

# EU GEOPOLITICAL RISK UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

No. 118 | 4 November 2024

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 <u>Jones Day COVID-19 Key EU Developments – Policy & Regulatory Update</u> (last issue <u>No. 99</u>) and <u>EU Emergency Response Update</u> (last issue <u>No. 115</u>).

## LATEST KEY DEVELOPMENTS

## **Competition & State Aid**

- European Court of Auditors releases Special Report on State aid in times of crisis
- European Commission approves further schemes under Temporary Crisis and Transition Framework to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies

## **Trade / Export Controls**

- European Commission publishes Fourth Annual Report on Screening of Foreign Direct Investments
- European Commission releases Fourth Annual Report on Implementation and Enforcement of EU Trade Agreements

## **Medicines and Medical Devices**

- European Commission publishes factsheet "Overcoming the COVID-19 pandemic together and building a Health Union"
- European medicines agency network publishes draft strategy 2028
- EMA announces initiatives to improve efficiency of approval process for new medicines in EU

#### Cybersecurity, Privacy & Data Protection

- European Commission and EU Member States simulate large-scale cyber-attacks in annual "Blueprint Operational Level Exercise"
- European Commission publishes NIS2 Implementing Regulation on critical entities and networks

## **COMPETITION & STATE AID**

European Court of Auditors releases Special Report on State aid in times of crisis (see here) The European Court of Auditors (ECA) released a Special Report on 31 October 2024 on "State aid in times of crisis – Swift reaction but shortcomings in the Commission's monitoring and inconsistencies in the framework to support the EU's industrial policy objectives."

<u>Backdrop</u>. In recent years, the European Commission introduced three temporary State aid frameworks. These were intended to enable Member States to support companies affected by (i) the COVID-19 pandemic in 2020, (ii) Russia's invasion of Ukraine in 2022, and (iii) the <u>European Green Deal</u> in 2023 by prolonging certain main features of the Ukraine crisis framework, as well as by introducing new measures (applicable until 31 December 2025) to further accelerate investments in key sectors for the transition towards a net-zero economy.

As a result, State aid spending in the EU nearly tripled, from a pre-crisis level of some €120 billion per year to surpassing €320 billion in both 2020 and 2021, and almost €230 billion in 2022.

<u>Findings</u>. The Special Report focuses on the Commission's effectiveness in adapting the State aid framework to respond to the above-referred economic disturbances, in addition to assessing the consistency of the State aid framework supporting the European Green Deal and other industrial policy objectives. According to the ECA, in particular:

(i) The Commission rapidly adopted the COVID-19 and Ukraine temporary crisis frameworks, which enabled Member States to act promptly by establishing a common framework for national aid measures, providing legal certainty to Member States, and limiting their administrative burden. However, such rapid action also meant that Member States had very limited time to provide feedback to the Commission on these crises frameworks.

State aid is also increasingly used to support <u>industrial policy goals</u> such as enhancing the EU's strategic independence and the transition towards a net-zero economy. <u>However</u>, the EU currently has a complex set of State aid rules that are not always consistent or supported by sufficient economic analysis.

- (ii) On <u>assessing crisis-related State aid</u>, the Commission often lacked details on Member State measures implemented under the temporary crisis frameworks, notably in relation to "<u>umbrella schemes</u>" (e.g., combining several crisis response measures and aid instruments (such as grants, loans, or tax relief)). In particular, the national conditions for granting the umbrella scheme aid were unknown, as support measures underlying such schemes were not assessed or subject to the Commission's approval.
- (iii) On monitoring of State aid to verify whether Member States were complying with State aid decisions and rules, the Commission has faced significantly higher State aid expenditure since 2020. However, during the crises, the Commission temporarily reduced its periodic monitoring of State aid, resulting in limited coverage of national schemes, before resuming annual monitoring in 2024. Furthermore, when examining the Commission's 2022-2023 monitoring exercise, the ECA considered the Commission's risk assessments as inadequately documented and that

these did not allow the ECA to conclude that all potential risks had been systematically identified and evaluated.

(iii) On <u>transparency</u>, the ECA's audit visits found that not all Member States reported comprehensive and accurate data on State aid to the Commission. The ECA considers that the <u>Commission currently lacks complete and reliable data on the State aid granted by Member States</u>, including a lack of data on overall amounts of such aid, nor the amounts granted to different economic sectors, including those where the EU is pursuing an active industrial policy (e.g., batteries, hydrogen, semiconductors).

Furthermore, the ECA considers that <u>required transparency regarding the</u> <u>beneficiaries of State aid is currently not ensured</u>, due to an inconsistent framework for transparency and with some Member States not meeting their transparency obligations.

<u>Recommendations</u>. To address the ECA's concerns, the Special Report provides various recommendations to the Commission, such as:

- Strengthening the assessment and monitoring of State aid schemes (target implementation date: 2025);
- Enhancing the transparency of State aid and improving State aid reporting for evidence-based policy making (target implementation date: (a) when adopting a future framework and (b) 2026).

For the Commission's response to the Special Report, see <a href="here">here</a>.

European Commission approves further schemes under **Temporary Crisis** and Transition Framework to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies (see here)

The Commission approved additional measures under the State aid Temporary Crisis and Transition Framework (TCTF) to support the economy in the context of Russia's invasion of Ukraine and in sectors key to accelerating the green transition and reducing fuel dependencies (as most lately amended on 2 May 2024 and 20 November 2023).

Among the most recently approved State aid schemes under the TCTF (up to 4 November 2024):

- — €84 million (BGN 164 million) Bulgarian scheme to support producers of grain and oilseed crops, and €84.9 million (BGN 166 million) scheme to support farmers in the context of Russia's war against Ukraine.
- €180 million Lithuanian scheme to support electricity storage to foster the transition towards a net-zero economy
- €520 million Luxembourgish schemes to foster the transition to a netzero economy.
- €500 million Romanian scheme to support investments in biofuel production capacity to foster the transition to a net-zero economy.
- €1.2 billion Polish scheme to support investments in electricity storage facilities to foster the transition to a net-zero economy.
- €120 million French scheme to support winegrowers in the context of Russia's war against Ukraine.

## TRADE / EXPORT CONTROLS

European
Commission
publishes Fourth
Annual Report on
Screening of
Foreign Direct
Investments (see
here)

On 17 October 2024, the European Commission published the Fourth Annual Report on the Screening of Foreign Direct Investments (FDI) into the Union.\* The Report covers the year 2023 and assesses the application of the FDI Regulation 2019/452, which became fully applicable in October 2020.

To recall, the FDI Regulation seeks to address concerns over foreign investors seeking to invest in European firms implicating technologies, infrastructure, inputs, or sensitive information critical for more than one Member State or on a project of Union interest. It also covers greenfield investments. The Regulation sets out a framework for identifying risks related to investments into strategic assets that could threaten security or public order. It also establishes a cooperation framework between Member States and the Commission, underpinning Member States' FDI assessments and facilitating a Member State's ultimate decision where the FDI is planned or completed.

The Report addresses areas such as the following:

Russia's war against Ukraine, Middle East conflict, and other geopolitical tensions. The Report notes the repercussions of these persisting and cumulating uncertainties affecting the EU economy:

- The Report notes a <u>downward trend in FDI into the EU in 2023</u> after a strong post-Covid recovery in 2021. <u>Foreign acquisitions</u> slowed annually in 2022 compared to 2021 (-5.4%) and once again in 2023 (-13%) compared to 2022. For <u>greenfield investments</u>, a 7.1% annual increase was recorded in 2022 compared to 2021, but the flow of projects into the EU declined significantly in 2023 compared to 2022 (-33%). In 2023, the EU received 1,885 foreign deals (down from 2,156 in 2022), and 1,902 foreign greenfield projects (down from 2,858 in 2022).
- New and emerging risks to security have brought a <u>continued focus on critical (advanced) technologies and infrastructure</u> (e.g. energy, space, defence sectors). Consequently, many Member States have either adopted new national screening mechanisms (7 Member States) or updated and expanded existing ones (10 Member States) in reaction to evolving circumstances. In 2023, 24 EU Member States had FDI screening legislation in place, with the remaining three Member States (Croatia, Cyprus, and Greece) having taken concrete steps towards such legislation.

## Efficiency of reviews under the FDI Regulation in 2023:

- 18 Member States notified a total of 488 transactions to the Commission under the cooperation mechanism, and the Commission closed the large majority (92%) of these within 15 days;
- 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.

On FDI trends, in particular:

- Most cases concerned manufacturing, ICT, and wholesale & retail
   (58%) in various industries, such as electrical equipment, defense,
   pharmaceuticals, data processing, telecommunications, and software.
- Of the 488 cases notified in 2023, the six main jurisdictions of origin of ultimate investors were the US, the UK, United Arab Emirates, China (including Hong Kong), Canada, and Japan. Compared to 2022, the share of the US as an investor slightly increased from 32% in 2022 to 33% of all transactions in 2023.

The accompanying <u>Staff Working Document</u> provides further details on the Report (see here).

<u>Looking ahead</u>. The Commission has conducted an extensive evaluation of the FDI Regulation, which identified shortcomings in the current system. It seeks to address these in a proposal presented in January 2024 to revise the FDI Regulation (see <a href="here">here</a>). This proposed Regulation is one of the Commission's <a href="five initiatives on trade">five initiatives on trade</a>, investment, and <a href="research">research</a> adopted in a comprehensive package to strengthen the EU's economic security in the face of rising geopolitical tensions and significant technological change, as set out in a <a href="Communication on Advancing European economic security: an introduction to five new initiatives">here</a> (see also <a href="EU Emergency Response Update No. 112 of 29 March 2024</a>).

The proposal to revise the FDI Regulation 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 towards procedural improvements to the cooperation mechanism. The Council of the EU and the European Parliament are currently reviewing the proposal.

\* For the Third Annual Report on the screening of FDI, see <u>EU Emergency</u> Response Update No. 109 of 3 November 2023.

European
Commission
releases Fourth
Annual Report on
Implementation
and Enforcement
of EU Trade
Agreements (see
here)

On 3 October 2024, the European Commission released its Fourth Annual Report on the Implementation and Enforcement of EU Trade Agreements, covering the period 2023 and the first few months of 2024.\*

The Report highlights that the value of EU trade (as of end-2023) covered by its extensive network of 42 agreements with 74 partners was over €2.3 trillion, or 45.8% of total EU external trade.

These trade agreements have supported the EU in boosting its resilience in the face of multiple challenges, including rising geopolitical tensions, the significant investment needed for the green and digital transitions, and the COVID-19 pandemic.

In particular, the EU's trade agreements:

- Expand export opportunities for EU producers, for example:
  - EU exports to <u>South Korea</u> have increased at an annual average of 7% and by 127% over the full period (2010-2023). The trade agreement supports exports in top sectors such as vehicles where EU exports grew by 264%; and
  - EU exports to <u>Vietnam</u> have increased at an annual average of 1% and by 3% over the full period (2019-2023), while agri-food

exports grew by 17%. The trade agreement supports exports in top sectors such as pharmaceuticals, where EU exports grew by 48%.

<u>Supporting the EU's green and digital transition</u>. The EU continued its cooperation with trading partners on topics of common interest, such as through its 2023 <u>EU-Korea Green Partnership</u> on climate change, energy, and supply chain security; and the 2021 <u>Japan-EU Green Alliance</u> for cooperation on climate change and the energy transition.

<u>Barriers to trade and addressing these</u>. In 2023, 41 trade barriers were removed in 28 partner countries. Different strategies and instruments were used, including diplomatic engagement and/or using the committees created under bilateral trade agreements and the WTO. 60% of resolved barriers were in the agriculture and fisheries sector.

The accompanying Staff Working Document provides further details on the Report (see <a href="here">here</a>), including additional information (country sheets) on 39 individual EU trade agreements and a list of new barriers recorded and barriers resolved in 2023.

\* For the Third Annual Report, see <u>Jones Day EU Geopolitical Risk Update No.</u> 110 of 24 November 2023.

## **MEDICINES AND MEDICAL DEVICES**

European
Commission
publishes
factsheet
"Overcoming the
COVID-19
pandemic together
and building a
Health Union" (see
here)

On 11 October 2024, the European Commission published a factsheet on "Overcoming the COVID-19 pandemic together and building a Health Union," which provides an overview of the Commission's key achievements in responding to the COVID-19 pandemic, and notably:

- Developing and administrating vaccines in record time;
- Preventing shortages of products; and
- Relaunching the economy with innovative economic strategies.

The factsheet also discusses the European Health Union ("EHU") which aims to better prepare the European Union ("EU") face public health emergencies in the future (see also <u>Jones Day EU Emergency Response Update No. 115 of 24 June 2024</u>). The three-pronged EHU focuses on:

- Strengthening EU coordination in responding to serious, cross-border health threats and public health emergencies;
- Ensuring the availability of qualitative, innovative, and affordable medicines; and
- Combating against cancer, which in 2020 was diagnosed in 2.7 million people in the EU and claimed the lives of another 1.3 million people.

European Medicines Agency Network publishes draft strategy 2028 (see here) On 3 October 2024, the European Medicines Agency Network ("Network"), comprising the national competent authorities ("NCAs") and the European Medicines Agency ("EMA"), published the draft "Seizing opportunities in a changing medicines landscape: The European medicines agencies network strategy 2028" ("EMANS 2028").

The draft EMANS 2028 reviews and updates the original five-year EMANS 2025 strategy, covering the period 2021 to 2025 (accessible <a href="here">here</a>). Since EMANS 2025's inception, various changes to the regulatory and technological landscape have necessitated a review and update of the strategy, such as:

- In response to the COVID-19 pandemic, the EU enacted new legislation to handle public health emergencies and establish the Directorate-General Health Emergency Preparedness and Response ("DG HERA") (see also <u>Jones Day COVID-19 Update No. 61 of 20</u> <u>September 2021</u>);
- Technological advances (such as artificial intelligence ("Al")) brought opportunities to transform the development of medicines and how they are regulated across the Network.
- The EU proposed a milestone revision of the pharmaceutical legislative framework (see also <u>Jones Day EU Emergency Response</u> Update No. 102 of 3 May 2023).

The draft EMANS 2028 aims to guide the Network in pursuing opportunities and meeting future challenges. It is centered around the overarching theme of "change" – rapid, unpredictable, but holding promise – and identifies strategic focus areas and related goals / strategies, such as:

- Accessibility of medicines: Patients can access medicines that have gone through the necessary steps for approval and reimbursement by healthcare systems. To facilitate access to medicines, the Network aims to increase cooperation and exchange of information with decision makers (such health technology assessment ("HTA") authorities and public healthcare payers) and healthcare policy makers.
  - The Network also aims to support the successfully implementation of Regulation 2021/2282 on Health Technology Assessment (see <a href="here">here</a>), which becomes applicable in January 2025 and provides a framework for EU-level clinical assessment of medicinal products and medical devices to inform national decision making on access;
- <u>Leveraging data, digitalization and artificial intelligence</u>: The Network aims to, in particular, maximize the generation, interoperability, use and exchange of data to support EU decision-making and leverage digitalization, experimentation and innovation to deliver optimized regulatory processes;
- Regulatory science, innovation and competitiveness: The Network seeks to deepen collaboration with stakeholders to bridge the gap between scientific research and regulatory decision making; simplify and modernize the Clinical Trials Information System ("CTIS") (see <u>Jones Day COVID-19 Update No. 96 of 27 January 2023</u>); and increase competitiveness by bolstering support for innovators and ensuring that the regulatory framework is conducive to research, develop and manufacture medicines:
- Antimicrobial resistance ("AMR") and other health threats: The Network
  will promote the responsible use of AMR, support antimicrobial
  development in collaboration with international partners, and strengthen
  regulatory preparedness for health threats (see <u>Jones Day EU</u>
  <u>Emergency Response Update No. 110 of 23 November 2023);</u>
- Availability and supply: The Network will focus on preventing shortages
  of vital medicines, including by identifying root causes of shortages and
  developing harmonized strategies for preventing and managing these,
  e.g., by coordinating activities within and outside the Network to

effectively tackle shortages, and reinforcing the oversight and protection of the supply chain.

<u>Looking ahead</u>. The EMA is currently assessing feedback from a public consultation on draft EMANS 2028. The final strategy is expected to be adopted by March 2025 and will be implemented via EMA's and Heads of Medicines Agency's ("HMA") respective multi-annual workplans.

The EMA and HMA also prepared a Reflection Paper providing more information on the drafting process and the focus areas driving EMANS 2028 (see <a href="here">here</a>).

EMA announces initiatives to improve efficiency of approval process for new medicines in EU (see here)

On 2 October 2024, EMA and the above-referred Network announced their work to improve efficiency in assessing and approving new medicines in the EU (e.g., by better managing use of the Network's expert resources; streamlining assessment processes; and encouraging stronger application dossiers from applicants at the time of initial submission).

A particular area in need of improvement is the <u>persistent unreliability of long-term planning for initial marketing authorization applications ("MAAs") for centralized procedures</u>,\* due to factors such as companies submitting premature data. This long-running problem for the Network, which has tied up assessment resources and delayed medicine approval times, became unsustainable with the COVID-19 pandemic, which strained resources to the limit.

The EMA and the HMA are seeking to address these challenges through a series of comprehensive measures. A focus group has also been created to analyze the causes of delays and to propose solutions.

Other ongoing measures to ensure the sustainability of the EU regulatory network include, in particular:

- Reinforced best practices for requests for "clock-stop" extensions, which
  interrupt the MAA assessment to allow more time for the applicant to
  reply to questions from EMA's scientific committees. In particular, a
  template for requesting clock-stop extensions was introduced in 2024
  (see <a href="here">here</a>), and the 2009 clock-stop guidelines will be applied more
  strictly (see <a href="here">here</a>);
- <u>Streamlined assessment report templates and guidance</u>, such as better distinguishing between evidence submitted by the applicant and EMA's assessment, better structuring of information, and removing duplication;
- Improved guidance for assessors in national competent authorities to increase efficiency and consistency in the assessment process, e.g., by issuing assessment report templates, guidance and/or checklists and training;
- Better communication between applicants, EMA and rapporteur teams well in advance of the anticipated MAA submission to avoid dossiers submitted with premature data and to improve submission predictability.

<u>Looking ahead</u>. A multi-stakeholder workshop took place on 25 September 2024 (see <a href="here">here</a>) to discuss submission predictability and how it can be improved. A report with further industry recommendations is planned to be published.

<sup>\*</sup> Under the <u>European Union-wide centralized procedure</u> for the authorization of medicines, there is a single application, a single evaluation, and a single

authorization throughout the European Union. Only certain medicines are eligible for the centralized procedure (see <a href="here">here</a>).

# CYBERSECURITY, PRIVACY & DATA PROTECTION

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

On 8 November 2024, the annual "Blueprint Operational Level Exercise" (Blue OLEx) took place. Senior cybersecurity representatives from the Commission and EU Member States 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 2023 Blue OLEx, see <u>EU Emergency Response Update – Key Policy & Regulatory Developments No. 108 of 17 November 2023</u>).

This year, the Italian authorities led Blue OLEx, with the support of the EU Agency for Cybersecurity (ENISA). Commenting on Blue OLEx, Margrethe Vestager, Executive Vice-President for a Europe Fit for the Digital Age stated: "This exercise will help us strengthen our cybersecurity defences and ensure a safer digital environment for our citizens and businesses across Member States."

The 2024 exercise focused on executive level cooperation, in particular via the Cyber Crisis Liaison Organisation Network (EU-CyCLONe), which was established in January 2023 by the NIS2 Directive (Directive 2022/2555 on measures for a high common level of cybersecurity across the Union) (see also Jones Day Alert, "EU Adopts Enhanced Legal Framework to Provide for High Common Level of Cybersecurity", December 2022, here).

The EU-CyCLONe aims to contribute to managing large-scale cyber incidents and crises at operational level. It complements, at EU level, existing cybersecurity structures through cooperation at both the <u>technical level</u> (e.g., Computer Security Incident Response Team (CSIRTs\*)) and <u>political level</u> (e.g., Integrated Political Crisis Response (IPCR)\*\*).

<u>Looking ahead</u>. The results of this latest Blue OLEx exercise will notably contribute to the evaluation of the Blueprint for a coordinated response to large-scale cybersecurity incidents and crises, adopted in 2017 (<u>Commission Recommendation (EU) 2017/1584 of 13 September 2017 on coordinated response to large-scale cybersecurity incidents and crises</u>).

- \* The EU CSIRTs network (notably composed of EU Member States' appointed CSIRTs) was established in 2016 under the <u>NIS Directive</u> (repealed) and was further strengthened in 2023 by the NIS2 Directive. The network's mission includes tasks such as providing EU Member States with assistance in addressing cross-border incidents and exchanging best practices in incident response.
- \*\* The EU's IPCR arrangements (<u>Council Implementing Decision (EU)</u>
  2018/1993 of 11 <u>December 2018 on the EU Integrated Political Crisis Response</u>
  <u>Arrangements</u>) support rapid and coordinated decision-making at EU political level for major and complex crises., whether natural or human-made (e.g., COVID-19 pandemic, acts of terrorism).

European
Commission
publishes NIS2
Implementing
Regulation on
critical entities and
networks (see here)

On 17 October 2024, the Commission adopted Implementing Regulation (EU) 2024/2690 on critical entities and networks under the NIS2 Directive, which aims at further harmonizing cybersecurity requirements and their implementation across the EU (see also above Blue OLEx item).

The Implementing Regulation lays down the <u>technical and methodological</u> <u>requirements</u> for companies (i.e. "relevant entities") providing digital services, such as cloud computing service providers, providers of online market places, data centre service providers, and DNS (Domain Name System) service providers.

When implementing and applying such technical and methodological requirements (outlined in the <u>Annex</u> to the Implementing Regulation), relevant entities must ensure a level of security of network and information systems appropriate to the risks posed. In particular, relevant entities must take due account of factors such as:

- The degree of their exposure to risks; and
- Their size and likelihood of occurrence of incidents and their severity, including their societal and economic impact.

Moreover, the Implementing Regulation provides <u>sets of criteria</u> for identifying "<u>significant incidents</u>" experienced by relevant entities under the NIS2 Directive, such as the following:

#### General criteria:

- An incident that has caused or is capable of causing direct financial loss for the relevant entity that exceeds €500,000 or 5% of the relevant entity's total annual turnover in the preceding financial year, whichever is lower;
- The incident has caused or is capable of causing the exfiltration of trade secrets;
- The incident has caused or is capable of causing the death of a natural person, or considerable damage to a natural person's health; and/or
- A successful, suspectedly malicious and unauthorized access to network and information systems occurred, which is capable of causing severe operational disruption.

### Criteria for identifying recurring incidents.

For incidents that individually are not considered a significant incident pursuant to the above-referred general criteria, these are <u>considered</u> <u>collectively as one significant incident</u> where they meet all of the following criteria:

- They have occurred at least twice within six months;
- They have the same apparent root cause; and
- They collectively meet the above general criterion of having caused or being capable of causing direct financial loss for the relevant entity that exceeds €500,000 or 5% of the relevant entity's total annual turnover in the preceding financial year, whichever is lower.
- Criteria specific to a given relevant entity:

For example, <u>cloud computing service providers</u> must consider criteria such as the following to identify a "significant incident":

- A cloud computing service provided is completely unavailable for more than 30 minutes;
- The availability of a cloud computing service of a provider is limited for more than 5% of the cloud computing service's users in the EU, or for more than 1 million of the cloud computing service's users in the EU, whichever number is smaller, for a duration of more than one hour; and
- The integrity, confidentiality or authenticity of stored, transmitted or processed data related to the provision of a cloud computing service is compromised as a result of a suspectedly malicious action.

The Implementing Regulation, following its publication in the Official Journal, entered into force on 7 November 2024.

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