

## EU EMERGENCY RESPONSE UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

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This regular alert covers key regulatory developments related to EU emergency responses, including in particular to Russia's war of aggression against Ukraine, COVID-19, 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 publishes State aid Scoreboard 2023
- European Commission approves further schemes under Temporary Crisis and Transition Framework to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies

#### Trade / Export Controls

- European Commission releases Report on significant distortions in economy of the People's Republic of China for purposes of trade defence investigations
- Launch of Minerals Security Partnership Forum

#### Medicines and Medical Devices

- European Parliament adopts provisional political agreement on European Health Data Space
- European Commission launches Critical Medicines Alliance
- European Parliament adopts Regulation amending MDR and IVDR

#### Cybersecurity, Privacy & Data Protection

- Interoperable Europe Act enters into force
- European Data Protection Board adopts its strategy for 2024-2027

## COMPETITION & STATE AID

**European Commission publishes State aid Scoreboard 2023 (see [here](#))**

On 9 April 2024, the Commission released the State aid Scoreboard 2023.\* 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.

Timeframe covered. The 2023 Scoreboard is based on State aid expenditure made by Member States in 2022 and provides updates of State aid expenditure in the previous years.

The Commission notes that despite a sizeable reduction in State aid expenditure in 2022, compared to 2021, Member States continued to support companies affected by Russia's war against Ukraine and the COVID-19 pandemic. More specifically:

- On crisis-related aid:
  - Total expenditure for measures to counterbalance the Russia's war Ukraine in 2022 amounted to Member States spending EUR 39.33 billion (some 17% of total State aid spending and 0.25% of EU GDP) under the Temporary Crisis Framework (TCF).\*\* Germany provided the most TCF aid in absolute terms and compared to 2022 GDP, amounting to €24.18 billion (approximately 0.62% of GDP), spent primarily in the form of recapitalizations, as justified by the systemic nature of energy supply companies, extending beyond the German wholesale energy markets.
  - Total expenditure for COVID-19 measures in 2022 amounted to Member States spending €76.65 billion (some 33.6% of total State aid expenditure and 0.48% of the 2022 EU GDP). Thus, expenditure for COVID-19 related measures fell by 60.5% compared to 2021, when it amounted to €194.17 billion.
- On non crisis-related aid:
  - Member States reduced their spending for non-crisis objectives in 2022, spending €112 billion (some 49% of total State aid spending and 0.7% of the EU-27 2022 GDP). This significantly decreased from 2021 by around 23.4% (i.e., €34.21 billion), with the reduction further accentuated when adjusting for the effects of inflation, in which case State aid expenditure for non-crisis objectives decreased by 28% compared to 2021 (i.e., €43.53 billion).

It appears that Member States lowered their spending in 2022 on non-crisis-related objectives, due to the need to implement measures related to the impact of Russia's war of aggression against Ukraine and the remaining expenditure related to the COVID-19 crisis.

- Outside of crisis aid, Member States' primary policy focus remained on environmental and energy savings, which received by far the most aid in 2022 (€41.51 billion (around 37% of the State aid expenditure for non-crisis measures), although the value of spending fell by 46% compared to 2021 in real terms. The second leading non-crisis policy objective was regional development (€13.91 billion (over 12% of State aid expenditure for non-crisis measures), which by contrast reflected a 4.8% increase in 2022.

- As concerns State aid expenditure for block-exempted measures (i.e. measures deemed compatible with EU State aid rules and thereby exempted from requirements for prior notification to and approval by the Commission):
  - The share of block-exempted measures continued to rise. In 2022, Member States implemented, in particular, the following new measures:
    - 1,901 measures under the [General Block Exemption Regulation](#) (GBER),
    - 284 measures under the [Agricultural Block Exemption Regulation](#) (ABER), and
    - 18 measures under the [Fishery Block Exemption Regulation](#) (FIBER).

Together, these amounted to 84% of the total number of new State aid measures. In this respect, the new GBER measures accounted for 93% of the total number of new non-crisis measures. Still, the expenditure under GBER measures decreased in 2022 (12% lower than 2021).

State aid expenditure data gathered by DG Competition is available on the new repository for statistics (2000-2022) (see [here](#)).

\* *For the State aid Scoreboard 2022, see [Jones Day EU Emergency Response Update No. 102 of 3 May 2023](#).*

\*\* *On 23 March 2022, the Commission adopted a [Temporary Crisis Framework](#) to enable Member States to use State aid rules to support the economy following Russia's war on Ukraine. On 9 March 2023, the Commission adopted a new [Temporary Crisis and Transition Framework](#) (consolidated version, most recently updated on 2 May 2024) to foster support measures in sectors viewed as key to the transition to a net-zero economy. This new Framework amended and prolonged in part the Temporary Crisis Framework.*

**European Commission approves further schemes under 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](#))**

The Commission approved additional measures under the State aid Temporary Crisis and Transition Framework (TCTF) to support the economy in the context of Russia's invasion of Ukraine and in sectors key to accelerating the green transition and reducing fuel dependencies (as most lately amended on 20 November 2023).

Among the most recently approved State aid schemes under the TCTF (up to 6 May 2024):

- €80 million French aid scheme aimed at supporting wine growers in the south of France in the context of Russia's war against Ukraine.
- €2.2 billion German State aid scheme to support the decarbonisation of industrial processes to foster the transition to a net-zero economy.
- €20 million Slovak scheme to support companies active in the primary production of agricultural products and/or in the fishery and aquaculture sector in the context of Russia's war against Ukraine.

- €35 million Italian scheme to support telecommunication operators in the context of Russia's war against Ukraine.
- Re-introduction of a Romanian scheme of approximately €2.5 billion (RON 12.5 billion) to support companies in the context of Russia's war against Ukraine, which had last expired on 31 December 2023. Under the re-introduced scheme, the aid will take the form of guarantees and direct grants.

## TRADE / EXPORT CONTROLS

### European Commission releases Report on significant distortions in economy of People's Republic of China for purposes of trade defence investigations (see [here](#))

On 10 April 2024, the European Commission published its Report on significant state-induced distortions in the economy of the People's Republic of China for the purposes of trade defence investigations.

This latest Report follows the previous 2017 report, which the Commission viewed as an essential tool for gathering evidence to initiate and conduct anti-dumping investigations in sectors where significant state-induced distortions impacted prices and costs.

According to the Commission, the Report provides certain factual information for ongoing and future EU trade defence investigations related to anti-dumping. The Report seeks to enable EU industry, when filing complaints about dumping practices, to use the most current information on the Chinese economy and specific market circumstances in selected industrial sectors. This includes developments such as recent Chinese legislation and industrial policies.

The Report notes, in particular, that in light of rising political and trade tensions between China and the US, as well as the economic and social impacts of the COVID-19 pandemic, the Chinese government's industrial policy agenda has given high importance to the concept of "dual circulation" and its key tenet of technological self-reliance.\*

The Report's main findings focus on the following market distortions:

- Cross-cutting distortions in the unique context of China's social market economy,\* e.g., dominant State-ownership, an extensive and sophisticated economic planning system, as well as interventionist industrial policies and a broad set of other tools to pursue the political and economic objectives of the CCP (Chinese Communist Party);
- Distortions in production factors, e.g., discriminatory allocation and access to resources, such as land, labor, capital, raw materials, and energy; and
- Distortions in specific sectors, e.g., State support, including preferential access to finance, in certain industrial sectors identified on the basis of criteria such as their frequent occurrence in the Commission's trade defence investigation practice or their particular economic or strategic importance (including steel, aluminium, telecommunications, semiconductors, railway equipment, environmental goods, and new energy vehicles, among others).

The Commission notes that during an investigation, all parties concerned can comment on the Report's findings, including the government of China and exporting producers.

The Report draws on numerous publicly available sources, such as Chinese legislation and policy documents, and information from international organizations (e.g., IMF, OECD, WTO) and academic sources, similarly to the preceding 2017 report published (see [here](#)).

\* *Under China's "dual circulation" concept: (i) domestic circulation is the mainstay (i.e., emphasis on the domestic economic cycle (production, distribution, consumption) to lower reliance on imports, and in particular, technological imports; alongside (ii) mutual reinforcement of domestic and international circulation to continue the ever rising penetration of global markets by Chinese industrial operators.*

### Launch of Minerals Security Partnership Forum (see [here](#))

On 5 April 2024, the EU, US, and other Minerals Security Partnership (MSP)\* partners announced, in the presence of Kazakhstan, Namibia, Ukraine, and Uzbekistan, the launch of the Minerals Security Partnership Forum (MSP Forum), presently co-chaired by the EU and US.

The MSP Forum provides a new cooperation platform for critical raw materials (CRMs), focusing on minerals and metals supply chains most relevant for clean energy technologies, e.g., lithium, cobalt, nickel, manganese, graphite, rare earth elements, copper, and others.

The MSP Forum builds on the EU's Critical Raw Materials Package adopted in March 2023 (see also [Jones Day COVID-19 Update No. 99 of 17 March 2023](#)), which highlighted the need for greater diversification and sustainability of CRM supply chains through new international partnerships. The CRM Package included the [CRM Communication](#) and the recently adopted [CRM Act](#) (see also [Jones Day EU Emergency Response Update No. 113 of 2 April 2024](#)).

The MSP Forum is open to countries that are prepared to commit to diversifying global critical mineral supply chains and to the MSP's [Principles on Responsible Critical Mineral Supply Chains](#). The Forum's efforts will be shaped by the following:

- a **project group** to support and accelerate the implementation of sustainable CRM projects; and
- a **policy dialogue** to identify policies to strengthen sustainable CRM production and local capacities, promote regulatory cooperation to enhance fair competition and predictability, and foster high environmental, social, and governance (ESG) standards in CRM supply chains.

**Next steps.** The MSP Forum is undertaking outreach to ensure broad participation of resource-rich countries in the Forum. Among other initiatives, the MSP Forum is also planning an inter-governmental seminar and government-business forum on ESG compliance and sustainable production and management of CRMs, including issues such as pricing challenges.

\* *The [MSP](#) is a collaboration between the EU and 14 countries (Australia, Canada, Estonia, Finland, France, Germany, India, Italy, Japan, Norway, Republic of Korea, Sweden, UK, and U.S.) to catalyze public and private investment in responsible critical minerals supply chains globally.*



## MEDICINES AND MEDICAL DEVICES

### European Parliament adopts provisional political agreement on European Health Data Space (see [here](#))

On 24 April 2024, the European Parliament formally adopted a provisional political agreement earlier reached with the Council on 15 March 2024 on the proposed Regulation on the European Health Data Space (“proposed EHDS”) (see also [Jones Day EU Emergency Response Update No. 113 of 2 April 2024](#)).

To recall, the European Commission released the proposed EHDS in May 2022 ([here](#)), which seeks to create a common space in which individuals can easily control their electronic health data (“EHD”) and that enables researchers, innovators and policy makers use this electronic data in a trusted and secure way through the use of common rules, standards, infrastructures and a governance framework (see also [Jones Day COVID-19 Update No. 84 of 17 May 2022](#)).

The adopted provisional political agreement introduced several amendments to the proposed EHDS, such as:

- An opt-out mechanism for individuals regarding the primary and secondary use of their personal EHD.
- Easing administrative burdens by allowing EU Member States to designate trusted data holders who can securely process requests for health data access; and
- More specific provisions to protect intellectual property rights, trade secrets, and data protection rights.

Once the Council formally approves the provisional agreement, the Regulation will be published in the Official Journal and enter into force 20 days after its publication. The Regulation will become applicable two years later, with certain exceptions (including as concerns primary and secondary use of data categories, which will apply four to six years later, depending on the use case and data type).

The text of the provisional political agreement can be found [here](#).

### European Commission launches Critical Medicines Alliance (see [here](#))

On 24 April 2024, the European Commission’s Health Emergency Preparedness and Response Authority (“HERA”) launched the Critical Medicines Alliance (“Alliance”).

The Alliance is among the EU actions to combat recent critical shortages of medicines, as highlighted in the Commission’s [Communication presenting actions to better prevent and mitigate critical medicine shortages in the EU](#) of 24 October 2023 (see also [Jones Day EU Emergency Response Update No. 109 of 3 November 2023](#)).

The Alliance is a consultative mechanism gathering national authorities, industry, healthcare organizations, civil society representatives, the Commission and EU agencies. The Alliance aims to identify the best measures to address and avoid shortages of critical medicines, including by analyzing key factors such as over-dependency on a limited number of external suppliers, limited diversification, and limited production capacities.

In particular, the Alliance will help decision-makers to develop an industrial policy toolbox to tackle shortages of critical medicines through actions including EU funding, partnerships with third countries to secure supply chains, market incentives, such as capacity reservation contracts and joint procurement to enhance security of the supply of critical medicines throughout the EU.

The Commission has launched the Alliance for five years. The Alliance is expected to publish its first recommendations on actions to improve the supply of critical medicines based on identified vulnerabilities and a strategic plan by end-2024.

**European Parliament adopts Regulation amending MDR and IVDR (see [here](#))**

On 25 April 2024, the European Parliament adopted the proposed Regulation amending the Medical Device Regulation (“MDR”) and the In Vitro Medical Device Regulation (“IVDR”).

The Commission released the proposed Regulation on 23 January 2024 in view of addressing, in particular, two urgent issues:

(i) Ensuring the availability of in vitro diagnostics (“IVDs”), such as by:

- Granting additional time to IVD manufacturers to transition to the new requirements of the IVDR, given the high number of IVDs now on the market that have not yet factored in the new rules. The extended transition periods depend on the type of device:
  - High individual and public health risk devices (such as HIV or hepatitis tests) (class D) will have a transition period until December 2027;
  - High individual and/or moderate public health risk devices (such as cancer tests) (class C) will have a transition period until December 2028; and
  - Lower risk devices (such as pregnancy tests) (class B) and sterile devices (such as blood collection tubes) (class A) will have a transition period until December 2029.

However, only certain IVDs can benefit from the extended transition periods (i.e., only “legacy devices” covered by a certificate or declaration of conformity issued under the previous legal framework (notably Directive 98/79/EC and that meet conditions set out in the proposed Regulation).

- Requiring manufacturers to give prior notice if they anticipate a disruption in the supply of certain IVDs or medical devices. This information must be provided six months in advance to competent authorities, distributors, and healthcare providers to allow enough time to take mitigating actions to safeguard patient care.

(ii) Increasing transparency in the medical device sector by speeding up the launch of certain elements of the European Database on Medical Devices (“EUDAMED”), an important tool towards ensuring traceability and transparency in medical devices by registering all medical devices placed on the EU market in view of providing a comprehensive overview of available devices in the EU.

EUDAMED is composed of six modules: (i) actor registration, (ii) unique device identification (UDI) and device registration, (iii) notified bodies and

certificates, (iv) clinical investigations and performance studies, (v) post-market surveillance and vigilance, and (vi) market surveillance.

In particular, the proposed Regulation:

- Enables accelerating EUDAMED's mandatory use by allowing the gradual roll-out of modules as soon as they have been audited and declared functional (currently, EUDAMED will only become mandatory when all modules function correctly). This will allow the mandatory use of several modules to start from end-2025.

The Council will now formally adopt the Regulation, which will enter into force on the day of its publication in the Official Journal.

## CYBERSECURITY, PRIVACY & DATA PROTECTION

### Interoperable Europe Act enters into force (see [here](#))

On 11 April 2024, the Interoperable Europe Act entered into force. It aims to facilitate cross-border data exchange and accelerate the digital transformation of the public sector. The Act is essential to attaining the EU's [Digital Decade](#) ambitions, and in particular, the full online availability of key public services by 2030 (see also [Jones Day COVID-19 Update No. 94 of 19 December 2022](#)).

The Commission notes that public sector interoperability (i.e., the ability of administrations to cooperate and make public services function across borders and organizational boundaries) serves a critical role in developing safe data flows and avoiding the duplicative efforts in public services. In different crises over the past years, public sector interoperability has facilitated coordination among Member States, mobilization of resources where they were most needed, and the swift development of joint solutions.

The Act will thereby help citizens, businesses, and public administrations when using interconnected digital public services that require the cross-border exchange of data. These services include the mutual recognition of diplomas or professional qualifications, vehicle data exchanges, access to health and social security data, etc.

Among the Act's key measures are the following:

- [Multi-level cooperation framework](#), which gathers digital government practitioners, civil society, experts, academics and local actors from the Member States to define a common interoperability agenda;
- [Mandatory interoperability assessments](#), which aim to build "interoperable-by-design" public services to support public sector bodies in addressing cross-border interoperability aspects already at the design phase of new services or tools;
- [Interoperable Europe Portal](#), a one-stop-shop to foster the reuse and sharing of reliable interoperability solutions; and
- [Innovation and policy support mechanisms](#), including training, regulatory sandboxes for policy experimentation, policy implementation support projects, etc.



Next Steps. Most of the Act's provisions will apply within 3 months of its entry into force. However, Member States will designate national competent authorities 9 months after the date of entry into force of the Regulation (by January 2025); and European institutions, bodies and agencies and public sector bodies will implement interoperability assessments as of January 2025.

**European Data Protection Board adopts its strategy for 2024-2027 (see [here](#))**

On 18 April 2024, the European Data Protection Board (“EDPB”) adopted its Strategy for 2024-2027, setting out key priorities.

These priorities are grouped around four pillars:

- (i) enhancing harmonization and promoting compliance, e.g., EDPB will develop concise and practical guidance on important topics concerning compliance with data protection law;
- (ii) reinforcing a common enforcement culture and effective cooperation, e.g., EDPB will continue building on the ambitions set out in its so-called “[Vienna Statement](#)” on enforcement cooperation of 28 April 2022, including strengthening the identification of strategic cases for which cooperation will be prioritized and to provide methodologies and tools promoting a harmonized approach to investigation and enforcement;
- (iii) safeguarding data protection in the developing digital and cross-regulatory landscape, e.g., affording particular attention to challenges raised by new technologies, such as Artificial Intelligence and digital identity; and
- (iv) contributing to the global dialogue on data protection, e.g., continuing to support cooperation on enforcement amongst EU and non-EU authorities, such as by adopting documents to facilitate implementation of the redress mechanisms under the EU-US Data Privacy Framework (see [here](#)).

In presenting the 2024-2027 strategy, EDPB Chair, Anu Talus, stated: “*The new strategy takes the existing vision in a new direction in order to respond to the data protection needs of today, and the ever-evolving digital landscape*”.

The EDPB will report on progress achieved under the Strategy as part of its annual report.

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