



EU EMERGENCY RESPONSE UPDATE

KEY POLICY & REGULATORY DEVELOPMENTS

No. 105 | 31 August 2023

This regular alert covers key regulatory developments related to EU emergency responses, including in particular, to COVID-19, Russia's war of aggression 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](#)).

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- European Commission approves further scheme to compensate for damage due to COVID-19 crisis

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COMPETITION & STATE AID

Competition

Council of the European Union approves European Chips Act (see [here](#))

On 25 July 2023, the Council approved the Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (European Chips Act).

To recall, the Chips Act is part of the Commission's package of measures released in February 2022 (see [here](#)) aimed at ensuring the EU's security of supply and technological leadership in the field of semiconductors (see also [Jones Day COVID-19 Update No. 76 of 9 February 2022](#); and [Jones Day Commentary, EU Chips Act: The EU's Push for Semiconductor Autonomy, March 2022](#)). (Micro-)chips or semiconductors are described as the "DNA of modern technology", with chip demand anticipated to double between 2022 and 2030, and the semiconductor industry's value expected to reach some \$1 trillion by 2030 (see [Council infographic on proposed Chips Act](#)).

In announcing its adoption of the Chips Act, the Council stated its view that Europe is currently "too dependent on chips produced abroad, which became even more evident during the COVID-19 crisis. Industry and other strategic sectors such as health, defence and energy faced supply disruptions and shortages."

The Chips Act seeks to respond to these perceived critical dependencies and contains three main pillars:

(i) The [Chips for Europe Initiative](#) aims at supporting large-scale technological capacity building. Notably, the planned [Joint Chips Undertaking](#) (a public-private partnership involving the EU, Member States, and the private sector) will undertake the selection of centers of excellence as part of its work program. The Council also passed an [amendment to the Regulation establishing joint undertakings under Horizon Europe](#) on 25 July 2023 to enable the establishment of this Chips Joint Undertaking, which builds on and renames the existing key digital technologies joint undertaking.

(ii) A [framework to ensure security of supply](#) seeks to spur investment and enhance production capacities. In particular, "first-of-a-kind" facilities, including those producing equipment used in semiconductor manufacturing, are expected to reinforce the EU's security of supply and can benefit from fast-tracked permit granting procedures.

On the funding of "first-of-a-kind" facilities, Executive Vice-President and Competition Commissioner Margrethe Vestager earlier commented that these require large investments that private investors cannot fund on their own, such that the Commission believes that it may be justified to cover up to 100% of a proven funding gap with public resources. She specified the Commission's view that such funding does not require creating new, modified, or "bended" rules. Rather, the Commission must assess projects directly on the Treaty in seeking to avoid any competition distortions and to avoid a subsidy race in Europe and elsewhere.

(iii) A [monitoring and crisis response coordination mechanism](#) will seek to anticipate supply shortages and provide responses in case of crisis. For example, early warning indicators in Member States will be used to trigger an EU-wide shortage alert. Such mechanism will allow the Commission to implement emergency measures such as prioritizing the supply of products

particularly affected by a shortage, or carrying out common purchasing for Member States. These would be last-resort measures in the event of a crisis in the semiconductors sector.

The Chips for Europe Initiative is expected to mobilize €43 billion in public and private investments, including €6.2 billion of public funds (of which €3.3 billion from the EU budget), which comes in addition to €2.6 billion public funding already foreseen for semiconductor technologies. The Initiative's actions will be primarily implemented through the above-mentioned Chips Joint Undertaking. The objective is to double the EU's global market share in semiconductors from 10% to at least 20% by 2030.

Next steps. The Chips Act will enter into force on the third day following its publication in the Official Journal of the European Union. The amendment to the Regulation establishing joint undertakings under Horizon Europe will be published in the Official Journal at the same time.

Foreign Subsidies Regulation becomes applicable / European Commission provides practical guidance (see [here](#))

On 12 July 2023, the [Foreign Subsidies Regulation](#) (FSR) became applicable.

To recall, the FSR affords the European Commission with extensive new powers to counteract alleged distortive effects of foreign subsidies in the EU Single Market, which have fallen outside of the existing EU State aid and Trade Defense framework (*see also Jones Day Alert, "EU Foreign Subsidies Regulation Filings Mandatory Starting in October 2023" of December 2022, [here](#)*).

In proposing the FSR, the Commission argued that the COVID economic crisis had led to higher levels of subsidization worldwide and that the problem of distortive foreign subsidies is becoming more pressing in the context of acquisitions, public procurement and other market situations.

The FSR, in particular, sets out notification obligations for certain large M&A transactions and public bids involving companies that receive subsidies from governments outside the EU:

- Mandatory notification for concentrations. In mergers and acquisitions ("concentrations") facilitated by foreign subsidies, the acquirer must submit a prior notification to the Commission when:
 - the acquired company, one of the merging parties, or the joint venture is established in the EU and generates an EU turnover of at least €500 million; and
 - where the parties to the transaction were granted combined aggregate so-called foreign financial contributions of at least €50 million over the past 3 years.
- Mandatory public procurement notification. Bidders in public procurement procedures must disclose any foreign subsidies received by submitting a prior notification to the Commission when:
 - the estimated contract value is at least €250 million; and
 - the bid involves combined aggregate foreign financial contribution of at least €4 million per non-EU country over the past 3 years.

Also effective as of 12 July 2023, in all other market situations, the Commission may start investigations on its own initiative (*ex-officio*), where

suspecting the presence of distorting foreign subsidies, or may request ad hoc notifications concerning smaller transactions.

Practicalities. The Commission published a [Communication on detailed arrangements for proceedings pursuant to the FSR](#) and other [practical information](#) on 12 July 2023 to guide companies through the mechanics of the notification process. Such process shall take place electronically, unless where the Commission exceptionally agrees that other means may be used, i.e. by hand or registered post delivery.

The Commission also earlier adopted the [Implementing Regulation](#) (IR) and the corresponding [notification forms](#) (Annexes I, II of IR) on 10 July 2023, which specify the information and documents that companies will need to disclose as part of notifications under the FSR (*see also Jones Day Alert, "EU Adopts Reporting Requirements for Transactions and Public Bids Under the Foreign Subsidies Regulation" of July 2023, [here](#)*).

Next steps. As of 12 October 2023, companies must notify concentrations and participation in public procurement procedures involving foreign financial contributions and meeting the relevant notification thresholds. The Commission is also reported to be receiving complaints with requests for the opening of *ex officio* investigations.

The Commission's [technical Q&A document](#) provides further details and guidance on applying the FSR.

State Aid

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 EU Update No. 99 of 17 March 2023](#)*).

Among the most recently approved State aid schemes under the new TCTF (from 11 July 2023 to 31 August 2023):

- €800 million Czech scheme to support companies facing increased energy costs in the context of Russia's war against Ukraine
- €176 million (PLN 780 million) Polish scheme to support companies in the context of Russia's war against Ukraine
- €60 million French scheme aimed at supporting organic farming producers in the context of the war led by Russia against Ukraine
- €54 million Italian scheme to support small and medium-sized companies active in the region of Abruzzo in the context of Russia's war against Ukraine
- €30 million Italian scheme to support companies active in the agricultural, forestry, fishery and aquaculture sectors in the context of Russia's war against Ukraine

- €2.36 billion (HUF 880 billion) Hungarian scheme for accelerated investments in strategic sectors to foster the transition towards a net-zero economy
- €113 million (PLN 500 million) Polish scheme to support the pig production sector in the context of Russia's war against Ukraine
- €5 billion Czech scheme to support energy producers in the context of Russia's war against Ukraine
- €47 million (PLN 210 million) Polish scheme to support the primary agricultural production sector in the context of Russia's war against Ukraine
- €3 billion German scheme to support private investments in specific strategic goods needed to foster the transition towards a net-zero economy
- Amendment to an existing Polish scheme, including an overall €266 million (PLN 1.1 billion) budget increase, to support agricultural producers in the context of Russia's war against Ukraine

European Commission approves further scheme to compensate for damage due to COVID-19 crisis (see [here](#) and [here](#))

The Commission has adopted a significant number of State aid measures under Article 107(2)(b), Article 107(3)(b), and the State aid COVID Temporary Crisis Framework adopted in March 2020 under Article 107(3)(b) TFEU. With certain exceptions, the Temporary Crisis Framework applied until 30 June 2022.*

Among the latest schemes (up to 31 August 2023):

- €750 million Austrian measure to support companies in the context of the coronavirus pandemic, in the form of direct grants to compensate companies for the damages suffered between 16 March 2020 and 31 March 2022 due to the coronavirus pandemic and the restrictive measures imposed by the Austrian authorities to limit the spread of the virus.

The Commission assessed the measure under Article 107(2)(b) TFEU, which enables the Commission to approve State aid measures granted by Member States to compensate specific companies or sectors for the damages directly caused by exceptional occurrences, such as the coronavirus outbreak.

** Exceptions notably include the possibility for Member States to (i) create direct incentives for private investments as a stimulus to overcome an investment gap accumulated in the economy due to the crisis (until 31 December 2023) and (ii) provide solvency support measures (until 31 December 2023) aimed at easing access to equity finance for smaller companies.*

The Temporary Framework had also provided for a flexible transition, under clear safeguards, in particular for the conversion and restructuring options of debt instruments (e.g., loans and guarantees) into other forms of aid, such as direct grants, until 30 June 2023.

TRADE / EXPORT CONTROLS

Council of the European Union prolongs and expands sanctions against Russia (see [here](#) and [here](#))

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 values, fundamental interests, and security; preserving peace; and supporting democracy and the rule of law.

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 20 July 2023, the Council decided to prolong by six months (until 31 January 2024) the restrictive measures targeting specific sectors of the economy of the Russian Federation. Such restrictions are subject to renewal every six months.

These sanctions, 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 1st package of sanctions (see [here](#)) and now with the 11th package of sanctions (see [here](#)) adopted by the Council on 23 June 2023.* (see also [Jones Day EU Emergency Response Update No. 103 of 23 June 2023](#)).

Additionally, on 28 July 2023, the Council decided to impose restrictive measures against seven Russian individuals and five entities responsible for conducting a digital information manipulation campaign called "RRN" (Recent Reliable News), aimed at distorting information and disseminating propaganda in support of Russia's war against Ukraine. This information manipulation is one facet of Russia's wider hybrid campaign against the EU and its Member States.

EU restrictive measures against individuals and entities concerning asset freezes and travel restrictions now apply to a total of nearly 1800 individuals and entities. These measures are subject to renewal every six months, as most recently extended to 15 March 2024.

The EU restrictions also concern economic relations (e.g. certain import/export bans; certain bans on advisory/consultancy services) with the illegally annexed Crimea and the city of Sevastopol, the non-government controlled areas of the Donetsk and Luhansk oblasts, as well as Zaporizhzhia and Kherson.

A consolidated latest version of all Commission FAQs on implementation of sanctions adopted following Russia's military aggression against Ukraine is available [here](#).

** 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)).*

Belarus and Iran. In the context of Russia's invasion of Ukraine, the EU has also adopted sanctions against these two countries, and most lately:

- Belarus. On 3 August 2023 (see [here](#)), the Council imposed sanctions against an additional 38 individuals and 3 entities. EU restrictive measures on Belarus now apply to a total of 233 individuals and 37 entities.

Furthermore, the Council extended export bans from the EU to Belarus to include firearms, aviation and the space industry. Belarus is also subject to restrictions in the financial sector, trade, energy, transport areas, among others.

For an overview of EU restrictive measures against Belarus, see [here](#).

Iran. On 20 July 2023 (see [here](#)), the Council established a new framework for restrictive measures, which prohibits exports from the EU to Iran of components used to produce Unmanned Aerial Vehicles (UAVs). This new regime complements the three previously adopted packages of drone-related sanctions targeting individuals and entities, the latest of which in February 2023.

The Council also listed six Iranian individuals under two already existing sanctions regimes against Iran's military support to Russia's war of aggression against Ukraine (drones) and to the Syrian regime (air defence systems).

For an overview of EU restrictive measures against Iran, see [here](#).

European Parliament issues Briefing on proposed Directive on violation of EU sanctions (see [here](#))

On 11 July 2023, the European Parliament (EP) issued a Briefing on the proposed Directive on the violation of EU sanctions (*Proposal for a Directive on the definition of criminal offences and penalties for the violation of Union restrictive measures, 2 December 2022* ([here](#))).

Main features / background. The proposed Directive sets out common EU rules in view of facilitating the investigation, prosecution, and punishment of violations of restrictive measures in all Member States.

As noted in the EP Briefing, the need to standardize and strengthen implementation of EU sanctions has been recognized for nearly two decades. Russia's war against Ukraine has prompted a sense of urgency and increased the interest of the European Commission and Member States in improving sanctions enforcement to ensure the credibility and effectiveness of the sanctions regime against Russia. In presenting the proposed Directive, Věra Jourová, Vice-President for Values and Transparency stated:

"EU sanctions must be respected and those trying to get around them must be punished. The EU will carry on cracking down on those helping Russia to finance its war against Ukraine. The EU is showing once again that it is united in this effort – harmonising penalties for violating EU sanctions means no more loopholes, no more safe havens and no more playing the system..."

Key features of the proposed Directive include:

- A list of criminal offences that violate EU sanctions, e.g.:

- making funds or economic resources available to a natural or legal person subject to restrictive measures; failing to freeze such funds/economic resources;
 - engaging in trade or financial activities that are prohibited or restricted; and
 - providing other services that are prohibited or restricted, such as legal advisory services, business and management consulting, and tax consulting services.
- Offences also notably include circumventing EU restrictive measures, i.e., by bypassing or attempting to bypass such measures by concealing funds or concealing the fact that a person is the ultimate owner of funds.
 - Common basic standards for penalties, such that depending on the offence, individuals could be subject, for the most serious offenses, to a maximum penalty of at least five years in prison; companies could be subject to penalties of no less than 5% of the total worldwide turnover of the company in the business year preceding the fining decision.

Legislative process. The proposed Directive will undergo discussion by the EP and the Council as part of the ordinary co-legislative procedure.

On 9 June 2023, the Council of the European Union adopted its general approach on the proposal as the basis for negotiations with the EP to reach a common position on the draft law. The EP Briefing notes that the Council's general approach sets out various changes to the proposed Directive (e.g., limiting its scope to serious violations, such that violations involving funds, economic resources, goods, services and transactions of a value of less than €10,000 should not be covered).

On 6 July 2023, the EP's Committee on Civil Liberties, Justice and Home Affairs (LIBE) adopted its report on the proposed Directive, along with a decision to enter into trilogue negotiations with representatives of the Council and the Commission. Once approved by the full EP, the LIBE report will become the MEPs' position for talks on the legislation's final form. The EP Briefing notes that the LIBE report takes a harsher approach than the Commission proposal (e.g., violations of EU sanctions are to be considered criminal offences if committed with negligence, as compared to serious negligence in the Commission's proposal).

The EP Briefing further notes that various stakeholders have criticized the Commission for lack of an impact assessment for the proposed Directive, which seeks to significantly revamp the enforcement of restrictive measures. The Commission has justified the lack of an impact assessment, asserting the urgent need to adopt such harmonized rules on criminal offences and penalties for violating EU restrictive measures.

European Commission releases reporting rules for transitional phase of CBAM Regulation

On 17 August 2023, the European Commission published the Implementing Regulation on the rules governing implementation of the Carbon Border Adjustment Mechanism (CBAM) during its transitional phase (from 1 October 2023 until 31 December 2025). The transition period is to serve as a pilot and learning period for all stakeholders (importers, producers and authorities) and to enable collecting useful information on embedded emissions to refine the methodology for the definitive period.

(Carbon Border Adjustment Mechanism) (see [here](#))

Background. To recall, CBAM addresses greenhouse gas emissions embedded in imports into the EU of certain products in carbon-intensive industries, in view 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, which jeopardizes the EU's greenhouse gas emissions reduction efforts 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 initially applies 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.

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.

Implementing Regulation (IR). The newly published IR sets out the (i) transitional reporting obligations for EU importers of CBAM goods, and (ii) transitional methodology for calculating embedded emissions released during the production process of CBAM goods.

The IR's reporting requirements and methodology during the transitional phase notably provide for some flexibility concerning the values used to calculate embedded emissions on imports. During the first year of CBAM's implementation, companies may choose to report in three ways: (i) full reporting according to the new methodology (EU method); (ii) reporting based on equivalent third country national systems; and (iii) reporting based on reference values. As of 1 January 2025, only the EU method will be accepted.

Guidance documents. Additionally, the Commission also published guidance aimed at assisting stakeholders with navigating the CBAM transitional period:

- Guidance document on CBAM installations for importers of goods into the EU ([here](#));
- Guidance document on CBAM installations for installation operators outside the EU ([here](#)); and

- CBAM communication template for installations – Preliminary ([here](#)).

CBAM timing / next steps. During the transitional period starting on 1 October 2023 until 31 December 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, with a definitive methodology expected by 2026.

Importers will be asked to collect fourth quarter data on emissions embedded in their goods subject CBAM as of 1 October 2023, although their first report need only be submitted by 31 January 2024.

A review of CBAM's functioning during its transitional phase will be concluded before the entry into force of the definitive system. The review will also include the scope of products concerned to assess the feasibility of including other goods produced in sectors covered by the EU ETS within the scope of the CBAM mechanism, such as certain downstream products. The review report will include a timetable setting out their inclusion by 2030.

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.

** The EU ETS is one of the EU's key climate change mitigation policies and is the world's first carbon market, aimed 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.*

MEDICINES AND MEDICAL DEVICES

Recommendations for actions to avoid shortage of key antibiotics issued by European Commission, Heads of Medicines Agencies and European Medicines Agency (see [here](#))

On 17 July 2023, the European Commission, the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) issued recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections for European patients in fall/winter 2023.

In particular, the EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)* agreed on recommendations for proactive actions:

- **Increasing production of key antibiotics:** To avoid shortages in the upcoming autumn/winter season, EMA and HERA (Health Emergency Preparedness and Response) are to continue engaging with marketing authorization holders (MAHs) to ramp up measures to increase production. Early action should give manufacturers adequate time to ensure sufficient manufacturing capacity to meet demand.
- **Monitoring of supply and demand:** EMA, the Commission and Member States will continue to monitor supply/demand of key antibiotics in cooperation with concerned MAHs. As the measures seek to ensure sufficient supply, all stakeholders are reminded to order medicines as normal. There is no need to stockpile medicines, which can further strain supplies and cause or aggravate shortages.
- **Public awareness and prudent use:** Antibiotics should be used prudently to maintain their efficacy and avoid antimicrobial resistance. Antibiotics,

which should only be prescribed for bacterial infections, are unsuitable and ineffective for treating viral infections such as cold and flu.

These recommendations on actions on antibiotics form part of the wider EU framework to prevent and reduce medicine shortages. The recommendations complement the process for developing an EU list of critical medicines, which aims to ensure the sustained availability of such medicines in the EU/EEA. The first version of such EU list of critical medicines is anticipated by end-2023.

Next steps. The EMA and the Commission (through HERA) will continue to track supply/demand and interact with MAHs to timely detect any unexpected shortfalls of supplies and take any necessary measures in close cooperation with Member States, including, if necessary, possible joint procurements.

** The MSSG was established as part of the EMA's expanded mandate following the COVID-19 pandemic under Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices of 31 January 2022, including to act in case of a cross-border major event (i.e., a public emergency likely to pose a serious risk to public health in relation to medicinal products in more than one Member State (see also [Jones Day COVID-19 EU Regulatory Update No. 75 of 1 February 2022](#)).*

Report published on EMA/ETF Workshop on Lessons Learned on Clinical Trials in Public Health Emergencies (see [here](#))

On 25 July 2023, EMA published the Report of the EMA/ETF (Emergency Task Force of EMA) Workshop (held 9 June 2023) on Lessons Learned on Clinical Trials in Public Health Emergencies, which gathered concerned stakeholders.

The Report notes that the COVID-19 and Mpox public health emergencies highlighted the need to improve the setting up and conducting of clinical trials in the EU during a crisis. In particular, to support rapid access to treatments and vaccines, it is vital that sufficient evidence is rapidly gathered from adequately sized clinical trials across multiple Member States.

The Report provides an overview of (i) issues identified as hampering the swift set up of clinical trials during public health emergencies; and (ii) possible concrete actions.

The proposed actions focused on two areas: (i) the processing and regulatory approval of large, multinational clinical trials; and (ii) the framework for funding and efficient allocation of resources for clinical trials.

The challenges and proposed actions discussed included, in particular:

- Slow assessment/authorization of clinical trial applications. Proposed remedial actions include the setting up of an EU-level cooperation mechanism between national ethics committees, open to participation from representatives from all Member States, in addition to creating a pre-submission consultation upon the sponsor's request on specific (individual) clinical trials applications.
- Lack of flexibility in Clinical Trial Regulation (CTR) for approval process. Proposed remedies include reconsidering CTR implementation with enhanced flexibility in mind, such as using a simplified template and simplified process for providing a final assessment report. Furthermore, it is proposed to revise the HMA/EMA/European Commission COVID-19 flexibilities paper in view of applying the paper to any public health emergency trial.

- Gaps in functioning and knowledge of Clinical Trial Information System (CTIS). Proposed actions include to ensure that sponsors of emergency clinical trials are represented at relevant clinical trials fora such as the CTIS Forum and ACT EU Multi-Stakeholder Platform. It is further proposed to continue to disseminate EMA training material at EU, national, regional, and local level.
- Insufficient coordination and fragmentation of clinical trials during emergencies. Proposed actions include establishing a Coordinating Committee for improved coordination of decisions on prioritizing clinical trials in Europe. Such Committee would make recommendations to support rapid decisions on selecting studies needed and the clinical trial network/platform to use in an emergency.
- Slow and uncertain funding mechanisms for larger, multinational trials: Proposed actions include setting up efficient and predictable funding mechanisms for high-priority emergency or preparedness trials and facilitating clinical trial sites contracting.

The Report's findings will serve as guidance for Member States, EMA, and the Commission in defining a roadmap towards enabling multinational clinical trials in the EU in emergency contexts.

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Parliament and Council move forward on draft Cyber Resilience Act (see [here](#) and [here](#))

On 19 July 2023, the European Parliament (Industry, Research and Energy Committee (ITRE)) approved, with proposed amendments, the draft proposal for a Regulation on cybersecurity requirements for products with digital elements (Cyber Resilience Act). On the same day, the Council (Committee of Permanent Representatives (Coreper)) also reached a common position on the proposed Act.

To recall, the proposed Act aims to safeguard EU businesses and consumers buying or using digital products against the risks arising from inadequate cybersecurity features. The rules would apply to products with digital elements connected to a device or network (e.g., phones, toys) (see also [Jones Day COVID-19 Update No. 87 of 4 October 2022](#)).

As explained in the Commission's Impact Assessment Report on the proposed Act (see [here](#)), both companies and consumers are increasingly dependent on products with digital elements, particularly since the COVID-19 pandemic, which accelerated the digitization of society and the spread of telework. The importance and impact of cyberattacks are also significantly increasing.

The Parliament's ITRE Committee suggests amendments such as the following to the proposed Act:

- Expand the list of products identified in the proposed Act (grouped based on their criticality and the level of cybersecurity risk that they raise) to include items such as smart watches, private security cameras, and password managers;
- Require that products receive security updates automatically and separately from functional updates;

- Implement education and training programmes, given the importance of professional skills in the cybersecurity field needed to undertake various tasks set out in the proposed Act.

In announcing the ITRE Committee's proposed amendments, lead MEP Nicola Danti stated: *"Thanks to the Cyber Resilience Act, hardware and software products will be more cyber secure, vulnerabilities will get fixed and cyber threats to our citizens will be minimised."*

Concerning the Council's (Coreper) common position, the Member States supported the draft Act's general approach, while suggesting certain amendments such as:

- Modifying reporting obligations, such that actively exploited vulnerabilities or incidents shall be reported to competent national authorities (Computer Security Incident Response Teams (CSIRTs), rather than the EU agency for cybersecurity (ENISA), with ENISA establishing and managing a single reporting platform;
- Establishing elements for determining the expected product lifetime by manufacturers;
- Clarifying provisions on dual-use products and software, including the status of open source components and Software-as-a-Service (SaaS);
- Implementing measures to support small and micro enterprises;
- Providing a simplified declaration of conformity.

Next steps. Trilogue negotiations will take place with representatives of the Parliament, Council, and the Commission in view of reaching a final version of the proposed Act.

European Commission publishes Communication on a common European tourism data space (see [here](#))

On 20 July 2023, the European Commission published a Communication *"Towards a Common European Tourism Data Space: boosting data sharing and innovation across the tourism ecosystem"*. The Communication sets out the building blocks for such European tourism data space, anticipated as a key tool for supporting the tourism sector's transition towards greater digitalization and sustainability. Tourism is a complex, fast-moving industrial ecosystem that produces and consumes significant amounts of data.

The tourism data space initiative concerns all stakeholders in the tourism ecosystem, including Member States, local and regional authorities, the private sector, and the European institutions.

The Communication recalls that data sharing is the focus of various sectoral legislative initiatives impacting the tourism sector, such as the [proposed Regulation on data collection and sharing relating to short-term accommodation rental services](#) (STRs). In releasing the proposed STR Regulation, the Commission noted that the COVID-19 crisis confirmed the trend that STRs have become critical to the EU tourism sector. The online platform economy has boosted fast-paced growth in STR bookings, which increased during the summers of 2020 – 2021 (as compared to 2018) (see also [Jones Day COVID-19 Update No. 91 of 9 November 2022](#)).

The common European tourism data space intends to:

- Facilitate data-sharing from diverse sources, such as businesses and local authorities (e.g., data on hotels' energy consumption can help monitor tourism's environmental impact on a given destination).
- Enhance data access by a broad range of users, including business intermediaries, destination managers, tourism service providers, and others (e.g., providing travel agents with a better overview of offers across cities, regions and borders).
- Foster a reliable and efficient framework for governance of the common European tourism data space, based on existing EU and national legislation on data.
- Offer interoperability across data domains and sectoral data spaces with clear ties to the tourism experience (e.g., energy; environment; health, etc.).

Next steps. By end-2023, two Coordination and Support Actions funded under DEP ([Digital Europe Programme](#))* will provide the Commission with an updated map of relevant public/private initiatives, an in-depth analysis of the key enablers of a data space for tourism, recommendations for a governance model and technical standards, and a blueprint for deploying the tourism data space.

* *Digital Europe Programme (DIGITAL) is a new EU funding program focused on bringing digital technology to businesses, citizens and public administrations.*

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