



# EU EMERGENCY RESPONSE UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

No. 103 | 23 June 2023

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

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

## LATEST KEY DEVELOPMENTS

### Competition & State Aid

- European Commission approves up to €8.1 billion in Member State support for IPCEI in microelectronics and communication technologies
- European Parliament voices concerns over control of EU's recovery and resilience funds
- European Commission approves further schemes under new Temporary Crisis and Transition Framework to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies

### Trade / Export Controls

- Council of the European Union expands sanctions against Russia
- CBAM Regulation (Carbon Border Adjustment Mechanism) enters into force
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- European Commission publishes Joint Communication on European Economic Security Strategy

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## COMPETITION & STATE AID

### State Aid

#### European Commission approves up to €8.1 billion in Member State support for IPCEI in microelectronics and communication technologies (see [here](#))

On 8 June 2023, the Commission approved up to €8.1 billion of public support by fourteen Member States\* for an IPCEI (Important Project of Common European Interest)\*\* in microelectronics and communication technologies spanning the value chain (e.g. materials, tools, chip design, manufacturing processes). Known as the “IPCEI ME/CT”, the project’s envisaged €8.1 billion in public support is expected to unlock an additional €13.7 billion in private investments.

Such IPCEI initiatives are a component of the EU’s ambitions for a leading role in the [green and digital transition](#), including under the Green Deal Industrial Plan released in February 2023 (see also [Jones Day COVID-19 Update No. 97 of 14 February 2023](#)). This Plan notes, in particular, that industry faces numerous challenges, such as high inflation, post-COVID supply chains disruptions, spikes in energy costs and input prices, and labor shortages.

The IPCEI ME/CT follows and complements the first IPCEI to support research and innovation in the field of microelectronics, approved by the Commission in [December 2018](#). It is the sixth IPCEI approved under EU State aid rules and third IPCEI approved on the basis of the 2021 IPCEI Communication.

In approving the IPCEI ME/CT, the Commission communicated its views, such as the following:

- The IPCEI [directly contributes to achieving various key objectives for a greener, digital, resilient and sovereign economy](#), as set out in important EU initiatives (e.g., [Europe’s Digital Decade](#) and [European Green Deal](#)).
- All 68 projects (from 56 companies) under the IPCEI are assessed as highly ambitious and as seeking to [develop technologies surpassing what the market currently offers](#). These projects are anticipated to enable major advances, notably in the areas of, e.g., sensors, high performance processors, and microprocessors including artificial intelligence and communication means for secure data exchange.
- The IPCEI raises [considerable technological and financial risks](#), and the Commission thus deems that public support is necessary to incentivize companies to undertake the investment.

The Commission anticipates that the first novel products resulting from the IPCEI may be introduced to the market as early as 2025, and completion of the overall project is planned for 2032. Some 8,700 direct jobs are expected to be created, in addition to numerous indirect ones.

Further information on the amount of aid to individual participants will be available in the Commission’s decision’s public version, once addressing confidentiality issues with Member States and third parties.

\* Austria, Czechia, Finland, France, Germany, Greece, Ireland, Italy, Malta, the Netherlands, Poland, Romania, Slovakia and Spain.

\*\* To recall, the IPCEI rules seek to enable Member States and industry to jointly invest in ambitious pan-European projects in a transparent and inclusive manner, where the market alone appears unable to deliver and particularly where the risks are deemed as too large for a single Member State or company to assume. On 25 November 2021, the Commission published a revised Communication on State aid rules for IPCEI, setting out criteria under which several Member States can support transnational projects of strategic significance for the EU under Article 107(3)(b) of the TFEU (see [Jones Day COVID-19 Update No. 69 of 29 November 2021](#)).

**European Parliament voices concerns over control of EU's recovery and resilience funds (see [here](#))**

On 10 May 2023, the European Parliament issued a [Resolution](#) accompanying its approval of the European Commission's budgetary performance in 2021. The EU budget in 2021 rose by some 30% compared to 2020, largely due to money spent from the €800 billion NextGenerationEU recovery plan, adopted in December 2020 and aimed at Europe's green and digital transformation and countering the COVID-19 pandemic's impact. To recall, the core instrument of NextGenerationEU is the [Recovery and Resilience Facility](#) (RRF), established in February 2021, to support faster and more resilient Member State recovery.

The Resolution welcomes the RRF's initial contribution and its further potential with regard to preventing a strong economic downturn following the pandemic. However, it also expressed a number of concerns, including citing concerns raised by the European Court of Auditors (e.g., the Court's [first assessment of the RRF](#) (Oct. 2022)). The Resolution, in particular, draws attention to:

- The EU's limited options in verifying use of money from the RRF, whose implementation takes place "under time pressure", such that control requirements are "much lighter" than those for other EU programmes and relies more on national authorities, which in some cases are "too error-prone and unreliable". Still, in this respect, the Resolution welcomed the Commission's launch in 2022 of system audits on the Protection of Financial Interest of the EU in 16 Member States, as well as plans to cover all Member States by end-2023;
- Shortcomings in the Commission's assessment of national compliance with "milestones and targets" (conditional criteria for disbursing RRF payments to Member States), emphasizing their lack of clarity and comparable definitions. The Resolution further asks the Commission to refrain from assessing such compliance "on the basis of political negotiations".
- Negligible contribution of the RRF to cross-border cooperation, especially in light of the amount of EU funding involved. The Resolution notes, in particular, that the RRF plays a significant role in steering the EU towards energy-independence and accelerating the energy transition. The Resolution highlights the need for an independent energy supply for Europe and corresponding investments in cross-border networks, interconnectors and hydrogen projects. The Resolution calls for, in particular, available RRF loans to be made available for Member States seeking to invest in cross-border projects focused on European energy-independence and transforming the energy grid.

The Resolution further calls for greater transparency to ensure protection of the EU budget, e.g., by making general and systematic use of EU digital and automated systems for reporting, monitoring and audit ([ARACHNE](#), [EDES](#), etc.) and by further developing the [RRF Scoreboard](#) in view of providing transparent descriptions of milestones and the target and outcome of audits.

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

The Commission approved additional measures under the new State aid Temporary Crisis and Transition Framework (new 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 (applied as from 9 March 2023, see also [Jones Day COVID-19 Update No. 99 of 17 March 2023](#)).

Among the most recently approved State aid schemes under the new TCTF (from 6 May to 14 June 2023):

- €837 million Spanish scheme to support the production of batteries for the industrial chain of electric and connected vehicles to foster the transition to a net-zero economy, in line with the Green Deal Industrial Plan.
- €31 million Greek scheme to support agricultural producers in the context of Russia's war against Ukraine.
- €122.6 million (PLN 561.6 million) Polish scheme to support the primary agricultural production sector in the context of Russia's war against Ukraine.
- Amendments to a Greek scheme, including a budget increase of €600 million, to support non-household electricity consumers in the context of Russia's war against Ukraine.
- €1 billion Polish scheme to support agricultural producers in the context of Russia's war against Ukraine.
- €346 million (PLN 1.5 billion) Polish scheme to support agricultural producers in the context of Russia's war against Ukraine.
- €150 million Slovenian scheme to support the rollout of renewable energy and heat as well as energy storage, in line with the Green Deal Industrial Plan.
- €31 million Croatian scheme to support livestock and crop production sectors in the context of Russia's war against Ukraine.
- €11 million (PLN 50 million) Polish scheme to support agricultural producers in the context of Russia's war against Ukraine.
- approximately €8 million (BGN 16 million) Bulgarian scheme to support primary agricultural production sector in the context of Russia's war against Ukraine.

## TRADE / EXPORT CONTROLS

**Council of the European Union expands sanctions**

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

**against Russia**  
(see [here](#))

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

Among the most recent developments to the EU sanctions regimes:

Russia: On 23 June 2023, the Council adopted an 11th package of sanctions, which includes, amongst others:

- Import-export restrictions, such as:
  - A new anti-circumvention tool to enable the EU to restrict the sale, supply, transfer or export of specified sanctioned goods and technology to certain third countries whose jurisdictions are viewed as a continued and particularly high risk of circumvention. The tool will focus on high-risk goods that are proven to reach Russia via third countries, despite being covered by EU sanctions.
  - Broadened transit prohibition on certain sensitive goods (e.g., advanced technology, aviation-related materials) that are exported from the EU to third countries, via Russia, in view of reducing the risk of circumvention.
  - Addition of 87 new entities to the list of those directly supporting Russia's military and industrial complex in its war against Ukraine. These entities are subject to tighter export restrictions for dual-use and advanced technology items. Expanding from the Russian and Iranian entities already listed, the list now also covers entities registered in China, Uzbekistan, the United Arab Emirates, Syria and Armenia.
- Energy measures, e.g., end of the possibility to import Russian oil by pipeline for Germany and Poland.
- Transport measures, e.g., a total ban on trucks with Russian trailers/semi-trailers from transporting goods to the EU, aimed at combating circumvention of the prohibition on Russian freight road operators from carrying goods in the EU.

Within this 11th package of sanctions, the Council also added 71 individuals and 33 entities (including two banks (MRB Bank and CMR Bank) which operate in the illegally annexed territories of Donetsk, Luhansk, Kherson and Zaporizhzhia) to the list of those subject to a freezing of their assets, and EU citizens and companies are forbidden from making funds and economic resources available to them. Natural persons are additionally subject to a travel ban, which prevents them from entering or transiting through EU territories.

Altogether, EU restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine now apply to nearly 1,800 individuals and entities.

The European Commission's Q&A on the 11th package of sanctions provides further details (see [here](#)). The Q&A, in particular, emphasizes that none of the EU's sanctions adopted against Russia prevents the supply of agri-food products, medical equipment or medicines for the general population in



Russia. For example, no EU sanctions would prohibit third countries from purchasing Russian fertilizers.

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 in February 2022 with the so-called [first package of sanctions](#) (see [here](#)). The [10th package of sanctions](#) was adopted by the Council on 24 February 2023 (see also [Jones Day COVID-19 Update No. 98 of 1 March 2023](#)).

*\* An in-depth analysis of the 11th package of sanctions against Russia is available from the authors of the EU Emergency Update (see contact details below for Nadiya Nychay (Brussels) and Rick van 't Hullenaar (Amsterdam)).*

**CBAM Regulation (Carbon Border Adjustment Mechanism) enters into force (see [here](#))**

On 17 May 2023, the CBAM (Carbon Border Adjustment Mechanism) Regulation officially entered into force, i.e., on the day following its publication in the Official Journal of the EU.

To recall, CBAM addresses greenhouse gas emissions embedded in imports into the EU of certain products in carbon-intensive industries, with the objective of ensuring equivalent carbon pricing for imports and domestic products. In this respect, the CBAM seeks to prevent the risk of so-called carbon leakage, whereby the EU's greenhouse gas emissions reduction efforts are jeopardized when businesses (i) increase emissions outside EU borders by relocating production to non-EU countries with less stringent policies to tackle climate change, or (ii) increase imports of carbon-intensive products.

The CBAM's [scope](#) will initially apply to imports of certain goods and selected precursors whose production is carbon-intensive and at greatest risk of carbon leakage: iron and steel, cement, fertilizers, aluminium, electricity and hydrogen. Indirect emissions will be covered after the transitional period for certain sectors (cement and fertilizers), based on a methodology to be defined.

The CBAM is designed to operate in parallel with the [EU Emissions Trading System](#) (EU ETS),\* to mirror and complement its functioning on imported goods. CBAM will gradually replace the existing EU mechanisms to address the risk of carbon leakage, and in particular the free allocation of EU ETS allowances for sectors covered by CBAM. The CBAM will equalize the price of carbon paid for EU products operating under the EU ETS and the one for imported goods. This will be done by requiring companies importing into the EU to purchase so-called CBAM certificates to pay the difference between the carbon price paid in the country of production and the price of carbon allowances in the EU ETS.

By way of background, CBAM is a key element of the [Fit for 55](#) package, a set of Commission proposals announced in July 2021 to update existing EU law to ensure that EU policies align with EU climate goals, and in particular, the reduction of net greenhouse gas emissions by at least 55% by 2030. Fit for 55 is part of the 2019 [European Green Deal](#) package of policy initiatives, which aims at guiding the EU to sustainability through a socially just transition. The Commission states that the importance of this basic goal has only been

reinforced with the COVID-19 pandemic and the war in Ukraine. The European Green Deal's ultimate target is to attain climate neutrality by 2050.

CBAM timing / next steps. During the transitional period starting on 1 October 2023 until end-2025, CBAM will apply only as a reporting obligation. At the end of each quarter, importers shall report emissions embedded in their goods subject to CBAM, but without paying a financial adjustment. This will allow time for the final system to be put in place.

CBAM's gradual phase-in, in parallel to the phase-out of free allowances under the revised EU ETS for the sectors covered by CBAM, will take place over a nine-year period between 2026 and 2034.

A draft Implementing Regulation, released on 13 June 2023, sets out reporting obligations for EU importers of CBAM goods and the provisional methodology for calculating embedded emissions released during the production process of CBAM goods. The Commission is expected to adopt the draft Implementing Regulation later this summer, after a public consultation and a vote in the CBAM Committee, composed of EU Member State representatives.

*\* The EU ETS is one of the EU's key climate change mitigation policies and is the world's first carbon market, aiming at providing an efficient mechanism to reduce emissions. Under the EU ETS companies must obtain emission allowances covering their carbon emissions. The default option is to purchase allowances at an auction, but these can also be allocated for free, which is a transitional method of allocating allowances.*

**European Commission proposes comprehensive reform of EU Customs Union (see [here](#))**

On 17 May 2023, the European Commission released proposals\* for the “*most ambitious and comprehensive reform of the EU Customs Union since its establishment in 1968.*” In announcing this reform, the Commission highlighted that the value of EU trade with other countries in 2021 amounted to €4.3 trillion, accounting for 14% of world trade.

The Commission's proposals notably follow findings that the Customs Union needs urgent structural changes and is not “*fit for purpose,*” with dangerous, non-compliant products entering the EU market, as well as billions of uncollected customs duties and taxes (see March 2022 Report on Reform of the EU Customs Union by the Wise Persons Group, [Jones Day COVID-19 Update No. 81 of 5 April 2022](#)).

Recent crises further highlight the “*indisputable need*” for a “*structural modernization*” to make EU Customs a strategic capability of the EU, as stated in the [Commission Communication on Customs reform: Taking the Customs Union to the next level](#), published on 17 May 2023. In particular, EU customs faces the challenge of the war in Ukraine at the European border, including the implementation of sanctions while supporting humanitarian efforts. The COVID-19 crisis also confronted EU customs with a massive increase of traffic of sub-standard and dangerous goods in the health area, from personal protective equipment to medicines and medical devices.

The proposed reform of the Customs Union comprises three main pillars:

- A first-of-its-kind partnership with business, enabling traders to directly provide all information on their imports and exports onto a single interface, a newly-created EU Customs Data Hub. This planned Hub is described as “*the engine*” of the reformed Customs Union, which will support and simplify traders' customs-related processes, while strengthening supervision and risk analysis for

authorities. The new partnership between customs and business is anticipated to tremendously simplify or even eliminate the need for customs declarations for the most trusted traders (so-called “Trust & Check” traders);

- A more robust surveillance and risk assessment model, featuring:
  - Greater collaboration between customs authorities at EU level, enabling the pooling of resources/expertise and information exchange for more effective controls at the EU's borders. National authorities will have access through the new EU Customs Data Hub to comprehensive, real-time information to allow them to target inspections and action where most needed.
  - A new EU Customs Authority (a decentralized agency pooling expertise and resources from the Member States and the Commission) will manage EU-level risk assessment using data from the EU Customs Data Hub and will assist Member States in focusing their control efforts and better enforcing compliance with EU standards; and
- A more modern framework for e-commerce to combat high levels of fraud in this sector while introducing more transparency and reliability for consumers. In particular:
  - For the first time, online platforms selling goods into the EU will be the so-called “deemed importer” and therefore responsible for ensuring that customs duties and VAT are paid at purchase and for passing this revenue onto their Member State of registration.
  - The current exemption from customs duty for goods valued at under €150 will be abolished, such that duty will be charged on every product sold online into the EU. Eliminating the threshold, in particular, will help to combat fraud from the undervaluation of goods entering the EU.
  - Customs duty calculation will be simplified for the most common low-value goods bought from outside the EU, reducing the thousands of possible customs duty categories down to only four. Overall, the new e-commerce regime is expected to bring some €1 billion in additional customs revenue per year.

Timing / next steps. The proposed Data Hub would be open for e-commerce consignments in 2028, followed (on a voluntary basis) by other importers in 2032.

The EU Customs Authority is anticipated to assume its tasks on 1 January 2028 and would be immediately operational as concerns its responsibilities in risk and crisis management. The Authority would gradually expand its scope in line with the roll-out of the EU Customs Data Hub.

The Commission's legislative proposals will now be examined by the European Parliament and the Council of the European Union for agreement and by the European Economic and Social Committee for consultation.

*\* The three proposals comprise: (1) [proposed Regulation](#) establishing the Union Customs Code and the European Union Customs Authority, and repealing Regulation (EU) No 952/2013 ; (2) [proposed Regulation](#) amending Regulation (EEC) No 2658/87 on introducing a simplified tariff treatment for the distance sales of goods and Regulation (EC) No 1186/2009 on eliminating the customs duty relief threshold ; and (3) [proposed Directive](#) amending Directive 2006/112/EC on VAT rules relating to taxable persons who facilitate distance sales of imported*



*goods and the application of the special scheme for distance sales of goods imported from third territories or third countries and special arrangements for declaration and payment of import VAT.*

**European Commission publishes Joint Communication on European Economic Security Strategy (see [here](#))**

On 20 June 2023, the European Commission published a Joint Communication on a European Economic Security Strategy, which addresses Europe's shortcomings in adequate preparedness for new and emerging risks.

The Joint Communication highlights that the COVID-19 pandemic exposed the risks of highly concentrated supply chains to the European economy. Russia's war against Ukraine has also shown how overreliance on a single country, especially one with systemically divergent values and interests, diminishes Europe's strategic options and jeopardizes its economy and citizens.

The Strategy proposes to undertake a thorough assessment of risks to economic security in four areas: (i) resilience of supply chains, including energy security; (ii) physical and cybersecurity of critical infrastructure; (iii) technology security and technology leakage; and (iv) weaponization of economic dependencies or economic coercion. Such assessment should be carried out by the Commission and Member States in cooperation with the High Representative, where appropriate, and with private sector input.

The Strategy also sets out how to mitigate identified risks through a three-pronged approach: (i) promoting EU competitiveness, e.g., by investing in skills and fostering the EU's research, technological and industrial base); (ii) protecting the EU's economic security through a range of existing policies and tools, and consideration of new ones to address possible gaps; and (iii) partnering with the widest possible range of partners to bolster economic security (e.g., furthering trade agreements and strengthening the international rules-based economic order and multilateral institutions, such as the WTO). Towards achieving these aims, the Communication sets out action items such as:

- Developing with Member States a framework for assessing risks affecting the EU's economic security, including establishing a list of technologies critical to economic security and assessing their risks with a view to devising appropriate mitigating measures;
- Engaging in discussions with the private sector to develop a collective understanding of economic security and encouraging the private sector to conduct due diligence and risk management in light of economic security concerns; and
- Further supporting EU technological sovereignty and resilience of EU value chains, including by developing critical technologies through the Strategic Technologies for Europe Platform ([STEP](#)).

Next steps: The Communication lays the basis for a strategic discussion with EU Member States and the European Parliament to develop a comprehensive approach to protect the Union's economic security. The European Council considered the Strategy during its meeting of 29-30 June 2023, as mentioned in closing remarks by President Charles Michel (see [here](#)).

## MEDICINES AND MEDICAL DEVICES

### European Commission President and EMA Executive Director issue statements on end of COVID-19 pandemic (see [here](#) and [here](#))

On 5 and 8 May 2023, Commission President von der Leyen and European Medicines Agency's (EMA) Executive Director Emer Cooke issued statements on the end of the COVID-19 pandemic. These follow the World Health Organization (WHO) Director General's statement on 5 May 2023 that COVID-19 is now an "established and ongoing health issue which no longer constitutes a public health emergency of international concern (PHEIC)" (see [here](#))\*.

President von der Leyen and Executive Director Cook both highlighted, in particular, important changes triggered by the COVID-19 pandemic:

- President von der Leyen stated: "This pandemic changed the face of the EU, which has become a true European Health Union. We are now far better prepared to face future health crises, with new tools to react quickly to emerging health crises.... We have established the Health Emergency and Response Authority (HERA) to be better prepared for future health emergencies. We have a stronger European Medicine Agency (EMA) and European Centre for Disease Prevention and Control (ECDC)."
- Executive Director Emer Cooke stated: "EMA initiated new and agile ways of working, many of which are here to stay. Our response was built on unprecedented collaboration and a united sense of purpose across regulators, developers, institutions and citizens. It was supported by the tireless commitment and work of countless experts from the regulatory authorities – at EMA and at national level. These activities were underpinned by a fruitful collaboration between international regulators through the International Coalition of Medicines Regulatory Authorities (ICMRA)."

In addition, both statements emphasized that COVID-19 remains a global health threat, such that it is necessary to maintain continuous surveillance and ensure that new or adapted vaccines and therapeutics can be made available.

\* The WHO Director General declared COVID-19 a PHEIC on 30 January 2020.

### EMA publishes Good Practices for Industry for Prevention of Human Medicinal Product Shortages (see [here](#))

On 15 May 2023, the European Medicines Agency (EMA) published Good Practices for Industry for the Prevention of Human Medicinal Product Shortages.\*

Medicine shortages are recognized as a global problem by European and international organizations, including the European Medicines Regulatory Network and the WHO. The Good Practices, which highlight that prevention is an essential aspect of shortage management, builds on experiences gained during the COVID-19 pandemic and provides recommendations on best practices on reducing the likelihood of shortages and on mitigating a shortage event.

The Good Practices focuses on actions to be taken by marketing authorization holders (MAHs), wholesalers, distributors and manufacturers, who all play a vital role in preventing and managing shortages.

The [Recommendations on shortage prevention and/or mitigation](#) strategies include, among others:

- MAHs, manufacturers and wholesalers, should notify the National Competent Authority of a potential or actual shortage as soon as possible in advance of any shortage (e.g., Early stage reporting of potential shortages is essential to provide sufficient time for actors in the supply chain and the health system to prepare and have adequate stock of alternative products to mitigate the patient impact).
- Increasing transparency relating to shortage information (e.g., Greater communication and knowledge-sharing across different stakeholders can, in particular, facilitate the identification of available products and alternatives. Furthermore, given the global nature of the supply chain, closer relationships with European and international partners is necessary to facilitate coordinated actions about medicines' supply).
- MAHs should increase the accuracy of notification detail provided (e.g., Transmitting key information is essential to prevent a shortage or reduce its impact. For example, not detailing specific manufacturing delays means that it is difficult to understand the impact and evaluate the likely timeframe for resumption of supply).
- MAHs, manufacturers and wholesalers should each have a shortage prevention plan specific to their role (e.g., For MAHs, which have overall oversight of the supply of their medicines, a prevention plan to identify/address existing vulnerabilities in the supply chain (i.e., before an issue arises) should encompass aspects from the sourcing of active ingredients through to wholesale distributors).
- Taking appropriate steps to minimize the risk of parallel trade or export exacerbating shortage (e.g., In situations of critical shortage, companies involved in parallel trade (activity of supplying medicines intended for patients in one country to another) should monitor the situation, and, in cases of an identified risk to public health, should inform and seek advice as necessary from the relevant authorities of the exporting Member State in relation to their parallel trade activity).

The European Commission's Pharmaceutical Strategy, which also specifically addresses medicine shortages, is complementary to the Recommendations in the Good Practices (see also [Jones Day EU Emergency Response Update No. 102 of 3 May 2023](#)).

\* *The Good Practices rely on the harmonized definition for shortages agreed by EMA-HMA: "A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level".*

## CYBERSECURITY, PRIVACY & DATA PROTECTION

### **Council of the European Union Conclusions on EU Policy on Cyber Defence** (see [here](#))

On 23 May 2023, the Council published Conclusions on EU Policy on Cyber Defence, as approved during its meeting on 22 May 2023. In presenting the Conclusions, the Council observes that cyberspace is an arena of strategic competition and that risks to EU security and defence are rising at a time of growing geopolitical tensions and increasing dependence on digital technologies.

The Conclusions highlight, in particular, that Russia's war against Ukraine has confirmed the need for the EU, its Member States and their partners to further build EU resilience and common cyber security and defence against aggression in cyberspace.

In view of responding to such need, the Council welcomes the Joint Communication on the [EU Policy on Cyber Defence](#) of November 2022 to further invest in the deployment of full-spectrum defensive cyber defence capabilities, cutting-edge technologies, and enhanced partnerships to address common challenges.

The Conclusions encourage pursuing objectives such as the following:

- Member States and other relevant actors should work together for stronger cyber defence by strengthening cooperation and coordination within the EU, between military and civilian cyber communities, and between the public sector and a trusted private ecosystem.
- The EU and its Member States should reduce their strategic dependencies across their capabilities and supply-chains, including by developing cutting-edge cyber defence technologies and strengthening the technological and industrial base of European defence.
- Member States should invest in interoperable cyber defence capabilities, including by establishing voluntary commitments for further developing national cyber defence capabilities and making the best use of collaborative research opportunities at EU level.

The Conclusions call upon the European Commission and the High Representative of the Union for Foreign Affairs and Security Policy\* to develop a plan in 2023, for approval by Member States, to implement the above-referred Joint Communication on EU Policy on Cyber Defence.

*\* High Representative Josep Borrell, who is also Vice-President of the European Commission, is responsible for steering the Union's Common Foreign and Security Policy.*

#### **Opening of European Cybersecurity Competence Centre (see [here](#))**

On 9 May 2023, the European Cybersecurity Competence Centre (ECCC) opened in Bucharest, Romania. The ECCC aims at supporting innovation and industrial policy in cybersecurity, as well as developing and coordinating EU cybersecurity projects.

In announcing the ECCC's opening, Thierry Breton, European Commissioner for the Internal Market, stated: *"Cybersecurity is a critical priority, and safeguarding our digital sovereignty requires joint efforts. The European Cybersecurity Competence Centre brings together top-tier experts and resources from across the EU to develop innovative solutions to cyber threats and enhance our resilience against attacks."*

The ECCC is tasked with, in particular:

- Managing EU cybersecurity funds for the current long-term EU budget (2021-2027), notably adopting cybersecurity work programmes.
- Overseeing projects on Security Operations Centres (SOCs), as part of the Commission's envisaged European Cyber Shield (a pan-European infrastructure composed of national and cross-border SOCs) for detecting and acting on cyber threats, as set out in the proposed EU Cyber Solidarity Act of 4 April 2023 (see [here](#)) to strengthen cybersecurity capacities in the EU.

- Collaborating with the Network of National Coordination Centres (NCCs), with one NCC per Member State, aimed at building an ecosystem for cybersecurity innovation and competitiveness across the EU.

The ECCC, together with the Network of NCCs, also supports collaboration and sharing of expertise and capacities between industry, public authorities, academia and other relevant cyber stakeholders.

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