EU EMERGENCY RESPONSE UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

No. 110 | 24 November 2023

This regular alert covers key regulatory developments related to EU emergency responses, including in particular to Russia's war of aggression against Ukraine, COVID-19, 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 publishes updated Q&As for Foreign Subsidies Regulation
- European Commission adopts amended Temporary Crisis and Transition Framework for State aid to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies
- 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
- European Commission approves further scheme to compensate for damage due to COVID-19 crisis

Trade / Export Controls

- EU and Angola sign first-ever Sustainable Investment Facilitation Agreement
- Access2Conformity tool launched to promote trade with third countries
- European Commission publishes 3rd Annual Report on Implementation and Enforcement of EU Trade Agreements

Medicines and Medical Devices

- Council and Parliament reach provisional agreement on Interoperable Europe Act
- European Commission calls for urgent action on antimicrobial resistance

Cybersecurity, Privacy & Data Protection

- European Commission welcomes final agreement on EU Digital Identity Wallet

- European Commission welcomes political agreement on automated data exchange for police cooperation (Prüm II)

COMPETITION & STATE AID

Competition	
European Commission publishes updated Q&As for Foreign Subsidies Regulation (see [here](#))	On 22 November 2023, the Commission published updated Q&As for the Foreign Subsidies Regulation (FSR) (*Regulation (EU) 2022/2560 of 14 December 2022 on foreign subsidies distorting the internal market*), which became applicable on 12 July 2023. 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 EU Emergency Measures Update No. 105 of 31 August 2023 and Jones Day Commentary, EU Adopts Reporting Requirements for Transactions and Public Bids Under the Foreign Subsidies Regulation, July 2023*). 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 or declaration obligations for certain large M&A transactions and public bids in the EU: • Mandatory notification for concentrations, 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 provide a notification when: – the estimated contract value is at least €250 million; and – the bid involves combined aggregate foreign financial contributions of at least €4 million per non-EU country over the past 3 years. The Commission's Q&As provide details and guidance on applying the FSR, and its most recent additions/updates cover topics such as the following: • On procedural and jurisdictional issues, for example: – Q&A No. 8 provides confirmation that the concepts of "concentration", "merger", "joint venture" and "acquired undertaking" in the FSR (Article 20) are inspired from those used under the EU Merger Regulation (*Regulation (EC) 139/2004 on the control of concentrations between undertakings*). General guidance on how these specific notions have previously been interpreted can be found in the Commission Consolidated Jurisdictional Notice.

	• On implementation issues, for example: – Q&A No. 20 indicates that the appropriate exchange rates to be used for any financial data to be reported are "*the average exchange rates prevailing for the years or other periods in question*" (*pursuant to the FSR Implementing Regulation (Regulation (EU) 2023/1441, Annex I, Recital 25*). Therefore, for reporting financial contributions provided in non-EUR currencies: o The yearly average European Central Bank (ECB) exchange rate should be used for the calendar year in which the foreign financial contribution was granted. o For foreign financial contributions granted in the same year as the notification [under the FSR], notifying parties can use the ECB exchange rate up to date (i.e. for the ongoing year). The Q&As are non-binding and may evolve from time to time.
State aid	
European Commission adopts amended Temporary Crisis and Transition Framework for State aid to support economy in context of Russia's invasion of Ukraine and accelerating green transition and reducing fuel dependencies (see here)	On 20 November 2023, the Commission adopted a Communication on an Amendment to the Temporary Crisis and Transition Framework for State Aid measures to support the economy following the aggression against Ukraine by Russia ("amended TCTF"). To recall, the TCTF (*adopted on 23 March 2022, and subsequently amended in 20 July 2022 and 28 October 2022 and replaced on 9 March 2023 – a consolidated version of the TCTF is here*) responds to Russia's war against Ukraine and its direct and indirect effects on the EU economy, as well as acceleration of the EU's green transition. The Commission noted that while the risks of energy supply shortages have overall receded, including as a result of Member State initiatives to diversify energy sources, the European Economic Forecast - Autumn 2023 reports that Russia's continuing war against Ukraine and geopolitical tensions continue to pose risks and remain a source of uncertainty. The amended TCTF allows Member States to grant the below crisis-related measures, as modified and prolonged: • "*Limited amounts of aid*" (Section 2.1): The ceilings for limited amounts of aid are raised to cover the winter heating period for the agricultural sector (from €250,000 to €280,000); for the fisheries and aquaculture sectors (from €300,000 to €335,000); and for all other sectors (from €2 million to €2.25 million). Such measures are also extended for six months (until 30 June 2024); and • "*Aid to compensate for exceptionally severe increases in natural gas and electricity prices*" (Section 2.4): Member States can continue to provide support by covering parts of additional energy costs, but only as far as the energy prices significantly exceed pre-crisis levels. This measure is also extended for six months (until 30 June 2024).

	These changes do not affect the remaining provisions of the amended TCTF: • For other crisis-related measures, the expiry date of 31 December 2023 was maintained for liquidity support in the form of State guarantees (Section 2.2) and subsidized loans (Section 2.3); and for measures aimed at supporting electricity demand reduction (Section 2.7). • For measures on the transition towards a net-zero economy, required to further decarbonize the European economy and accelerate greater independence from fossil fuels (Sections 2.5, 2.6 and 2.8), these remain available until 31 December 2025. Looking ahead. The Commission will continue to monitor economic developments and will respond to eventual new crisis situations. However, the Commission does not currently plan to consult Member States again on the crisis-related measures of the amended TCTF that will phase out on 30 June 2024 as above-mentioned.
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 (applied as from 9 March 2023 and amended on 20 November 2023, *see also above item*). Among the most recently approved State aid schemes under the TCTF (up to 24 November 2023): – €3 billion Austrian State aid scheme to support companies facing increased energy costs in the context of Russia's war against Ukraine. – Two Slovak schemes, with a total budget of €560 million to support small and medium-sized enterprises (SMEs) and large enterprises in the context of Russia's war against Ukraine. – €60 million Dutch scheme to support companies having implemented renewable heat projects active in the Netherlands 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)	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 24 November 2023): – €39 million Italian scheme to compensate travel agencies and tour operators in the context of the coronavirus pandemic. Under the measure, the aid takes the form of direct grants to compensate companies for the damages suffered during the coronavirus pandemic. The approved scheme covers the period between 1 January 2021 and 31 December 2021, when travel agencies and

tour operators were affected by the restrictive measures imposed by the Italian authorities to limit the spread of the virus.

** 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

EU and Angola sign first-ever Sustainable Investment Facilitation Agreement (see here)

On 17 November 2023, the EU and Angola (Parties) signed a Sustainable Investment Facilitation Agreement (SIFA). This is the EU's first-ever agreement on investment facilitation.

The SIFA's stated objective is to facilitate the attraction, expansion and retention of foreign direct investment between the Parties for the purposes of economic diversification and sustainable development.

The SIFA is aligned with the European Commission's 2021 Trade Policy Review, which emphasized that trade would be key to recovery from the COVID-19 crisis and to achieving the EU's green and digital transition (*see also Jones Day COVID-19 Update No. 37 of 24 February 2021*). In this respect, the Trade Policy Review included a focus on the EU's partnerships in Africa and neighboring enlargement countries, notably in view of strengthening supply chain resilience.

The SIFA's aim of expanding foreign direct investment focuses on various commitments by the Parties, such as:

- Increasing transparency and predictability of investment-related measures (e.g., by publishing all investment laws and conditions and supporting the use of single information portals for investors);
- Streamlining investment authorization procedures (e.g., by avoiding, to the extent practicable, requiring an applicant to approach more than one competent authority for each application for authorization);
- Fostering e-government (e.g., to the extent possible, accepting applications in electronic format for required authorizations); and
- Facilitating interactions between investors and administration (e.g., by holding stakeholder consultations).

SIFA provisions also address environmental, climate and labor rights, including the Parties' commitments to the following in particular:

- Committing against weakening or waiving environmental or labor laws and standards in order to attract investment; and
- Promoting corporate social responsibility and responsible business practices in view of contributing to sustainable development and

	responsible investment, e.g. through the exchange of information and best practices. The EU will provide technical support to assist in implementing the SIFA, including through a new, regional €2.8 million programme by the EU with UNCTAD (UN Conference on Trade and Development) to assist Angola in identifying initial priority implementation needs. Angola is the EU's 6th investment destination in Africa, covering 7% of EU foreign direct investments in the continent and amounting to €14.1 billion in 2021. Angola's investment in the EU amounted to € 3.5 billion in 2021. The EU is Angola's main trade and investment partner. Next steps. Following the SIFA's signature, the EU and Angola will notify each other on the completion of their respective internal procedures. For the EU, this includes the consent of the European Parliament, whose Committee on International Trade (INTA) met on 27-28 November 2023 to discuss the SIFA with European Commission Executive Vice-President and Commissioner for Trade, Valdis Dombrovskis (*see here for draft INTA Recommendation to consent to the SIFA*).
Access2Conformity tool launched to promote trade with third countries (see here)	On 13 November 2023, the European Commission's Directorate-General for Trade announced the launch of a new "Access2Conformity" tool to assist EU exporters with reducing red tape and increasing trade by better benefiting from the EU's Mutual Recognition Agreements (MRAs) with third countries. MRAs promote trade in goods between the EU and third countries by ensuring that both trading partners accept each other's conformity assessment and that the products traded fulfil all necessary requirements. Companies thereby need not test their products twice in order to trade. MRAs currently exist with Australia, Canada, Japan, New Zealand, the United States, and Switzerland. Access2Conformity, integrated into the Commission's Access2Markets trade portal, will assist EU exporters in identifying where they can perform product testing and certification in the EU when exporting to certain third countries. For example, an EU exporter could determine if its product can benefit from the MRA with Australia, which covers certain products in sectors such as automotive equipment, low voltage equipment, and medical devices. The Access2Conformity initiative is in line with the European Commission's 2021 Trade Policy Review, which emphasized that trade would be key to recovery from the COVID-19 crisis and to achieving the EU's green and digital transition (*see also Jones Day COVID-19 Update No. 37 of 24 February 2021*). In this respect, the Trade Policy Review raised the importance of: • Strengthening the EU's partnerships with third countries, including facilitating trade through measures such as agreements on conformity assessment; and • New online tools to support EU businesses, in particular SMEs, including extending the Access2Markets trade portal to increase information for EU services exporters and investors and other upgrades to the platform.

	Outlook. The Commission forecasts that by making full use of MRAs, which help companies to save time and money through less paperwork, this could boost trade by up to 40% and increase the likelihood that SMEs will export by up to 50%. This greater participation in trade will reinforce competition and a more diverse global supply chains through a level playing field.
European Commission publishes 3rd Annual Report on Implementation and Enforcement of EU Trade Agreements (see here)	On 11 November 2023, the European Commission released its 3rd Annual Report on the Implementation and Enforcement of EU Trade Agreements, covering the period 2022 and Q1 2023.* The Report highlights that the value of EU trade through free trade agreements with global partners exceeded €2 trillion for the first time in 2022, with trade with the EU's top 20 trade agreement partners rising by nearly 30% on average in 2022. The EU has the world's largest network of trade agreements, with a total of 74 countries, accounting for 44% of all EU trade. The Report emphasized that these agreements have helped to build trade, investment, and resilient supply chains in a difficult global business environment characterized by growing geopolitical challenges, such as Russia's war against Ukraine. In particular, the EU's trade agreements: • Create new export opportunities for EU producers (e.g., under respective trade agreements, EU exports in pharmaceuticals to Vietnam increased by 152%; cars and parts to South Korea by 217%; and EU services' exports to Canada by 54%); • Shield exports from external shocks (e.g., Between 2021 and 2022, EU exports of sanctioned goods to Russia fell by €27 billion, while EU exports of the same goods to preferential partners increased by €174 billion); • Securing diversified access to key inputs (e.g., in the first five years of the EU-Canada (CETA) agreement, which provisionally entered into force starting in 2017, EU imports of critical raw materials from Canada rose by 56%, compared to growth of only 25% of these materials from other sources), contributing to the EU's strategy to diversify away from Russia. Also notably in 2022, the Commission resolved (fully or partially) 31 trade barriers in 19 partner countries. These solved barriers have a direct positive effect for EU exporters in key sectors such as agri-food, pharmaceuticals, and health and beauty. The accompanying Staff Working Document provides further details on the Report (see here), including additional information (country sheets) on 39 individual EU trade agreements and a list of new barriers recorded and barriers resolved in 2022. * *For the 2nd Annual Report, see COVID-19 Update No. 89 of 14 October 2022.*

MEDICINES AND MEDICAL DEVICES	
Council and Parliament reach provisional agreement on Interoperable Europe Act (see here)	On 13 November 2023, the Council of the EU and the European Parliament reached a provisional agreement on the proposed Regulation laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act), proposed on 18 November 2022 (see here). In welcoming the provisional agreement, the European Commission noted that the COVID-19 pandemic had shown that interoperability fosters resilience and responsiveness in times of crisis. Notably, interoperability of the European Digital COVID-19 certificates across all Member States enabled swifter and safe re-opening of cross-border travel in Europe, and allowed for real-time sharing of data on available beds in intensive care in hospitals. The COVID-19 crisis also pushed public administrations to adapt to the online paradigm. The digital transformation of the public sector, as enabled by interoperability, is therefore viewed as integral to post-pandemic society. Against this background, the European Commission proposed the Interoperable Europe Act, which aims to set up a new cooperation framework for public administrations across the EU to facilitate the seamless cross-border exchange of data through strengthened interoperability and cooperation in the public sector. In particular, the proposed Act introduces: • A structured EU cooperation where public administrations, supported by public and private actors, come together in the framework of projects co-owned by Member States, as well as regions and cities; • The sharing and reuse of solutions, often open source, powered by an "Interoperable Europe Portal", a one-stop-shop for solutions and community cooperation on the cross-border interoperability of trans-European digital public services; • Mandatory assessments to evaluate the impact of changes in information technology systems on cross-border interoperability in the EU; and • Innovation and support measures, including regulatory sandboxes for policy experimentation, and public-private "GovTech" projects to develop and scale up innovative solutions for the public sector, and training support. The proposed Act identifies the health sector as one of the areas with a strong public sector connection and where interoperability will particularly facilitate successful implementation of policies. In this respect, the Commission has noted that European citizens would greatly benefit from cross-border interoperability of key digital public services, such as electronic health records at national and regional level that would enable citizens to access their personal health data. The main changes to the proposed Act in the Council and the Parliament's provisional agreement address, for instance, consistency with the provisions of the General Data Protection Regulation (GDPR) and the forthcoming Artificial Intelligence Act (*see also Jones Day Alert, EU Strikes Political Deal on Landmark Artificial Intelligence Act, December 2023*) with

	regard to establishing and participating in interoperability regulatory sandboxes. Next steps. The co-legislators will need to confirm the text of the full agreement, before formally adopting the Act.
European Commission calls for urgent action on antimicrobial resistance (see here)	On 17 November 2023, the European Commission called for urgent action on antimicrobial resistance (AMR), particularly in light of new AMR data released the same day by the European Centre for Disease Prevention and Control (ECDC). To recall, combating AMR is among the Commission's top priorities and an essential component of many initiatives under the European Health Union. AMR is a key element of the proposed reform of EU pharmaceutical legislation announced in April 2023, the most significant revision since 2004 and which takes heed of lessons learned from the COVID-19 crisis (*see also Jones Day EU Emergency Response Update No. 102 of 3 May 2023*). As part of the reform of EU pharmaceutical legislation, in particular, the Council adopted a Recommendation on stepping up EU actions to combat AMR in a One Health approach on 13 June 2023 (see here). Seeking to lower the risk that microorganisms will become resistant to medical intervention, the Recommendation encourages the prudent use of antimicrobials (such as antibiotics in human and animal health) through a series of voluntary measures, e.g., concrete targets to reduce antimicrobial use by 2030, including a 20% reduction in total human consumption of antibiotics and a 50% reduction in overall EU sales of antimicrobials used for farm animals and aquaculture. As concerns the ECDC's new data on AMR, this was released in two reports: • Antimicrobial resistance in the EU/EEA - Annual epidemiological report for 2022, which indicates slow progress in certain areas, but that antimicrobial resistance remains a significant challenge in the EU/EEA; and • Antimicrobial consumption in the EU/EEA - Annual Epidemiological Report for 2022, which indicates overall progress between 2019-2022 towards the target to cut antimicrobial use by 20% by 2030, but that consumption increased again in 2022, as many Europeans resumed their pre-COVID-19 pandemic way of life. Stella Kyriakides, Commissioner for Health and Food Safety, emphasized: *"Tackling AMR is a public health priority and an economic necessity. The figures are concerning, showing that urgent and ambitious action is needed. We must work together, Member States, stakeholders as well as citizens to ensure that all necessary measures are taken to meet the agreed targets.*" The ECDC estimates that over 35,000 people die annually from infections resistant to antibiotics in the EU, Iceland, and Norway, with AMR costing EU/EEA countries some €11.7 billion a year (see OECD report on fighting AMR, released on 14 September 2023).

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission welcomes final agreement on EU Digital Identity Wallet (see here)	On 8 November 2023, the European Commission welcomed the final agreement reached by the European Parliament and the Council of the EU on the Regulation on establishing a framework for a European Digital Identity, which introduces the European Digital Identity Wallet.* To recall, the Commission noted the urgency of this forthcoming Regulation, given the COVID-19 pandemic and the sudden need for accessing and using all types of public and private services online. Consequently, demand had "radically increased" for means to identify and authenticate online, in a secure manner and with a high level of data protection (see also *Jones Day COVID-19 Update No. 78 of 4 March 2022* and *Jones Day COVID-19 Update No. 98 of 1 March 2023*). The forthcoming Regulation aims to ensure universal access for individuals and businesses to trustworthy electronic identification and authentication across the EU by means of a European Digital Identity Wallet, which will in particular: – Provide a harmonized means of electronic identification, accepted in all Member States, that will enable natural and legal persons to authenticate and share data linked to their identity; and – Offer uses such as: opening bank accounts online; making online payments; submitting tax declarations; bidding in an online call for tender; holding digital documents (e.g., driving licenses, medical prescriptions, travel documents, etc.); reporting alleged data protection violations; and interacting between Wallets. Notably, while holding a Digital Identity Wallet will be voluntary, certain entities will be required to recognize Wallets (e.g., public services and certain private services (Very Large Online Platforms (i.e., platforms or search engines having more than 45 million users per month in the EU, as defined by the Digital Services Act) and those required by law to use strong user authentication). Next steps. The final agreement of the co-legislators is now subject to formal approval by the Parliament and the Council. Once adopted, the Regulation will be published in the Official Journal and will enter into force on the 20th day following its publication. * *Commission's proposed Regulation of 3 June 2021 on establishing a framework for a European Digital Identity (see here). The proposed Regulation will amend the eIDAS Regulation (Regulation (EU) No 910/2014 on electronic identification and trust services for electronic transactions.*
European Commission welcomes political agreement on automated data exchange for police cooperation (Prüm II) (see here)	On 20 November 2023, the European Commission welcomed the political agreement reached by the European Parliament and the Council of the EU on the Regulation on automated data exchange for police cooperation (Prüm II). The forthcoming Regulation revises the existing framework on automated data exchange for police cooperation (Prüm I), which has enabled law

enforcement authorities to consult the national databases of other Member States as concerns DNA, fingerprint, and vehicle registration data.

To further enhance EU police cooperation and security in Europe, the Prüm II framework will significantly broaden the data categories subject to automatic exchanges by adding facial images and police records.

Furthermore, Prüm II will modernize the technical infrastructure underpinning the exchange of information by centralizing data flows to make law enforcement swifter and more effective.

The new rules will improve and facilitate data exchange between enforcement authorities, for instance, by:

- Preserving the existing automated exchange on DNA profiles, dactyloscopy data (fingerprints,) and vehicle registration data;
- Commencing automated data exchanges on facial images and police records;
- Creating the European Police Records Index System (EPRIS) for automated exchange of police records; and
- Aligning exchanges under the Prüm framework to the data protection framework with robust safeguards.

Next steps. The Council and European Parliament will formally adopt the Regulation in line with the political agreement.

LAWYER CONTACTS

Kaarli H. Eichhorn
Partner, Antitrust & Competition Law; Government Regulation; Technology
Brussels
keichhorn@jonesday.com
+32.2.645.14.41

Cristiana Spontoni
Partner, Health Care & Life Sciences; Government Regulation
Brussels
cspontoni@jonesday.com
+32.2.645.14.48

Dr. Jörg Hladjk
Partner, Cybersecurity, Privacy & Data Protection; Government Regulation; Technology
Brussels
jhladjk@jonesday.com
+32.2.645.15.30

Rick van 't Hullenaar
Partner, Government Regulation; Investigations & White Collar Defense
Amsterdam
rvanthullenaar@jonesday.com
+31.20.305.4223

Nadiya Nychay
Partner, Government Regulation; Antitrust & Competition Law
Brussels
nnychay@jonesday.com
+32.2.645.14.46

Dimitri Arsov *(Associate),* ***Benedetta Brambati*** *(Associate),* ***Lucie Fournier*** *(Associate),* ***Guillermo Giralda Fustes*** *(Associate),* ***Cecelia Kye*** *(Consultant), and* ***Justine Naessens*** *(Associate) in the Brussels Office contributed to this Update.*