unprovoked and illegal war of aggression against Ukraine has contributed to a global food and energy crisis, exacerbating already increasing inequalities. In this context, the Council notes the increased urgency of adopting a whole-of-government approach to combatting corruption, whenever and wherever it occurs, to ensure that support reaches those most in need and is used in the most efficient manner."*

The anti-corruption package comprises the following:

- A Commission Communication on the fight against corruption sets out an overview of current EU anti-corruption legislation and policies, examines challenges, and considers how to strengthen future EU action. In particular, the Communication:
  - Announces that the Commission will establish an EU network against corruption to support existing networks and maximize the exchange of best practices between national authorities, civil society, and independent experts. A key task of the Network will be to support the Commission in mapping common areas where corruption risks are high across the EU.
- A proposed Directive on combating corruption to update and harmonize EU rules on the definitions of and penalties for corruption offences, towards ensuring high standards against the full range of corruption offences. In particular, the proposal:
  - Addresses public and private sector corruption in a single legal act for the first time at EU level.
  - Extends the list of EU corruption offences to cover misappropriation, trading in influence, abuse of functions, as well as obstruction of justice and illicit enrichment related to corruption offences, beyond the more "classic" bribery offences. It also sets out consistent penalty levels and defines aggravating and mitigating circumstances.
  - Member States will ensure the presence of key preventive tools, including effective rules for (i) disclosure and management of conflicts of interests in the public sector, (ii) disclosure and verification of assets of public officials and (iii)

interaction between the private and the public sector (e.g., so-called “revolving doors” between public and private functions).

- A proposed dedicated CFSP (Common Foreign and Security Policy) sanctions regime to fight corruption where acts of corruption seriously affect or risk affecting the EU’s fundamental interests. This proposed regime is intended to complement the current CFSP sanctions toolbox of restrictive measures.

  Josep Borrell (High Representative of the Union for Foreign Affairs and Security Policy and Commission Vice-President) presented the proposed regime, with the Commission’s support (see here). In this respect, he submitted to the Council a proposal for a Council Decision and, jointly with the Commission, a proposal for a Council Regulation for a thematic framework for CFSP sanctions targeting corruption, to complement the EU’s internal and external policy actions to fight corruption.

  In particular, the proposed CFSP sanctions regime will enable the EU to:

  – Target serious acts of corruption worldwide, whereas the current EU framework targeting corruption outside the EU is limited to only a few countries

  – Adopt restrictive measures when acts of corruption seriously affect or risk affecting the CFSP’s objectives (e.g., acts such as passive or active bribery of a public official or the embezzlement or misappropriation of property by a public official).

  – Prohibit entry into EU territory of perpetrators, their associates and those facilitating such acts and freeze their assets.

Next steps. The proposed Directive on combating corruption will undergo negotiation by the European Parliament and the Council in view of its adoption.

The proposed new framework of CFSP sanctions targeting corruption will undergo discussion by the Council in view of its adoption.

**Council of the European Union expands sanctions against Iran and proposed 11th package of sanctions underway (see here)**

The EU relies on restrictive measures (sanctions) as one of its tools to advance its Common Foreign and Security Policy (CFSP) objectives, such as safeguarding EU's values, fundamental interests, and security; preserving peace; and supporting democracy and the rule of law.

Sanctions include measures such as travel bans (prohibition on entering or transiting through EU territories); asset freezes; prohibition on EU citizens and companies from making funds and economic resources available to the listed individuals and entities; ban on imports and exports (e.g., no exports to Iran of equipment that might be used for internal repression or for monitoring telecommunications), and sectoral restrictions.

Among the most recent developments to the EU sanctions regimes:

Iran: On 24 April 2023, the Council decided to impose restrictive measures on eight additional individuals and one entity responsible for serious human rights violations in Iran (see here). The Council is sanctioning, among others:

- Ariantel, an Iranian mobile service provider, which contributed to the Iranian government's telecommunications surveillance architecture to repress dissent in Iran.
- Members of the Islamic Revolutionary Guard Corps (IRGC) and the IRCG Cooperative Foundation, the body managing the IRGC's investments and, in that framework, responsible for channeling money into the regime's brutal repression.

Restrictive measures now apply to a total of 216 individuals and 37 entities. They consist of an asset freeze, a travel ban to the EU, and a prohibition to make funds or economic resources available to those listed. A ban on exports to Iran of equipment which might be used for internal repression and of equipment for monitoring telecommunications is also in place.

This seventh package of listings complements the previous six packages adopted by the Council on 17 October, 14 November, and 12 December 2022, 23 January, 20 February and 20 March 2023.

Additionally, in particular, in light of Iran's military cooperation with Russia, the Council had earlier added 4 individuals and 4 entities on 12 December 2022 to the list of those subject to restrictive measures for undermining or threatening the territorial integrity, sovereignty and independence of Ukraine, in view of their role in developing and delivering Unmanned Aerial Vehicles (UAVs) used by Russia in its war against Ukraine (see here).

Russia: The European Commission is moving ahead with a proposal for an 11th package of sanctions. According to diplomatic sources, as reported by the press in early May 2023, the proposal focuses in particular on tackling the circumvention of current trade restrictions via third countries such as China, Turkey, United Arab Emirates, as well as potentially countries in central Asia and the Caucasus.

To recall, EU restrictive measures taken against Russia, as first introduced in 2014 in response to Russia's actions destabilizing the situation in Ukraine, have significantly expanded following Russia's military aggression against Ukraine, starting in February 2022 with the so-called first package of sanctions (see here) and now with the 10th package of sanctions (see here) adopted by the Council on 24 February 2023* (*see also Jones Day COVID-19 Update No. 98 of 1 March 2023*).

The Council's overview of EU sanctions against Russia over Ukraine (since 2014) is available here.

** An in-depth analysis of the 10th package of sanctions against Russia is available from the authors of the COVID-19 Update (see contact details below for Nadiya Nychay (Brussels) and Rick van 't Hullenaar (Amsterdam)).*

## MEDICINES AND MEDICAL DEVICES

**European Commission publishes proposed reform of EU pharmaceutical legislation (see here)**

On 26 April 2023, the Commission published its proposed reform of EU pharmaceutical legislation ("Reform"), the most significant revision since 2004 (*see also Jones Day Vital Signs: Digital Health Law Update | Spring 2023*).

The proposed Reform takes heed, in particular, of lessons learned from the COVID-19 crisis and introduces, for example, new measures to address shortages of medicines, rolling reviews (i.e., a phased review of data as they become available), and temporary emergency marketing authorizations for health emergencies.

The proposed Reform notably aims at:

- Creating a Single Market for medicines to promote timely and equitable access to safe, effective, and affordable medicines for all patients across the EU (*e.g., establishing new incentives to encourage companies to make their medicines available to patients in all EU countries*);
- Enhancing security of supply and addressing shortages of medicines (*e.g., earlier warnings from companies on shortages and withdrawals of medicines, including establishment of prevention plans*)
- Cutting administrative burden by significantly accelerating procedures and thereby reducing authorization times for medicines so that they reach patients faster (*e.g., the European Medicines Agency (EMA) assessment would be 180 days, instead of 210 days. For the authorization, the Commission would have 46 days, instead of 67 days*);
- Offering an attractive innovation and competitiveness friendly environment for research, development, and production of medicines in Europe (*e.g., special incentives foreseen for medicines delivering on high unmet medical needs in the case of rare diseases*);
- Combating antimicrobial resistance (AMR) (*e.g., setting targets to be achieved by 2030 (compared to the 2019 baseline), such as a reduction of 20% of the total consumption of antibiotics in humans*); and
- Making medicines more environmentally sustainable (*e.g., strengthening environmental risk assessments for all medicines, including those already authorized, to limit the potential adverse effects of medicines on the environment and public health*).

Towards meeting these objectives, the proposed Reform consists of:

- A proposed EU regulatory framework for all medicines (including those for rare diseases and for children), thereby simplifying and replacing the previous pharmaceuticals legislation and consisting of:
  - A proposed Directive on the Union code relating to medicinal products for human use (here), which notably:
    - Contains all requirements for authorization, monitoring, labelling and regulatory protection, placing on the market

and other regulatory procedures for all medicines authorized at EU and national level.

- A proposed Regulation laying down Union procedures for the authorization and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency (EMA) (here), which notably:
  - Sets specific rules (in addition to those in the above-mentioned proposed Directive) for medicines authorized at EU level, in particular the most innovative ones;
  - Provides rules on coordinated management of critical shortages and security of supply of critical medicines; and
  - Sets out the rules governing the EMA.

- A proposed Council Recommendation on ramping up EU actions to combat AMR in a One Health approach (here), as the EU has identified AMR as one of its top three health threats; and

- A Communication on revising the pharmaceutical legislation and measures addressing AMR (here), which seeks to explain the reasons behind the proposed Reform.

Next steps. The proposed Reform will now be discussed by the Parliament and the Council. The Commission stated that discussions will start "*as soon as possible, but we cannot predict the timing for adoption at this stage*."

Further information on the proposed Reform is provided in the Commission's accompanying Q&A on revising pharmaceutical legislation (here) and Q&A on the proposed Council Recommendation on combating AMR (here)

**EDPS publishes Annual Report 2022 (see here)**

On 26 April 2023, the European Data Protection Supervisor ("EDPS")* published its Annual Report 2022: tackling the challenges of tomorrow, which provides insights into the EDPS' activities during the course of 2022.

The EDPS notes, in particular, that its work and strategies have been confronted by the challenges of the COVID-19 pandemic, the war on Ukraine, and the global economic crisis. In response, EDPS is focusing additional attention to priorities such as fostering international cooperation to promote global common approaches on privacy and data protection challenges.

On health-related topics, in 2022, EDPS issued various opinions, such as:

- Joint Opinion 03/2022 with the EDPB (European Data Protection Board) on the proposed European Health Data Space, a key pillar of the European Health Union, which will provide wider access to safe health data to healthcare professionals, while spurring research into new and innovative treatments (*see also Jones Day EU Emergency Response Update No. 101 of 19 April 2023*).

  In particular, the Joint Opinion emphasized the need to add a requirement to store electronic health data in the EEA, given that the proposed Health Data Space foresees infrastructure for the exchange of electronic health that would process large amounts of highly sensitive data, which would require stringent surveillance and protection from unlawful access;

- Joint Opinion 02/2022 with the EDPB on the proposed Data Act, which aims at enhancing data access and use within the EU by establishing harmonized rules on the access to, and use of, data generated from a broad range of products and services, including connected objects ('Internet of Things'), medical or health devices and virtual assistants (*see also Jones Day COVID-19 Update No. 94 of 19 December 2022*).

  In particular, the Joint Opinion underscored that access to data by public authorities should always be properly defined and limited to what is strictly necessary and proportionate, but according to the Joint Opinion, the draft Data Act did not meet such requirements.

- Several Supervisory Opinions (e.g., see here and here) on the use of COVID certificates and passes, which emphasized that measures introduced during a global health crisis, like COVID-19, should be limited in time and only where they are necessary and proportional in light of the objectives pursued, particularly given the increase of data collected during COVID-19. The EDPB also made clear that personal data initially collected for managing this health crisis should not be repurposed for other objectives.

The Annual Report also provided an overview of categories of data in personal data breaches in 2022, as reported by EU institutions, offices, bodies and agencies (EUIs), which must notify EDPB of such breaches, unless a risk to the affected individuals is unlikely. While 80% of data breach notifications concerned no special categories of data, 20% of the notifications involved special categories of data, with the majority of these breaches implicating health data (e.g., errors when sending medical invoices, during the reimbursement processes). The EDPB recommend that EUIs (raise their staff's (or contractors) awareness and consider additional safeguards to avoid human error.

For additional information about the EDPS and its activities, see its Frequently Asked Questions.

* *The EDPS is the EU's independent data protection authority responsible for supervising the processing of personal data by the European institutions, bodies, offices and agencies.*

*For further details on the EDPS Annual Report, see also below Section on Cybersecurity.*

## CYBERSECURITY, PRIVACY & DATA PROTECTION

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In 2022, the EDPS's activity focused on key topics, and notably:

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| | • Protection of individuals (e.g., international transfers of personal data to non-EU/EEA countries and audit of large-scale IT systems).<br>• Collaboration with the EU legislator in a wide range of sectors (e.g., artificial intelligence, initiatives to combat crime), such as:<br>  ○ Opinion 20/2022 on the AI Convention (*Opinion on the Recommendation for a Council Decision authorising the opening of negotiations on behalf of the European Union for a Council of Europe convention on artificial intelligence, human rights, democracy and the rule of law*), which emphasized the need to include appropriate, robust and clear data protection safeguards to protect individuals who may be affected by the use of AI systems;<br>  ○ Opinion 1/2022 on two proposed Council Decisions authorizing Member States to (i) sign the Second Additional Protocol to the Budapest Convention on Cybercrime, and (ii) ratify this same Protocol. Again, the EDPS highlighted the need to protect the fundamental rights of privacy and data protection (*On the subsequent adoption of these two Decisions, see Jones Day COVID-19 Update No. 81 of 5 April 2022 and Jones Day COVID-19 Update No. 98 of 1 March 2023*).<br>• Technology monitoring (e.g., engagement with experts and data protection authorities to understand technologies and analyze their privacy and data protection implications).<br>• Digital innovation (e.g., promoting data protection friendly tools, including by leading by example, such as EDPS's use of open-source applications and platforms that offer privacy-friendly alternatives to products and services provided by big tech companies).<br><br>For additional information about the EDPS and its activities, see its Frequently Asked Questions.<br><br>*For further details on the EDPS Annual Report, see also above Section on Medicines.* |
| **EU Digital Markets Act now applicable (see here)** | On 2 May 2023, most provisions of the Digital Markets Act ("DMA", see here) became applicable.*<br><br>To recall, the DMA entered into force on 1 November 2022 and aims to prevent the imposition of unfair conditions on businesses and end users by those designated as "gatekeepers" (i.e., large digital platforms deemed as significantly impacting the internal market, serving as an important gateway for business users to reach their end users, and which enjoy, or will foreseeably enjoy, an entrenched and durable position) that provide a "core platform service" (e.g., online search engines; online social networking services, web browsers, virtual assistants) (*see also Jones Day EU Emergency Update No. 101 of 19 April 2023*).<br><br>The DMA thereby subjects gatekeepers to a series of specific obligations, such as the required provision to business users of access to the data generated by their activities on their platform; and prohibition on use of data of business users when gatekeepers compete with them on their own platform.<br><br>With respect to data protection, in particular, where consent for collecting, processing, cross-using and sharing of personal data is required to ensure |

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| | compliance with the DMA, a gatekeeper shall take the necessary steps either to enable business users to directly obtain the required consent to their processing, where such consent is required under the GDPR or ePrivacy Directive 2002/58/EC, or to comply with EU data protection and privacy rules and principles in other ways, including by providing business users with duly anonymized data where appropriate.<br><br>The process of designating the first gatekeepers is now underway. Potential gatekeepers (i.e., companies that meet the quantitative thresholds) must notify their core platform services to the Commission within two months (i.e., by 3 July 2023).<br>•<br><br>The Commission will then have 45 days (i.e., by 6 September 2023) to decide whether companies meet the thresholds and to designate gatekeepers. Following their designation, gatekeepers will have six months to comply with the requirements of the DMA (i.e., by 6 March 2024).<br><br>For additional information on the DMA, *see Jones Day White Paper "Digital Markets Act: European Union Adopts New "Competition" Regulations for Certain Digital Platforms", August 2022*.<br><br>* *The following provisions are applicable as of 25 June 2023: (i) class action suits based on DMA violations under the EU Collective Action Directive (EU) 2020/1828); and (ii) whistleblower reporting and the protection of such persons who report breaches of Union law under the EU Whistleblower Directive (EU) 2019/1937*. |
| **European Commission designates first set of very large online platforms and search engines under DSA (see here)** | On 25 April 2023, the Commission adopted the first designation decisions under the Digital Services Act ("DSA" see here) for Very Large Online Platforms (VLOPs) and Very Large Online Search Engines (VLOSEs) that reach at least 45 million monthly active users (i.e., exceeding 10% of the EU's population).<br><br>To recall, the Digital Services Act ("DSA") entered into force on 16 November 2022, and certain provisions also became applicable on the same day (e.g., certain transparency obligations for online platforms, the Commission's obligation to designate very large online platforms/search engines and to charge these an annual supervisory fee, and enforcement provisions concerning such very large online platforms/search engines). Most DSA provisions will be applicable as of 17 February 2024 (*see also Jones Day EU Emergency Update No. 101 of 19 April 2023 and Jones Day COVID-19 Update No. 97 of 14 February 2023*).<br><br>The Commission's first designations concern 17 VLOPs (e.g., Amazon Store, Apple AppStore, Booking.com, Facebook, Google Play, Instagram, and LinkedIn) and two VLOSEs (i.e., Bing and Google Search).<br><br>These designated companies must ensure, in particular:<br><br>• Increased user empowerment (e.g., users will receive clear information on why they are given certain recommended information and will be able to report illegal content);<br><br>• Robust protection of minors (e.g., obligation to ensure a high level of privacy, security, and safety of minors, and prohibition of targeted advertising based on profiling towards children); |

- Reinforced content moderation and less disinformation (e.g., obligation to address and analyze risks regarding the dissemination of illegal content online);
- Transparency and accountability (e.g., obligation to provide researchers with access to publicly available data and to ensure the external and independent audit of risk assessments and compliance with all DSA requirements).

Following their designations as VLOPs and VLOSEs, the above-mentioned companies have four months to comply with their new obligations under the DSA.

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