

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, Middle East conflict, health threats, and cyber threats. It does not purport to provide an exhaustive overview of developments.

This regular update expands from the previous EU Emergency Response Update (last issue No. 115), and COVID-19 Key EU Developments (last issue No. 99).

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COMPETITION & STATE AID

Important Projects of Common European Interest (IPCEIs) – Speech by Executive Vice-President and Competition Commissioner Ribera (see here)

On 12 October 2026, Executive Vice-President and Competition Commissioner Teresa Ribera provided remarks on the role of Important Projects of Common European Interest (IPCEIs) in safeguarding Europe's industrial future.

To recall, the 2021 *Commission Communication on IPCEIs* sets out the criteria for assessing the public financing of IPCEIs under EU State aid rules. The aim is 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 (*see also Jones Day EU Geopolitical Risk Update No. 122 of 31 August 2025*).*

Commissioner Ribera emphasized that the Commission considers Europe's industrial future to depend on economic security, reducing strategic dependencies, and building industrial capabilities, including by securing critical materials, supplying clean energy, producing advanced semiconductors, and developing artificial intelligence.

Towards attaining these objectives, Commissioner Ribera expressed her view that IPCEIs provide a practical means for Europe to promote connecting national investments around a common European objective, fostering collaboration, and ensuring that the benefits extend beyond the direct recipients of aid.

New IPCEI initiatives. Commissioner Ribera highlighted that the Commission is working with Member States and stakeholders on two major new IPCEI initiatives in:

(i) Advanced semiconductor technologies, which underpin the digital systems and industrial technologies on which the Commission argues Europe's future competitiveness will depend.

This candidate IPCEI would build on the existing 2023 Chips Act pilot lines and European design platform, eventually covering AI chips and accelerators, photonic integrated circuits, sensors, power electronics, energy-efficient solutions and secure communication, spanning the full semiconductor value chain including equipment, testing and materials (see here).

(ii) Artificial intelligence (AI), as European companies are argued to need the capacity to develop AI, shape it to their industrial needs, and compete at scale with its AI developments.

Earlier, on 16 September 2026, the Commission announced the initiative of 19 Member States** to create and pre-notify, under State aid rules, the first IPCEI in the field of AI (see here). The IPCEI AI aims to cover the full AI stack (i.e., collection of technologies, frameworks and infrastructure components that facilitate using AI systems) and to develop advanced and highly innovative AI and compute management technologies and applications, industrial products and services that surpass the state of the art in the sector concerned.

Business sector concerns. Commissioner Ribera acknowledged the business community's call for better predictability, less bureaucracy, swifter decisions and greater flexibility in the IPCEI regime. While the Commission has sought

	to improve connections with other EU funding instruments, as well as develop best practices and templates, Commissioner Ribera recognized the need for further improvements. In this respect, in particular, the Commission has proposed closer ties between the IPCEI regime and the broader European investment framework (such as Horizon Europe, the EU's research & innovation framework programme for 2021-2027 with a budget of €95.5 billion; and the anticipated European Competitiveness Fund proposed in July 2025 to invest in strategic technologies) towards maximizing the impact of Europe's collective investment. On business certainty, Commissioner Ribera further noted that Member States must honor their commitments under IPCEIs, including by delivering their pledged funding, so that companies can invest with confidence and that interconnected projects can proceed together. * *The Commission has thus far approved 11 integrated IPCEI projects that have brought together 332 projects, 257 companies, and 23 Member States, plus Norway, implicating some €38 billion in public funding. For all approved IPCEI projects, see here.* ** *Austria, Belgium, Croatia, Estonia, Finland, France, Germany (serving as coordinator), Hungary, Ireland, Italy, Latvia, Luxembourg, the Netherlands, Poland, Romania, Slovakia, Slovenia, Spain and Sweden.*
European Commission presents Fifth Annual Report on Recovery and Resilience Facility (RRF) (see here)	On 7 October 2026, the Commission presented its Fifth Annual Report on the Recovery and Resilience Facility (RRF).* The Report covers data and information up to 31 August 2026, unless otherwise specified. Backdrop. To recall, the Recovery and Resilience Facility (RRF) is the cornerstone of the €723.8 billion NextGenerationEU package, created in December 2020 to support Europe's pandemic recovery and to respond to geopolitical and energy challenges, towards strengthening Member State's long-term resilience, economic growth and competitiveness. *Disbursements.* The RRF is set to disburse up to €573 billion in grants and loans to EU Member States, whose national recovery plans for implementing the RRF must allocate a significant part of RRF funding to measures for Europe's green and digital transitions. As of 1 October 2026, disbursements under the RRF amounted to €450 billion (79% of total allocation), reflecting 4,082 milestones and targets (out of 5,981 in total) that the Commission had deemed as satisfactorily fulfilled. *Challenges.* The RRF's implementation has faced the challenge of successive crises, and in particular, Russia's war against Ukraine and the consequent energy crisis, high inflation, and supply chain disruptions. In response, Member States modified their national recovery plans by adding chapters reflecting the REPowerEU Plan launched in 2022 (*see also Jones Day EU Geopolitical Risk Update No. 122 of 31 August 2025*), aimed at reducing dependencies and energy imports from Russia and diversifying the EU's energy supplies. Report highlights. These include, in particular:

- *RRF accomplishments.* The Member States' concrete outputs and results stemming from the implementation of RRF measures are featured in so-called common indicators covering 14 areas, such as the following (based on the latest reporting round, ending on 31 December 2025):
  - Deploying over 987,000 new or upgraded clean vehicle recharging stations (up from some 915,000 in end-2025), spurred by investments and reforms supporting charging stations for electric vehicles;
  - Connecting over 18.67 million households to high-speed internet (up from 16 million in end-2025); and
  - Supporting over 1.56 million enterprises to develop digital products, services, and apps (up from 1.2 million in end-2025).

REPowerEU – Middle East and Russia crises. The RRF remains a key instrument for REPowerEU's implementation, with Member State national recovery plans including specific REPowerEU chapters to support reforms and investments to diversify energy supplies, enhance energy efficiency, widen clean energy production, and reinforce the resilience and sustainability of the EU energy system. The Report highlights, in particular, the following:

- *Middle East.* Recent instability in the Middle East and market volatility linked to shipping disruptions through the Strait of Hormuz have further highlighted the continued strategic relevance of the REPowerEU Plan and its objectives and the need to implement corresponding RRF chapters.
- *Russia.* As a result of all measures taken thus far in the context of the REPowerEU plan, the EU reduced the volumes of imported Russian gas from 150 billion cubic metres (bcm) in 2021 to 36 bcm in 2025 (i.e., the share of Russian gas imports dropped from 45% to 12%).

Implementation of measures set out in the REPowerEU chapters of Member State national recovery plans is now moving towards its final stage. Of the 537 milestones and targets included in these chapters, 287 were already reported as completed or assessed by the Commission as satisfactorily fulfilled by 30 April 2026, the end of the latest bi-annual reporting round.

Next steps. As of end-September 2026, all Member States had submitted their final payment requests to complete the milestones and targets reflecting the reforms and investments set out in their recovery and resilience plans (see here). The Commission is now assessing these final 32 payment requests, with the remaining disbursements, amounting to €123 billion (21% of the envelope), to be completed by end-2026.

For an overview of implementation of the RRF and national recovery plans, see the RRF Scoreboard.

* *RRF Regulation (EU) 2021/2411 establishing the RRF entered into force in February 2021 and was amended twice by (i) Regulation (EU) 2023/435 incorporating REPowerEU objectives; and (ii) Regulation (EU) 2024/795 establishing the Strategic Technologies for Europe Platform ('STEP').*

For the Fourth Annual Report on the RRF, see also Jones Day EU Geopolitical Risk Update No. 123 of 8 October 2025.

European Commission approves schemes under Middle East Crisis Temporary State Aid Framework (METSAF) (see here)	The Commission approved additional measures under the Middle East Crisis Temporary State Aid Framework (METSAF) of 5 May 2026 to enable targeted support to the EU economy in response to the impact of the Middle East crisis. The METSAF seeks to allow Member States to act swiftly to shield the most exposed companies in key sectors by providing for, e.g.: – Aid based on actual consumption in agriculture, fishery, land transport, and intra-EU short sea shipping, enabling Member States to compensate up to 70% of a beneficiary's extra costs due to the price increase of fuel and fertilizer caused by the crisis. – A simplified approach for small amounts of aid, allowing Member States to calibrate individual aid amounts on elements such as the size and type of beneficiaries' activities, a general estimate of fuel consumption in the sector (or other relevant proxies), with each beneficiary able to receive up to €50,000. – For eligible energy-intensive industries, a temporary adjustment to the Clean Industrial Deal State Aid Framework (CISAF) of 25 June 2025,* allowing further flexibility and higher aid intensities to address electricity price spikes. Aid intensity can increase from 50% to up to 70% for the electricity cost of eligible consumption. Measures under the METSAF must be notified to the Commission, and the framework aims to allow for a rapid approval process. Among the most recently approved State aid schemes under the METSAF (up to 28 October 2026): – €500,0000 Slovenian State aid scheme for agriculture, fishery and marine aquaculture companies facing increased fuel prices. – €52 million budget increase to a Spanish State aid scheme for agricultural companies facing increased fuel prices. – €23.3 million to support transport companies and €17.2 million to support agricultural, fishery and aquaculture companies in two French State aid schemes to support companies affected by increased fuel prices for a total maximum budget of €40.5 million. – €8 million Maltese State aid scheme to support companies providing scheduled maritime transport of persons and cargo by high-speed craft between Malta and Sicily and that are facing increased fuel prices. – €750,000 Spanish State aid scheme for farmers in the Balearic Islands facing increased fuel prices. – €170 million Bulgarian State aid for farmers facing increased fuel and fertiliser prices. – €25 million French State aid scheme to support companies active in the primary production of fishery products facing increased fuel prices. Looking ahead. The METSAF will be in place until 31 December 2026, and the Commission will keep the content, scope and duration under review in the light of developments in the Middle East and in the general economic situation.

Additionally, in responding to the Middle East crisis, Member States can continue relying on specific State aid rules applicable to sectors covered by the METSAF, e.g., for agriculture, Guidelines for State aid in the agricultural and forestry sectors and in rural areas; for fishery, Guidelines for State aid in the fishery and aquaculture sector; for road and maritime transport, Guidelines on State aid to maritime transport.

** The CISAF replaced the Temporary Crisis and Transition Framework ((TCTF), 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).*

The CISAF 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).

TRADE / EXPORT CONTROLS

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

On 14 October 2026, the European Commission published its Sixth Annual Report on the Screening of Foreign Direct Investments (FDI) into the EU.* The Report covers the year 2025 and assesses the application of FDI Regulation 2019/452, which became fully applicable in October 2020. It will be replaced by the new FDI Regulation 2026/1386, which entered into force on 17 June 2026 and takes effect on 17 January 2028.**

Backdrop. To recall, the EU FDI framework is intended to identify risks related to foreign investors seeking to invest in European firms implicating strategic assets (e.g. technologies, infrastructure, inputs, or sensitive information) critical for more than one EU Member State or a project of EU interest. It also covers greenfield investments, which typically involve the creation of a new company or establishment of facilities.

The Sixth Annual Report highlighted, in particular, that Russia's war against Ukraine and uncertainties over geopolitical developments have brought the need to secure critical raw materials, (advanced) technologies and infrastructure even more into focus.

The EU FDI framework also established 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.

While Member States retain sole competence to approve, condition, or block an investment, the EU cooperation framework underpins Member States' FDI assessments and increasingly reinforces control across the EU, particularly whenever an investment may affect the security or public order of more than one Member State.

All 27 EU Member States now have screening regimes, with the last introduced by Cyprus in April 2026. Six other Member States (Czechia, Lithuania, Luxembourg, Poland, Slovakia and Spain) acted to update and expand existing ones in response to changing circumstances in 2025.

Findings. Among the Sixth Annual Report's findings:

- A sharp rise in FDI screening activity in 2025: National FDI authorities handled 4,773 cases (+52% from 2024) and notified 667 of these to the Commission via the cooperation mechanism (+40% from 2024), the highest annual increase ever recorded.

- Efficiency of reviews under the FDI Regulation:
  - Of the 667 cases notified to the Commission in 2025 (477 cases notified in 2024), 88% of these (92% in 2024) were closed in Phase 1, i.e. within 15 calendar days following the notification by the screening Member States;
  - Of the 667 notified cases, the share of Phase 2 assessments rose by 50% in 2025 to some 80 cases (+12% (up from 8% in 2024)). Phase 2 involves a more detailed security assessment, with the Commission seeking additional information 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 (27% of all transactions (up from 25% in 2024)); ICT (information and communication technologies) (19% (down from 22% in 2024)); financial activities (17% (from 10% in 2024)); and wholesale and retail (13% (from 14% in 2024)).
  - Of the 667 cases notified in 2025, the six main jurisdictions of origin of ultimate investors were the same as in 2024, i.e., the US, the UK, China (including Hong Kong), Japan, Canada, and the United Arab Emirates. Notably, though, the share of FDI from US investors notified to the cooperation mechanism dropped from 40% in 2024 to 33% of all transactions in 2025 (reverting to 2023 level).
  - Among the Member States, Germany and France remained the main destinations for foreign M&As, while Spain and Germany attracted the largest number of greenfield projects.

The accompanying Staff Working Document provides further details on EU Member States' legislative developments in 2025.

* *See also Jones Day Commentary (October 2026): Beware of FDI Screening: EU Figures Show Rising Impact on Investments (here).*

For the Fifth Annual Report on the Screening of FDI, see Jones Day EU Geopolitical Risk Update No. 124 of 30 November 2025.

** *The new FDI Regulation notably introduces a mandatory common minimum EU standard for national FDI screening regimes, while allowing Member States to have stricter national rules (see also Jones Day Commentary (July 2026): Foreign Investment Screening in the EU: Revised Regulation to Take Effect in 2028 (here).*

European Commission releases Sixth Annual Report on Implementation	On 28 September 2026, the European Commission released its Sixth Annual Report on the Implementation and Enforcement of EU Trade and Economic Security Policy, covering the year 2025.

and Enforcement of EU Trade and Economic Security Policy (see here)	The Report emphasizes that in a "rapidly deteriorating" international environment, the EU's large network of trade agreements has served to strengthen its geopolitical presence. In particular, the EU's trade agreements: • Facilitate access of EU operators to export markets, e.g.: – As of end-2025, the EU had 44 preferential trade agreements with 76 partners, accounting for 46.3% of total EU external trade. – EU trade with preferential partners increased by 3.1% between 2024 and 2025, while trade with non-FTA (free trade agreement) partners increased 1.4%. To illustrate: ○ The EU-Canada Comprehensive Economic and Trade Agreement (CETA), first provisionally applied in 2017, has increased the EU's gross domestic product by some €3.2 billion each year; with a 71% increase in bilateral trade in goods and services between the EU and Canada (from €72.2 billion in 2016 to €123 billion in 2023). ○ EU agri-food exports to preferential partners grew by 4.6%, while EU exports to non-FTA partners decreased by 3.6%. • Support supply chain resilience and reduce dependencies, e.g.: – The €54.5 billion fall in EU exports of goods to Russia was more than offset by an increase of over €250 billion in exports to EU FTA partners. For example, the €7 billion decrease in electrical machinery exports to Russia was offset by higher exports (€9 billion) to trading partners such as Mexico, Norway, Switzerland, and the UK. – EU critical raw materials imports from Canada increased by 62% to €3.3 billion, and imports from the Democratic Republic of Congo increased by 79% to €2.9 billion. China and the US. In the midst of geopolitical tensions, economic fluctuations and shifts in trade policies, one of the EU's main challenges has been to manage "volatile relations" with China and the US, the EU's largest non-preferential trading partners. Among the EU's efforts to address these challenges: – US. The EU and US signed a Memorandum of Understanding on a strategic partnership on critical minerals on 24 April 2026 (see here). The Partnership covers critical minerals along the entire value chain and life-cycle management (e.g., exploration, extraction, processing, refining, recycling and recovery), in accordance with applicable domestic laws and international obligations. – China. The EU made progress on ensuring the ability of European technology companies to effectively defend their intellectual property rights. Notably, the WTO appeal arbitrator's award on 21 July 2025 in the EU's dispute with China on the enforcement of intellectual property rights (DS611) marked a significant win for EU standard essential patent (SEP)** holders (see here). The arbitrator's decision safeguards the protection of European innovators' rights in key technologies, such as 5G and wireless, which are important assets for the EU economy.

	* *For the Fifth Annual Report, see Jones Day EU Geopolitical Risk Update No. 124 of 30 November 2025.* ** *SEPs are the patents necessary for a product or technology to meet specific industry standards, such as those used in mobile communications.*
Council of the European Union discusses and extends sanctions against Russia	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. Among recent developments implicating Russia: • On 12 October 2026, the Council adopted the largest-ever package of listings, targeting 1569 individuals and entities in Russia's military and industrial complex (see here), comprising 826 Russian companies and 743 individuals serving as CEOs of these companies. In particular, the package targets mid-level suppliers of key components to some of Russia's most advanced weapons systems, such as missiles, aircraft, and UAVs (Unmanned Aerial Vehicles (drones), which represent the "core" of the Russian military industry and generate an annual turnover of at least €20 billion. • On 12 October 2026, the Council added three individuals and four entities under its autonomous sanctions list on the Democratic People's Republic of Korea (DPRK) over programmes related to nuclear weapons, missiles, and other weapons of mass destruction (see here). The new listings target activities linked to the growing military and economic cooperation between Russia and the DPRK, including the deployment of DPRK workers in Russia, commercial and industrial cooperation, and the "arms-for-oil" trade. • On 8 October 2026, the Council prolonged restrictive measures until 9 October 2027 (see here) against those responsible for Russia's destabilizing actions abroad (80 individuals and 20 entities), given Russia's continued and intensified hybrid activities, including Foreign Information Manipulation and Interference (FIMI) against the EU and its Member States and partners. Altogether, EU restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine now apply to nearly 4,600 individuals and entities, who were targeted in response to Russia's ongoing unjustified military aggression against Ukraine. The current restrictive measures include travel restrictions for natural persons, the freezing of assets, and a ban on making funds or other economic resources available to the listed 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) and up to the present 21st package of sanctions** (see also Jones Day EU Geopolitical Risk Update No. 128 of 22 September 2026).

** *An in-depth analysis of the 21st 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)).*

MEDICINES AND MEDICAL DEVICES

Proposed Pharma Package nears completion with formal endorsement of Council of the European Union (see here)

On 28 September 2026, the proposed "Pharma Package" (see here) moved one step closer to becoming law, with the Council's adoption of a position that fully reflects the political agreement reached between the European Parliament ("EP") and the Council on 11 December 2025 (*see also Jones Day Commentary "The EU Pharma Package Is a Done Deal: a Holiday Gift, or Not?" of December 2025*).

The proposed Pharma Package, which consists of a proposed Regulation and a proposed Directive (see here and here), is the first comprehensive reform of the EU pharmaceutical legislation in 20 years and will completely overhaul and replace the current pharmaceutical legislative framework.* The new set of rules seeks to balance innovation incentives with broader and earlier access to medicines.

The initial Commission Proposal for the Pharma Package was published in April 2023 (see here and here) ("Commission Proposal") (see also Jones Day *EU Emergency Response Update – Key Policy & Regulatory Developments No. 102*, May 2023). The Council and EP deviated from the Commission Proposal on various aspects, such as:

- **Regulatory protection –** Pre-clinical and clinical data protection / Market protection:

  The current legislative framework provides eight years of data protection (such that generic and biosimilar companies cannot rely on an originator's pre-clinical and clinical data in their own applications). This is followed by two additional years of market protection, during which generics and biosimilars can be filed and approved, but cannot be placed on the market. The originator can get one extra year of market protection for a new therapeutic indication** with significant clinical benefit. This gives the familiar "8+2+1" model, up to 11 years in total.

  The Commission Proposal set forth a modulated approach to cut the baseline data protection from eight to six years. Extra periods would then be earned: two years for launching in all Member States where the product is authorized; six months for meeting an unmet medical need; six months for running comparative trials; and one year for a new indication. Market protection would have stayed at two years, for a maximum of 12 years in total.

The Council's adoption of the terms of the political agreement keeps the baseline of eight years of data protection. In exchange, it cuts market protection to one year and moves the modulated approach to the market protection period, which can be extended:

- by 12 months for medicines that meet an unmet medical need, or for new active substances backed by comparative trials together with an EU-first filing (or filing within 90 days) or trials in several Member States;
- by one further year for a new therapeutic indication with significant clinical benefit.

Market protection is capped to a total of two years, plus the new therapeutic indication year. That gives a maximum of 11 years, or 12 where a priority antimicrobial voucher adds a year of data protection.

- **Tackling antimicrobial resistance ("AMR")**. The proposed Pharma Package seeks to strengthen the combat against AMR, one of the most significant current health threats, i.e., when bacteria and other microbes stop responding to existing antimicrobials. The problem is exacerbated by market failure, since developing new antimicrobials is expensive, but these treatments must be used sparingly, which keeps sales low and discourages investment.

  In response, the Commission Proposal aimed to reward the development of "priority antimicrobials" *** through "transferable data exclusivity vouchers," which give 12 months of extra data protection. The developer can use it on any centrally authorized product of its own, or sell it once to another EU-centrally authorized product of the marketing authorization holder's choice, subject to certain safeguards. The Commission proposed up to 10 vouchers over 15 years.

  The Council's adoption of the terms of the political agreement keeps the voucher, but makes it considerably harder to obtain and use. In particular:

  - Eligibility for the voucher is limited to antimicrobials that address multi-drug-resistant organisms and are filed in the EU first, or within 180 days of the first filing elsewhere.
  - To avoid overcompensation, a "blockbuster clause" was added such that the voucher cannot be used in relation to products with annual gross sales over EUR 490 million during any of the first four years after their marketing authorization.
  - The number of vouchers is halved to five over 15 years.

- **Orphan exclusivity**:

  The Commission Proposal's tiered approach varied the length of market exclusivity by product type: 10 years for products addressing a "high unmet medical need," nine years as the standard, and five years for well-established-use products.

  The Council's adoption of the terms of the political agreement keeps the tiered approach, but widens the gap between the tiers. It gives 11 years to a new category of "breakthrough" orphan medicines (which must treat a condition that has no authorized treatment and clearly reduce illness or death); keeps nine years as the standard; and cuts well-established use to four years. An additional year of market exclusivity is possible twice for one or more therapeutic indications for a different orphan condition.

	All of these additional years amount to a maximum 13 years of market exclusivity. • **Security of supply obligations**: The scope of application of shortage prevention plans was narrowed and is now only required for prescription medicines and for products that the Commission specifically designates. All other products need a regular documented supply-chain risk assessment, to be submitted within two days if requested by the competent authority. Next steps. The proposed Pharma Package now awaits the European Parliament's adoption before it can be published in the EU's Official Journal and enter into force. Most of the provisions of the adopted Directive and Regulation will apply two years after their entry into force, with some exceptions. * *The proposed Directive and Regulation are complementary and replace four existing legal acts: The Community code on medicinal products for human use (Directive 2001/83/EC); Regulation (EC) No 726/2004 establishing a European Medicines Agency (EMA); Paediatric Medicines Regulation (EC) No 1901/2006; and Orphan Medicines Regulation (EC) No 141/2000.* ** *A therapeutic indication is the primary information on the use of a medicine. It should clearly state the disease/condition and population that a medicine is intended to treat.* *** *A priority antimicrobial must show significant clinical benefit against AMR and also either (a) belong to a new class; (b) have a distinctly new mechanism of action; or (c) contain a new active substance that addresses a multi-drug-resistant organism and a serious infection.*
EU Health Security Committee discusses climate change, public health preparedness and mosquito-borne diseases (see here)	On 27 and 28 October 2026, the EU Health Security Committee ("HSC") held a senior-level meeting to discuss, in particular, the impact of climate change on health, the rise in mosquito-borne diseases, civil-military cooperation, and vaccination as a crucial preventative measure. To recall, the HSC coordinates the EU's rapid response to serious cross-border threats to health. It is also the main forum where countries share information on their national measures.* Together with the Commission, the HSC sets the actions to be taken on preparedness, planning, risk and crisis communication, and response (see here). This high-level HSC meeting brought together representatives from the EU and EEA countries, the European Commission, and specialized agencies (e.g., European Centre for Disease Prevention and Control; European Medicines Agency, and European Environment Agency). The meeting, in particular, adopted new opinions on: – Mosquito-borne diseases (see Opinion here), which identifies priority areas for strengthening action at EU and Member State level in the face of mosquito-borne diseases and their control measures, which pose a multidimensional challenge affecting human health, animal health and the environment; and – Preparedness and resilience of critical healthcare infrastructure (Opinion not yet published), which provides several action points for the EU and Member States to prepare for and mitigate impacts on

	critical health infrastructure during crises. In particular, the Director for Logistics of the Military Staff – European External Action Service stressed the importance of having civil-military interdependence and cooperation during emergencies to ensure they can work efficiently. Additionally, the HSC followed up on its earlier Opinion on extreme heat and heatwaves of 30 July 2026 (see here), including anticipating a workshop to exchange lessons learned following the severe heatwaves and extreme heat events of 2026. * *HSC comprises representatives of EU countries' health authorities with EEA countries, candidate and potential candidate countries participating as observers.*
European Commission adopts the EU4Health financing and 2026 work program (see here)	On 19 October 2026, the European Commission adopted the Implementing Decision on financing of the EU4Health Programme (Programme for Union's action in the field of health) and adopting the EU4Health Work Programme for 2026. To recall, the EU4Health Programme is the EU's €4.4 billion Programme for action in the field of health for the period 2021-2027 (established by Regulation (EU) 2021/522). Created in 2021, the Programme is the EU's main financial instrument for funding EU health initiatives, as implemented through annual work programs. Its objectives are to: • improve public health through disease prevention and health promotion; • protect people from serious cross-border health threats; • improve access to medicinal products, medical devices and crisis-relevant products; and • strengthen national health systems, including through better use of health data and the implementation of EU health legislation (see here). Through the 2026 Work Programme, with a budget of €680.68 million, the Commission will financially support EU health priorities across key strands such as: 1. Crisis preparedness, which is allocated €429.70 million, including, e.g.: – €165 million for "ever-warm" vaccine manufacturing capacity; – €86 million to accelerate the development of medical countermeasures; and – €70 million ceiling for emergency purchases of medical countermeasures. 2. Health systems and healthcare workforce, allocated €111.03 million, including, e.g.: – €40 million for new or expanded EU manufacturing capacity for critical medicines and their active substances, following the political agreement on the proposed Critical Medicines Act reached on 12 May 2026; – €10.9 million for multinational biotech clinical trials, in preparation for the European Biotech Act proposed in December 2025; and

	– €15.8 million for implementing the EU rules on medical and in vitro devices. 3. Digital health, allocated €46.15 million, including, e.g.: – €44.15 million for implementing the European Health Data Space, which establishes a common framework for the use and exchange of electronic health data across the EU; and – €2 million for AI in healthcare, such as by supporting the design of the ecosystem for multimodal AI driven prevention and early detection of neurodegenerative diseases. Most calls and tenders are expected to be published in Q4 2026. A summary of the EU4Health Work Programme for 2026 is available here.
EU-China Trade and Investment Consultations – Towards addressing market access for pharmaceuticals and medical devices (see here)	On 9 October 2026, Maroš Šefčovič (European Commissioner for Trade and Economic Security, Interinstitutional Relations and Transparency) and Wang Wentao (Minister of Commerce of China) issued a Joint Statement following the second meeting of the EU-China Trade and Investment Consultations (TIC) in Beijing. As key trading partners, the two sides reiterated their commitment to appropriately handling differences under the framework of WTO rules and to working to stabilize and make the bilateral relationship more balanced. In the area of healthcare, the Joint Statement agreed to: • Follow-up on consultations on their respective pharmaceutical (and cosmetics) related regulatory frameworks, in view of further addressing existing and emerging market access barriers; and • Continue to engage in dialogue on market access of medical devices. The EU welcomed China's effort to increase the import of medical devices from the EU, including through a matchmaking event during the 9th China International Import Expo (5-10 November 2026), one of the biggest trade fairs in China. In particular, the matchmaking event: – aimed to support the increase of imports of EU-made medical devices in China by connecting EU manufacturers with Chinese buyers, showcasing European medical technologies, and exploring new commercial opportunities; and – included a government-to-business session to discuss policies impacting foreign medical device suppliers in China and engage with companies. MedTech Europe, which represents the interests of the medical technology industry in Europe, commented that the matchmaking initiative: "…*underlines the importance of our sector in the bilateral trade relationships. Thank you to the European Commission and Ministry of Commerce, China (MOFCOM) for convening this exchange and for advancing market access discussions*." Looking ahead. A third TIC ministerial meeting will be held in March 2027. In the interim, the EU and China will maintain close communications, including a ministerial video-conference planned in January 2027.

CYBERSECURITY, PRIVACY & DATA PROTECTION

EU and Ukraine hold 5th Cyber Dialogue (see here)

On 9 October 2026, the EU and Ukraine held their 5th Cyber Dialogue, in Brussels.

Against the backdrop of Russia's war against Ukraine and an increasingly complex cyber threat environment, the Dialogue's core topics included:

- Expanding cybersecurity cooperation.
  - A major practical outcome of the Dialogue was the signing of an Administrative Arrangement between Ukraine's SSSCIP (Administration of the State Service of Special Communications and Information Protection of Ukraine) and the EU's CERT-EU (Cybersecurity Service for the Union institutions, bodies, offices and agencies).

    This Administrative Arrangement establishes a direct channel for sharing cyber incident intelligence between CERT-EU and its Ukrainian counterpart (CERT-UA), which operates under the SSSCIP. This initiative is expected to ramp up both parties' capabilities to detect, prevent, and mitigate the impact of cyberattacks.
  - Ukraine reaffirmed its readiness to continue sharing its unique expertise and operational insights to support the EU's efforts to counter state-sponsored cyber threats and malicious cyber activity.

- Aligning Ukrainian legislation with European standards. The participants discussed, in particular, Ukraine's advancement in implementing the EU's 5G Cybersecurity Toolbox,* as a key priority for the security of the telecommunication networks and an economic backbone for the EU and Ukraine's economies.

The EU also advances shared interests in cybersecurity policy in the context of other bilateral Digital Partnerships and Digital Dialogues, including Cyber Dialogues with Brazil, India, Japan, the Republic of Korea, and the UK (see here).

* *The 5G Cybersecurity Toolbox (2020) sets out measures to strengthen security requirements for 5G networks, to apply relevant restrictions for high-risk suppliers, and to ensure the diversification of suppliers.*

Building on work already carried out under the current 5G Cybersecurity Toolbox, a proposed revised EU Cybersecurity Act, released in January 2026 (see here), would notably enable the mandatory derisking of European mobile telecommunications networks from high-risk third-country suppliers. The proposed revised Cybersecurity Act is one component of the EU's proposed new Cybersecurity Package (see also Jones Day EU Geopolitical Risk Update No. 126 of 16 October 2025).

European Commission publishes Study on strategic digital technologies for EU Research and Innovation funding

On 29 September 2026, the European Commission released a Study on strategic digital technologies for EU Research and Innovation funding beyond 2027 ("Study").

Aims. The Study seeks to assist with identifying the critical digital technologies that the EU should prioritize for investment in research, development, and innovation under the next proposed nearly €2 trillion Multiannual Financial

beyond 2027 (see here)	Framework – A dynamic EU Budget for the priorities of the future (MFF 2028–2034).* The Study's findings will inform the future digital component of Horizon Europe, the EU's key funding programme for research and innovation, and identifies the critical research trends with disruptive potential for the European digital leadership ambitions. The Study's analysis draws on extensive research, stakeholder and experts' consultation, and foresight exercises including a series of focus groups and workshops. Among its key findings: • Europe is lagging in critical digital technologies. – The EU's performance in scientific excellence has been stagnant and falls behind China and the US across all digital technologies, as measured by EU publications ranking in the top 1% or top 10% most cited globally. – The EU trails the US, China, and Japan in patent applications across most digital fields (except for Quantum and Photonics), with research not consistently reaching the global top tier and a limited ability to commercialize research. • Opportunities – Building on Europe's important assets. Despite the challenges in digital research and innovation, several key drivers are anticipated to boost the EU's future position, such as. – The presence of over 60,000 EU tech companies (mainly in AI and cybersecurity) developing critical digital technologies and driving private research & innovation (R&I). These companies form the basis of the EU's next opportunities in such technologies. – The EU landscape of 12 key digital technology areas has attracted a total of €82 billion in venture capital since 2015. Investment in European start-ups has grown significantly since 2015, with early-stage funding more than doubling and growth-stage funding tripling. – The EU has various strengths and opportunities in targeting R&I investments on research objectives that cross-fertilize various technology areas (e.g., cybersecurity and digital identity technologies providing a more secure continuum through end-to-end protection and user-centric privacy). • The Study sets out 30 recommendations, such as: – Focusing on investing in emerging disruptive R&I domains to develop Europe's lead in technology subdomains expected to have high impact (e.g., Explainable and Trustworthy AI, Cryptography, DNA-based data storage, Nanorobotics). – Strengthening and prioritizing R&I in energy-efficient digital technologies, as energy efficiency emerges as a strategic, cross-cutting priority across all technology domains. Europe should actively invest in next-generation, low-power AI computing technologies (e.g., energy efficient AI accelerators (AI chips) that enable high-performance computing while reducing energy consumption and overcoming the limitations of conventional chip designs). – Allocate greater emphasis to strategic public-private collaboration to increase the likelihood that funded research will deliver advances of

	direct relevance to real-world challenges. This collaboration should be embedded throughout the research lifecycle (e.g., through co-designed research agendas, joint programme governance, and co-investment mechanisms within European Partnerships and Joint Undertakings (see here)). For the Study's summary report on stakeholder and expert consultations, see here. * *An agreement on the proposed Budget is targeted by end-2026 to allow the EU to adopt the related legislation in 2027, in time for the start of the next budgetary period on 1 January 2028.*
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. Recent developments. Since our previous update (*see Jones Day EU Geopolitical Risk Update No. 127 of 21 June 2026*), new developments on the EU AI Act notably include: • On 12 October 2026, the Commission published the first harmonized standard supporting implementation of the EU AI Act, as set out in Implementing Decision (EU) 2026/2274 on the harmonised standards for high-risk AI systems drafted in support of the AI Act. Key milestone in implementing the AI Act. The Implementing Decision formally recognizes that providers of high-risk AI systems that comply with the new standard EN 18286:2026 (Artificial intelligence - Quality management system (QMS) for EU AI Act regulatory purposes) will benefit from a presumption of conformity with the AI Act's Article 17, which requires providers of high-risk AI systems to implement and maintain a documented QMS covering the full lifecycle of their AI systems. It is the only AI QMS standard with a presumption of conformity. Developed by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), Standard EN 18286:2026 addresses, in particular, regulatory compliance strategies, testing and validation procedures, data management processes, and serious incident reporting mechanisms. Looking ahead. Additional harmonized standards are expected to be developed by CEN and CENELEC to support compliance with other requirements of the EU AI Act, including those relating to risk management, transparency, accuracy, cybersecurity, and human oversight. Compliance with such standards will also confer a presumption of conformity with the corresponding obligations under the EU AI Act. • On 9 October 2026, the Commission convened a special meeting of the AI Scientific Panel ("Panel") to discuss recent AI safety concerns and emerging technical developments (see here).

The Panel, established under the EU AI Act (Article 68), is composed of 60 independent experts from the EU and worldwide (e.g., Canada, China, Egypt, Ukraine, UK, US) who support the implementation and enforcement of the AI Act,** particularly by advising the AI Office on general-purpose AI models and systems***.

The Panel is investigating several recent "loss of control" incidents involving advanced AI systems that reportedly exhibited unexpected or concerning behavior. Discussions focused on, particular:

- The facts currently known, key unresolved questions, and the additional information needed from the companies that developed the affected models.
- Recent technical developments, including evidence relating to the potential for recursive AI self-improvement (i.e., AI systems autonomously improving their own capabilities or those of successor systems) and advances in training techniques that may reduce the monitorability of AI systems, complicating future oversight and risk mitigation efforts.

Recommendations. The Panel presented recommendations aimed at strengthening frontier AI safety and security, such as:

- Ensuring governance of the risk posed by internal models throughout development and testing;
- Improving the EU's capacity to detect, evaluate and investigate serious AI incidents, including through a task force preparing the technical and procedural groundwork for future investigations; and
- Establishing an international initiative to facilitate information-sharing and common requirements for frontier AI developers, in addition to joint crisis response and prevention.

For opening remarks to the special Panel meeting by the Executive Vice-President and European Commissioner for Digital Services, Henna Virkkunen, see here.

* *Regulation (EU) 2024/1689 laying down harmonized rules on artificial intelligence* (*see also Jones Day Alert, European Commission Publishes Final Code of Practice on Marking and Labelling AI-Generated Content, June 2026; and Jones Day Commentary, EU AI Act: First Rules Take Effect on Prohibited AI Systems and AI Literacy, 28 February 2025*).

*** Experts were selected based on ensuring top-tier expertise, as well as geographic balance (at most 3 nationals from each country) and gender balance. Most experts work in academia, while others work in organizations linked to the public sector, independent research, or civil society.*

**** A "general-purpose AI model" is defined by the EU AI Act as an AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications.*

A "general purpose AI system" is defined by the EU AI Act as "an AI system which is based on a general-purpose AI model and which has the capability to serve a variety of purposes, both for direct use as well as for integration in other AI systems."

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