EU GEOPOLITICAL RISK UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

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This regular alert covers key policy and regulatory developments related to EU geopolitical risks, including in particular, economic security, Russia's war against Ukraine, health threats, and cyber threats. It does not purport to provide an exhaustive overview of developments.

This regular update expands from the previous Jones Day COVID-19 Key EU Developments – Policy & Regulatory Update (last issue No. 99) and EU Emergency Response Update (last issue No. 115).

LATEST KEY DEVELOPMENTS

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- European Commission approves schemes under Clean Industrial Deal State Aid Framework (CISAF)

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COMPETITION & STATE AID

European Commission approves €450 million in Czech State aid to support new semiconductor manufacturing facility (see here)

On 23 November 2025, the Commission announced the approval of a €450 million Czech State aid measure to support US chipmaker Onsemi in building the European Union's first integrated chip manufacturing plant for Silicon Carbide ("SiC") power devices* in Rožnov pod Radhoštěm, Czech Republic. The State aid will take the form of a €450 million direct grant to Onsemi to support the company's €1.64 billion investment.

Basis. 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, which entered into force on 21 September 2023 (*Regulation (EU) 2023/1781 of 13 September 2023 establishing a framework of measures for strengthening Europe's semiconductor ecosystem*).

To recall, the Chips Act is part of the Commission's package of measures released in 2022 (see here) aimed at ensuring the EU's security of supply and technological leadership in the field of semiconductors. (Micro-) chips or semiconductors are key building blocks for digital products, e.g., smartphones, computers, and medical equipment *(see also Jones Day EU Emergency Response Update No. 107 of 29 September 2023)*.

The Commission also deemed the Czech measure as in line with the objectives of the Political Guidelines for the European Commission 2024-2029, which encompass boosting investment in innovative technologies (e.g., semiconductors, supercomputing, quantum computing) to ramp up Europe's competitiveness.

Assessment. According to the Commission's assessment of the Czech measure, the State aid to Onsemi will contribute to both reinforcing the EU's technological autonomy in semiconductor technologies and to accelerating the digital and green transitions. In particular, the Commission deemed the Onsemi facility as:

- first-of-a-kind, as the plant will use innovative manufacturing technologies and will aim to manufacture products with superior performance, which are currently not present in Europe; and
- contributing to security of supply in Europe (e.g., by committing to comply with priority-rated orders to produce in Europe in case of a supply crisis and by helping to halt overreliance on semiconductor devices manufactured outside of Europe).

This State aid measure is the Commission's eighth approval based on principles set out in the Chips Act, with earlier measures including, for example, the Commission's approval on 18 December 2024 of a €1.3 billion Italian State aid measure to support Silicon Box in constructing a semiconductor advanced packaging and testing facility in Novara, Italy *(see Jones Day EU Emergency Response Update No. 119 of 31 December 2024*).

Looking ahead. The new facility is expected to start commercial operations by 2027.

	The non-confidential version of the decision will be made available under case number SA.117291 in the State aid register on the Commission's competition website after addressing confidentiality issues. * *SiC power devices are vital to enabling efficient, compact, high-performance power electronics used in electric vehicles, fast-charging stations, renewable energy generation, and other industrial applications. The integrated Onsemi plant aims to cover all manufacturing steps, from SiC crystal growth to finished devices.*
European Commission evaluates and consults on EU Public Procurement Directives (see here and here)	On 14 October 2025, the Commission published its Evaluation of the EU Public Procurement Directives*, a first step towards their planned revision. The Evaluation, spanning 2016 to 2024, is based on EU and Member State procurement data, as well as other sources such as studies contracted by the Commission and stakeholder input. Backdrop / objectives. The Evaluation indicates that public authorities in the EU spend over €2 trillion per year (representing some 15% of GDP) on purchasing services, works and supplies in sectors such as energy, transport, healthcare, and education. Last reformed in 2014, the Public Procurement Directives aim to ensure transparency and integrity in public spending and strengthen competition in the EU for the provision of public goods and services with respect to higher-value public tenders (with monetary values exceeding certain thresholds)** and which are presumed to be of cross-border interest. The Evaluation states that it takes place against the background of a changed geopolitical and global trade landscape, the EU's shortcomings in economic competitiveness, and the need to foster resilience of the EU's economic infrastructure and sustainability goals. To recall, the Commission's planned revision of the Public Procurement Directives, as set out in its Political Guidelines 2024-2029 issued by Commission President Ursula von der Leyen, seeks to: – enable giving preference to European products for certain strategic sectors in public procurement; – ensure EU security of supply for vital technologies, products and services; and – modernize and simplify EU public procurement rules, in particular for EU start-ups and innovators. The Commission's plan to give preference to European products in certain strategic sectors has already raised the concerns of, *inter alia,* U.S. companies active in Europe. Evaluation's findings. The Evaluation notably states its view that the Public Procurement Directives have only partially met their objectives, e.g.: – There are shortcomings in the advancement of legal clarity, flexibility, and simplification. Procedures are still viewed as too complex and rigid, thereby impeding contracting authorities from effectively attaining their public investment objectives;

	– While transparency has improved and contract values have doubled, data gaps impede compliance checks and corruption risks persist; and – Direct cross-border procurement – where the successful bidder is not located in the same Member State as the contracting authority and the bidder is not domestically owned – remains limited. According to the Evaluation's conclusions, the current public procurement framework lacks the agility, coherence, and strategic focus needed to effectively tackle current and emerging challenges. Next steps. On 3 November 2025, the Commission opened a consultation, seeking input and evidence from stakeholders to further inform the ongoing review of the Public Procurement Directives. The consultation runs until 26 January 2026, and feedback will contribute to preparing a legislative proposal anticipated for release in Q2 2026. * *Commission Staff Working Document SWD(2025) 332 final of 14 October 2025 – Evaluation of Public Procurement Directives comprising (i) Directive 2014/24/EU on public procurement; (ii) Directive 2014/25/EU on procurement by entities operating in the water, energy, transport and postal services sectors (Utilities Directive); and (iii) Directive 2014/23/EU on the award of concession contracts*
European Commission approves schemes under Clean Industrial Deal State Aid Framework (CISAF) (see here)	The Commission approved additional measures under the Clean Industrial Deal State Aid Framework (CISAF) of 25 June 2025 (*see also Jones Day EU Geopolitical Update No. 122 of 31 August 2025*). The CISAF is a key component of the Commission's Clean Industrial Deal: A joint roadmap for competitiveness and decarbonization of 26 February 2025, which aims to support the EU manufacturing industry's competitiveness and resilience, while accelerating decarbonization. The CISAF replaces the Temporary Crisis and Transition Framework (TCTF)* and sets out streamlined rules aimed at the simplified and swifter approval of priority State aid measures that seek to accelerate Europe's competitiveness and green transition goals (e.g., accelerating renewable energy rollout; facilitating industrial decarbonization and energy-efficiency projects; ensuring sufficient EU manufacturing capacity for net-zero technologies; and easing private investment risk). The Commission Staff Working Document of 4 November 2025, accompanying the CISAF, also sets out main policy choices taken and the main evidence and experience that the Commission considered when adopting the CISAF. Among the most recently approved State aid schemes under the CISAF and deemed in line with the objectives of the Clean Industrial Deal (up to 30 November 2025): – €219 million Italian scheme to support clean technology manufacturing capacity in the region of Lazio, contributing to the transition towards a net-zero economy;

- €700 million Spanish scheme to support strategic investments that add clean technology manufacturing capacity in Spain, contributing to the transition towards a net-zero economy; and
- €61.5 million Italian scheme to support strategic investments that add clean technology manufacturing capacity in the region of Emilia Romagna, contributing to the transition towards a net-zero economy.

Looking ahead. The CISAF, applicable since 25 June 2025, will remain in force until 31 December 2030.

** The TCTF was established in 2022 to support the EU economy in the context of Russia's invasion of Ukraine and in sectors key to accelerating the green transition and reducing fuel dependencies.*

From March 2022 to June 2024, nearly €796 billion of aid was approved either under the TCTF or directly under the Treaty and based on TCTF principles (see also the Commission brief on the use of State aid measures under the TCTF of 20 February 2025, here).

TRADE / EXPORT CONTROLS

European Commission released Fifth Annual Report on Implementation and Enforcement of EU Trade Policy (see here)

On 3 November 2025, the European Commission released its Fifth Annual Report on the Implementation and Enforcement of EU Trade Policy, covering the period 2024 and the first seven months of 2025.*

The Report emphasizes that during these uncertain economic times and a challenging geopolitical environment, the EU's extensive network of trade agreements has supported companies in finding alternative markets for their exports and reducing dependencies.

In particular, the EU's trade agreements:

- Strengthen the competitiveness of EU economic operators, e.g.:
  - In 2024, the EU's export of goods to its 76 preferential trade partners grew twice as much as exports to countries not covered by a free trade agreement (FTA) – 1.4% vs. 0.7%. For example, EU exports to Canada have grown by 51% since 2017 (compared to 20% to the rest of the world).
  - Total EU agri-food exports in 2024 reached a new record of €235 billion (an increase of 2.8% compared to 2023). Agri-food exports to preferential trade partners, worth €138 billion, increased by 3.6%, compared to 1.6% with non-FTA partners.
- Enable diversifying supply sources and finding new export destinations for EU operators, e.g.:
  - EU trade agreements have helped the EU to diversify its energy and raw material supply away from Russia. For example, imports of gas and liquefied natural gas from Norway, Algeria, and Kazakhstan (supplementing imports from the US) have helped make up for the supply shortfall generated by sanctions on Russian gas; and imports of copper from Chile and the Democratic Republic of the Congo filled the gap left by the drop in copper imports from Russia.
  - After trade sanctions were imposed on Russia, EU firms rapidly found new alternative markets, often in countries with an existing

trade agreement with the EU. For instance, sales of vehicles and vehicle parts to Russia, lowered by €8 billion, were offset by higher exports to the UK worth €8.8 billion alone.

On barriers to trade, in 2024, notably:

- 44 trade barriers were fully or partially removed in 27 partner countries. This was accomplished through a combination of diplomatic outreach and the effective use of institutional mechanisms under bilateral trade agreements and in the WTO. Most of these barriers (48%) related to the agriculture and fisheries sector.
- 23 new trade barriers were recorded, up from 16 in 2023; with the highest number of new barriers from the so-called Southern Neighbourhood (Middle East, Turkey, Russia, and Central Asia). Agriculture and fisheries remained the most affected sector.

The accompanying Staff Working Document contains further information (country sheets) on 41 of the EU's major preferential trade agreements.

** For the Fourth Annual Report, see EU Emergency Response Update No. 118 of 4 November 2024.*

European Commission publishes Fifth Annual Report on the Screening of Foreign Direct Investments (FDI) into the EU (see here)

On 14 October 2025, the European Commission published the Fifth Annual Report on the Screening of Foreign Direct Investments (FDI) into the EU.* The Report covers the year 2024 and assesses the application of FDI Regulation 2019/452, which became fully applicable in October 2020.

Background. To recall, the FDI Regulation aims to address concerns over foreign investors seeking to invest in European firms implicating technologies, infrastructure, inputs, or sensitive information critical for more than one EU Member State or on a project of EU interest. It also covers greenfield investments, which typically involve the creation of a new company or establishment of facilities.

The Regulation sets out a framework for identifying risks related to investments in strategic assets that could threaten security or public order. It also establishes a cooperation framework between the Commission and EU Member States for the exchange of information and for raising concerns in notified cases from the Member States that have screening mechanisms.**

The Regulation sets out a framework for EU Member States to identify risks related to investments in strategic assets in their territory that could threaten security or public order. It also establishes a cooperation framework between the Commission and EU Member States for the exchange of information and for raising concerns in notified cases from the Member States that have screening mechanisms.**

This cooperation framework between Commission and the Member States underpins Member States' FDI assessments and facilitates a Member State's ultimate decision where the FDI is planned or completed.

Findings. Among the Report's findings:

- Total FDI inflows experienced a downward trend in the last two years, with declines of 23% from 2022 to 2023 and 8.4% from 2023 to 2024. The Report attributes this to persisting uncertainties affecting the EU economy and investors' risk perception, including Russia's war against Ukraine and additional geopolitical tensions, given the Middle East conflict and escalating global trade tensions.
- Efficiency of reviews under the FDI Regulation in 2024:
  - Of the 477 cases notified in 2024 (488 cases notified in 2023), the Commission closed 92% of these in Phase 1, i.e. within 15 calendar days following the notification by the screening Member States (same as in 2023);
  - The use of detailed assessments remained targeted and limited to exceptional cases, with the Commission requiring only 8% of cases to undergo a second phase involving a more detailed security assessment, with additional information being requested from the notifying Member State. The screening decision then remains the exclusive responsibility of the Member State in which the investment is being made.
- On FDI trends, in particular:
  - The sectors with the highest number of transactions were manufacturing (25% of all transactions), ICT (information and communication technologies) (22%), wholesale and retail (14%), and financial activities (10%).
  - Of the 477 cases notified in 2024, the six main jurisdictions of origin of ultimate investors were the US, the UK, China (including Hong Kong), Japan, Canada, and the United Arab Emirates. Compared to 2023, the share of FDI from US investors notified to the cooperation mechanism significantly increased from 33% in 2023 to 40% of all transactions in 2024.

The accompanying Staff Working Document provides further details on EU Member States' legislative developments in 2024 (see here).

Looking ahead. In view of addressing identified shortcomings in the current FDI system, the Commission presented a proposal in January 2024 to revise the FDI Regulation (see here), which would notably (i) require all EU Member States to have a FDI screening mechanism in place, (ii) introduce a minimum level of harmonization of national screening laws across the EU; and (iii) strive for procedural improvements to the cooperation mechanism.

The Council of the EU and the European Parliament reached a provisional political agreement on the proposal to revise the FDI Regulation on 11 December 2025 (see here), which notably agreed on establishing a common minimum scope for national screening mechanisms and consistency across national mechanisms. The provisional agreement will now be endorsed by the Council and the Parliament before being formally adopted.

* *For the Fourth Annual Report on the screening of FDI, see EU Emergency Response Update No. 118 of 4 November 2024.*

** *As of 25 October 2025, 25 Member States had FDI screening legislation in place (with 24 Member States having screening mechanisms). Croatia and Cyprus are preparing draft laws* (*see here for Commission presentation*).

Council of the European Union extends sanctions against Russia (see here and here)	The EU employs restrictive measures, commonly known as sanctions, as a key instrument to advance its Common Foreign and Security Policy (CFSP) objectives. These objectives include safeguarding the EU's values, fundamental interests, and security; preserving peace; and supporting democracy and the rule of law. Sanctions encompass a range of measures, including travel bans that prohibit entry or transit through EU territories, asset freezes, and restrictions on EU citizens and companies from providing funds and economic resources to listed individuals and entities. Additionally, sanctions may include bans on imports and exports, such as prohibiting the export to Iran of equipment that could be used for internal repression or telecommunications monitoring, as well as sectoral restrictions. **Russia**: Among recent developments: (i) On 23 October 2025, the Council adopted the **19th package of sanctions**.* This sanctions package further intensifies pressure on Russia's war economy, targeting strategic sectors such as energy, finance, and the military industrial base. In particular, the 19th package focuses on: • Further constricting Russia's energy revenues, e.g.: – Introducing a total ban on Russian Liquefied Natural Gas (LNG) for (i) long-term contracts as of 1 January 2027 and (i) for short-term contracts as of 25 April 2026. These represent the strongest sanctions yet on Russia's crucial energy sector. – Taking measures against major third country operators that enable Russia's revenue streams, including by sanctioning Chinese entities (two refineries and an oil trader) that are significant buyers of Russian crude oil. • Intensifying financial sector measures , e.g.: – Expansion of banks subject to transaction bans, such that no EU operator can engage with any of these listed banks, whether directly or indirectly. These include five additional banks in Russia (Istina, Zemsky Bank, Commercial Bank Absolut Bank, MTS Bank, and Alfa-Bank) and four banks from Belarus and Kazakhstan, due to their connections to Russian financial messaging and payment systems. – Clamping down on Russia's widening use of cryptocurrencies to circumvent sanctions by imposing full-fledged sanctions on the developer of the widely used rouble-backed stablecoin A7A5, the Kyrgyz issuer of that coin, and a related major trading platform where significant volumes of A7A5 is traded. For the first time, the new sanctions measures also prohibit the use of this A7A5 stablecoin. – EU operators are banned from providing crypto services and certain fintech services that enable Russia to develop its own financial infrastructure and possibly circumvent sanctions. • Expanding measures against military industry, e.g.: – Widening the application of tighter export restrictions with respect to dual-use goods and items that might generally contribute to the technological enhancement of Russia's defence sector by imposing such restrictions on an additional 45 entities directly supporting Russia's military and industrial complex (for example, by enabling the circumvention of export restrictions on computer numerical control

(CNC) machine tools, microelectronics, unmanned aerial vehicles (UAVs), and other advanced technology items).

Of these 45 entities subject to tighter export restrictions, 17 of them are located in third countries other than Russia (12 in China (including Hong Kong), three in India, and two in Thailand).

- More stringent export bans on items such as salts and ores, construction materials and articles of rubber, valued at some €155 million in EU exports in 2024 prices.

- Introducing service bans, e.g.:
  - Blocking Russian access to advanced digital capabilities within the EU, including certain artificial intelligence, high-performance computing, and space-based services.
  - Requiring prior authorization for any non-prohibited services to the Russian government, ensuring that all such activities are subject to strict scrutiny and oversight.

(ii) On 20 November 2025, the Council imposed **additional restrictive measures against ten individuals for human rights violations in Russia**.

The new measures target, for example, high level officials in the main directorate of the Federal Penitentiary Service of the Russian Federation for the Rostov Oblast. In the facilities under the authority of the listed individuals, the Council reports that least 15 detainees have died as a result of ill-treatment, including Ukrainian investigative journalist Victoria Volodymyrivna Roshchyna.

EU restrictive measures in view of Russia's destabilizing activities now apply to 62 individuals and 1 entity.

Altogether, EU restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine now apply to over 2,700 individuals and entities.

The Council's overview of EU sanctions against Russia over Ukraine (since 2014) is also available here. 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 on 23 February 2022 in adopting the so-called first package of sanctions (see here).

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

European Commission hosts meetings on sanctions implementation with EU Member States and international partners (see here)

On 28 October 2025, the European Commission held two meetings on enhancing sanctions implementation:

(i) The 8th meeting of the High-Level Group on Union Restrictive Measures gathered high-level Commission officials and EU Member State representatives. The discussion focused on strengthening coordination in sanctions implementation and enforcement, which are essential for sanctions effectiveness.

In this respect, Member States shared enforcement "success stories" and ideas on how to tackle new trends emerging in sanctions circumvention by those who seek to enable and profit from Russia's war against Ukraine.

(ii) The 6th Sanctions Coordinators Forum, a bi-annual event, was led by EU Sanctions Envoy David O'Sullivan. The Forum gathered EU Member States and international partners (e.g., Australia, Canada, Japan, New Zealand, South Korea, the UK and the US, as well as Ukraine). Discussions focused on vital common efforts to combat circumvention occurring, in particular, through third country financial institutions and crypto channels.

In announcing these meetings, the Commission noted that successive packages of EU sanctions have led to a substantial decoupling with Russia and heavy costs to Russia's economy. It indicated that EU trade with Russia has been severely curtailed, with the elimination of 74% of pre-war EU imports from Russia (€106 billion) and 58% of pre-war EU exports (€48 billion) to Russia (both in 2021 terms). In particular, revenues for Russia from oil exports to Europe have fallen by 90% over the past three years.

MEDICINES AND MEDICAL DEVICES

European Commission publishes Union prevention, preparedness and response plan (see here)

On 28 November 2025, the European Commission published a Communication on Introducing the Union prevention, preparedness and response plan for health crises ("Union Plan") and accompanying Staff Working Document (see here).* The Union Plan is a key action under the EU Preparedness Union Strategy to tackle cross-sectoral threats and hazards.

Backdrop / purpose: The Union Plan seeks to respond to an era of rising uncertainty and multifaceted threats and risk, with the EU facing a complex and intensifying threat landscape – from pandemics and cyberattacks to disinformation, climate-related disasters, and geopolitical instability. Many of these intersecting threats have the potential to lead to a cross-border health crisis.

The Union Plan provides an EU-level reference framework that aims at providing a coordinated approach to managing serious cross-border threats to health. It is intended to operate in parallel with, and in support of, national prevention, preparedness and response plans. The Plan, in particular, builds on lessons from the COVID-19 pandemic and emphasizes the importance of the development of national plans for health crises and seeks to guide Member States in developing these in coherence with EU frameworks.

The Union Plan, in turn, seeks to:

(i) Cover all-hazards, encompassing all types of disruptive events, irrespective of their nature or cause,

(ii) Adhere to the One Health strategy, reflecting the closely linked determinants for the health of humans, domestic and wild animals, plants, and the wider environment,

(iii) Bring together the whole-of-government at all levels of administration, and

(iv) Draw on the whole-of-society, in view of furthering an inclusive approach preparedness and resilience.

	Scope: The Union Plan covers a wide range of crises, whether natural, accidental or intentional, including those of biological, chemical, environmental and unknown origin, and other cross-border health threats. The Plan is organized around four phases of the health crisis management cycle, setting out existing governance arrangements, coordination mechanisms, and resources available at EU level:** 1. The prevention and preparedness phase emphasizes advance planning, regular reporting and assessment of national preparedness, healthcare system resilience, workforce capacity, vaccination, and the availability of medical countermeasures (e.g., with respect to manufacturing, procurement and stockpiling). 2. The detection and assessment phase focuses on surveillance and public health intelligence (e.g., epidemiological, laboratory and wastewater surveillance, early warning systems, and coordinated national and EU-level risk assessments). 3. The response phase describes how EU coordination mechanisms operate during a crisis (e.g., information exchange, situational awareness, risk and crisis communication, emergency research and funding, and arrangements to support cross-border continuity of care). This phase also explains the procedure for recognizing a public health emergency at Union level, which can enable releasing additional capacities and resources, particularly in relation to the supply of and access to crisis-related medical countermeasures. 4. The recovery phase addresses post-crisis restoration of health systems, evaluation of response measures, and the identification of lessons learned through reviews and simulation exercises, all aimed at enabling better planning. Next steps: Member States are expected to continue aligning their national prevention, preparedness and response plans with the Union Plan where appropriate, participate in regular reporting and assessment cycles, and engage in regular EU-level simulation exercises (involving Member States, EU agencies, and stakeholders) planned from 2026. The European Commission has indicated that the Union Plan will be reviewed and updated over time, based on assessments, simulation exercises, and experience from actual health crises. * *The Union Plan was developed in consultation with Member States and other stakeholders, including via a Call for Evidence held from 1 to 29 October 2025, which received 57 responses, mainly from business associations and non-governmental organizations (see also Jones Day EU Geopolitical Risk Update No. 123 of 8 October 2025).* ** *EU support and coordination mechanisms include bodies such as the EU Health Security Committee, the European Medicines Agency (EMA), and the Health Emergency Preparedness and Response Authority (HERA).*
European Medicines Agency publishes Guidance for	On 17 November 2025, the European Medicines Agency (EMA) published Guidance for Applicants: the ETF (Emergency Task Force) scientific advice that facilitates clinical trial authorisations (SA-CTA)* (“Guidance”).

Applicants: the Emergency Task Force scientific advice that facilitates clinical trial authorizations (see here)	The Guidance sets out the ETF's new approach to providing scientific advice for the most promising medicines and vaccines under development for health threats having the potential to cause public health emergencies, including antimicrobial resistance (AMR). The aim is to accelerate the development of such medicines for use ahead of or during such emergencies. Scope / approach: The Guidance applies to clinical trials conducted in the EU/EEA and within the ETF's scope, such as those focusing on treatments for AMR and other serious health threats. The Guidance describes the formal SA-CTA procedure under which developers of medicines falling within the ETF's remit may seek coordinated scientific advice at an early stage of development. More specifically, under the SA-CTA procedure, applicants can request joint scientific advice that seeks to: • Consolidate views across the EU medicines regulatory network within a single advisory process by covering both clinical trial and marketing authorization considerations, involving the EMA, national competent authorities responsible for clinical trials, and a dedicated group of ethics experts established for public health emergencies; and • Clarify regulatory expectations upfront through this early coordination and promote alignment between clinical trial and subsequent marketing authorization requirements, without altering existing legal frameworks or timelines. Process / outcome: Applications for the SA-CTA procedure are submitted through the ordinary EMA scientific advice route, with additional information triggering the SA-CTA process (e.g., identifying the relevant Member States for the planned trial). The outcome is a consolidated scientific advice letter reflecting input from EU-level and national experts, including ethics expertise, and is intended to support more consistent interpretation of scientific requirements across jurisdictions. The advice letter is non-binding, but applicants remain responsible for justifying any divergence in later submissions for a formal Clinical Trial Application and Marketing Authorization Application. Next steps: Developers working on medicines for serious public health threats may consider whether the SA-CTA procedure is relevant for upcoming EU/EEA clinical trials and factor it into early regulatory strategy. The EMA has indicated that experience with the procedure will be reviewed and may inform future refinements based on feedback from applicants and authorities. ** SA-CTA is defined as a type of scientific advice (SA) offered in the context of the EMA's Emergency Task Force's (ETF) mandate under Article 16 of Regulation (EU) 2022/123 of 25 January 2022 on a reinforced role for the EMA in crisis preparedness and management for medicinal products and medical devices. The SA-CTA's aim is to foster harmonization of scientific advice provided by EU regulatory authorities responsible for either medicines authorization or clinical trial authorization (CTA).*

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission publishes Digital Omnibus proposals to simplify EU digital rules and boost innovation

On 19 November 2025, the European Commission published the following two "Digital Omnibus" proposals as part of a wider Digital Package (see also *Jones Day Commentary, EU Digital Omnibus: How EU Data, Cyber, and AI Rules Will Shift, 19 December 2025*):

(1) The **proposed Digital Omnibus** amends and consolidates substantial portions of the EU's existing digital rulebook—including the General Data Protection Regulation ("GDPR"); ePrivacy Directive; eIDAS Regulation (electronic identification and trust services for electronic transactions); Data Act; and key cybersecurity laws.* Among the proposed changes, these notably concern:

- GDPR:
  - Refined definition of "personal data". The proposal codifies a more "relative" concept of personal data under Article 4(1) GDPR, whereby information qualifies as personal data only if the controller can reasonably identify the individual with the means available to it.
  - Exemptions for processing special-category data.** Limited residual processing of special-category data would be permitted under Article 9 GDPR for developing and operating AI systems/models, and biometric processing would be allowed when performed under the user's sole control for identification.
  - AI development and operation recognized as a legitimate interest. AI development and operation would be expressly recognized as a legitimate interest under Article 6(1)(f) GDPR, although EU Member States may still require consent.
  - Expanded information obligation exemptions. Exemptions from Article 13 GDPR would apply where processing poses low risk and it is reasonable to assume data subjects already know the controller's identity, contact details, and purposes.
- GDPR / eIDAS / cybersecurity laws:
  - Streamlined incident reporting. A higher threshold for data breach notifications is introduced (covering only "high-risk" cases), the notification deadline would extend from 72 to 96 hours, and a single EU-wide reporting portal (piloted by ENISA (EU Agency for Cybersecurity)) would cover incidents under GDPR, eIDAS, NIS2, DORA, and CER.
- ePrivacy Directive:
  - Streamlined cookie rules. ePrivacy cookie provisions would be moved into the GDPR. Consent would remain the default for storing and accessing terminal equipment data, but a closed list of low-risk, consent-exempt purposes would be introduced. Controllers would also be required to honor machine-readable consent, refusal, and objection signals.
- Data Act:
  - Strengthening protections against harmful data sharing, particularly where trade secrets are at risk,

- Limiting mandatory business-to-government data access to clearly defined public emergencies, with compensation for SMEs,
- Consolidating into the Data Act the following: the Free Flow of Non-Personal Data Regulation, the Data Governance Act, and the Open Data Directive, and
- Clarifying smart contract obligations.

* *Key cybersecurity laws include, in particular, the Network and Information Security Directive 2 ("NIS2 Directive"), the Digital Operational Resilience Act ("DORA"), the Critical Entities Resilience Directive ("CER"), and the Digital Identity Regulation*

** *Special categories of data under GDPR Article 9 include, for example, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health, as well as personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs.*

(2) The **proposed Digital Omnibus on AI** streamlines and partially delays elements of the EU AI Act. Among the key amendments, these include:

- New compliance deadlines for high-risk AI. The Commission acknowledges the need for flexibility in deadlines, given delays in standards and other support tools needed to implement the AI Act.

  Thus, AI systems classified as high-risk in sensitive areas such as employment and law enforcement (Annex III) would now need to comply by 2 December 2027, while high-risk AI embedded in products like medical devices (Annex I) would face a later deadline of 2 August 2028.

  However, if the European Commission determines that the necessary standards, specifications, or guidance are already in place, these obligations could take effect earlier: six months after such a Commission decision for Annex III systems and twelve months for Annex I systems.
- Permission to process special-category data for de-biasing. Processing of special-category data under Article 9 GDPR would be permitted for both high-risk AI (as currently foreseen), as well as other AI systems and models.
- Shift of AI literacy obligations. AI literacy obligations on providers and deployers are transferred to the European Commission and EU Member States.
- Expanded role for the AI Office. The AI Office will have competence over AI systems based on general-purpose models, when both the model and system are provided by the same provider (excluding Annex I systems), and over AI systems integrated into designated VLOPs (very large online platforms) / VLOSEs (very large online search engines).
- EU level AI sandbox. The AI Office would be empowered to operate an EU wide sandbox for systems within its remit and enhance cross border coordination among national sandboxes.

Next steps. As the Digital Package's proposals remain in draft form, substantial debate and amendments are expected in order to reach the required approval from the European Commission, European Parliament, and Council of the European Union.

	The Commission's Q&A provides further details on the Digital Package (see here).
EU AI Act - Recent developments	The EU AI Act*, which entered into force on 1 August 2024, aims to guarantee that AI systems placed on the European market and used in the EU are safe and respect fundamental rights and EU values (see also *Jones Day Commentary, EU AI Act: First Rules Take Effect on Prohibited AI Systems and AI Literacy*, *28 February 2025*). Recent developments. Since our previous update (*see Jones Day EU Geopolitical Risk Update No. 123 of 8 October 2025*), new developments on the EU AI Act notably include: • On 8 October 2025, the European Commission published the Apply AI Strategy, a deployment plan that aims to accelerate AI adoption across Europe, structured in three parts: 1. Introduction of sector-specific flagship initiatives to scale AI in ten key industries (e.g., healthcare, mobility, manufacturing, energy, agri-food, defense and space, electronic communications, and cultural and creative sectors), as well as in the public sector. For example, in healthcare, the European Commission intends to establish AI-driven screening centers to speed the rollout of preventive and diagnostic tools and expand services in underserved areas. 2. Tackling cross-cutting challenges to AI deployment, to scale the development and integration of AI across the EU strategic sectors and, ultimately, increase technological sovereignty. Challenges identified include, for instance: – Fostering opportunities for SMEs, which face difficulties in adopting AI, with many of them fearing that AI is too complicated or too expensive; – Building an AI-ready workforce across sectors; and – Supporting AI as a production factor, alongside traditional inputs. 3. Setting out a unified governance framework connecting: (i) the AI Board, as established under the AI Act; (ii) a new Apply AI Alliance, launched on 8 October 2025, to coordinate across providers, industry, academia, and the public sector; and (iii) an AI Observatory to track trends and assess sectoral impacts (launch anticipated in Q2 2026). • On 8 October 2025, the European Commission also published the AI in Science Strategy ("Strategy"), which complements the above Apply AI Strategy. The Strategy is designed to support and incentivize the European scientific community's development and use of AI. To operationalize this, the European Commission will pilot the Resource for AI Science in Europe (RAISE), launched on 2 November 2025 (see here). RAISE is a coordinated vehicle aimed at pooling strategic resources – funding, compute, data, and talent – around two pillars: 1. Science for AI, advancing foundational research with a focus on safe and secure frontier AI; and

2. AI in Science, accelerating the application of AI across scientific disciplines.

In addition, in support of addressing the challenge of developing a robust data ecosystem in Europe, the Data Union Strategy was adopted on 19 November 2025 as part of the Digital Package (see summary above). This Strategy seeks to open new sources of high-quality, large-scale data by enabling businesses and public administrations to share such data, which is essential to facilitate AI solutions to scientific questions and workflows.

- On 24 November 2025, the European Commission launched the AI Act Whistleblower Tool, a secure channel set up by the European AI Office for individuals to anonymously report suspected violations of the EU AI Act. Reports are submitted through an online portal (available here) with a description of the facts and any supporting documents.

  After submission of a report, the AI Office assesses whether it is the appropriate authority, provides feedback on the report's merits within three months (or six in exceptional cases), and communicates the final outcome. It may request additional information or clarifications during the process, though whistleblowers are not required to provide them. Further details are available in the AI Office's FAQs.

* *Regulation (EU) 2024/1689 laying down harmonized rules on artificial intelligence*.

European Commission and EU Member States simulate large-scale cyber-attacks in annual "Blueprint Operational Level Exercise" (see here)

On 4 November 2025, the annual "Blueprint Operational Level Exercise" (Blue OLEx) took place. Senior cybersecurity representatives from the European Commission and EU Member States, with the support of the EU Agency for Cybersecurity (ENISA), simulated large-scale cyber-attacks to test and identify areas for improving the EU's preparedness and standardized responses in cyber-related incidents and crises (*for the 2024 Blue OLEx, see EU Emergency Response Update No. 118 of 4 November 2024*).

This year's exercise was the first conducted after the revised EU Cyber Blueprint was adopted on 6 June 2025, which sets out how the EU, its Member States, and designated coordination bodies should prepare for and jointly manage large-scale cyber incidents.

In particular, the 2025 edition emphasized the role of senior executives in shaping a coherent, EU-level crisis management framework and highlighted practical measures to achieve that objective. Participants worked through scenario-based exercises, examined strategic partnership models, and refined incident response methodologies.

Looking ahead. Insights from this year's Blue OLEx will help shape the EU's Preparedness Union Strategy, launched on 26 March 2025. The Strategy addresses cross-sector threats and hazards across the EU, including cybersecurity risks.

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