



EU EMERGENCY RESPONSE UPDATE KEY POLICY & REGULATORY DEVELOPMENTS

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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](#)).

LATEST KEY DEVELOPMENTS

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COMPETITION & STATE AID

Competition

European Commission's merger simplification package becomes applicable (see [here](#))

On 1 September 2023, the European Commission's merger simplification package entered into force. Adopted on 20 April 2023, the package's three measures further simplify procedures for reviewing concentrations under the EU Merger Regulation: (1) a revised [Merger Implementing Regulation](#); (2) a [Notice on Simplified Procedure](#); and (3) a [Communication on the transmission of documents](#). The Commission's [Merger Policy Brief](#), dated 1 September 2023, also provides further details on the package.

To recall, the merger simplification package's primary measures aim at streamlining merger review and include, among others:

For the simplified procedure:

- Broadening and/or clarifying cases that can be reviewed under the simplified procedure, e.g.:
 - The Notice identifies two new categories of cases that can benefit from simplified treatment. These comprise cases where under all plausible market definitions:
 - The individual or combined upstream market share of the merging parties is below 30% and their combined purchasing share is below 30%; and
 - The individual or combined upstream and downstream market shares of the merging parties are below 50%, the market concentration index (HHI delta) is below 150, and the company with the smallest market share is the same in the upstream and downstream markets.
- Facilitating the review of simplified cases. The Implementing Regulation introduces a new notification form (so-called "tick-the-box" Short Form CO) for simplified cases, which includes primarily multiple-choice questions/tables and streamlined questions on the jurisdictional and substantive assessment of cases.

Notably, the following two categories of simplified cases can benefit from "super-simplified" treatment:

- (i) joint ventures whose activities are exclusively located outside the EEA (Notice on Simplified Procedure, point 5(a)); and
- (ii) concentrations without any horizontal overlaps or any non-horizontal (i.e., vertical or conglomerate) relationships between merging parties' activities (Notice on Simplified Procedure, point 5(c)).

The information required for these cases is significantly reduced, and merging parties are advised to save time by directly notifying, without pre-notification contacts with the Commission.

For the non-simplified procedure:

- The Implementing Regulation reduces and clarifies the information requirements in the notification form for these cases (Form CO, Annex I of Implementing Regulation), such as by:
 - Clarifying information on possibilities for waivers from certain information requirements, which codifies existing practice;
 - Eliminating certain previous information requirements concerning “Cooperative Agreements”, “Trade between Member States and imports from outside the EEA”, and “Trade associations”.

On transmitting documents to the Commission, the new Communication introduces electronic notifications by default, and notably:

- Following exceptional measures taken due to the COVID-19 pandemic, since May 2020, the Commission has been temporarily accepting (and encouraging) notifications in digital format. Based on this experience and to promote the Commission’s digital transformation, it is appropriate to establish permanent rules on digital transmissions of documents in the context of EU merger control.
- Technical specifications are provided for the signature of documents submitted electronically (where a signature is required). In this respect, documents submitted electronically must be signed using at least one Qualified Electronic Signature (QES) complying with the requirements set out in the [eIDAS Regulation](#) (Regulation (EU) No 910/2014).
- A fall-back mechanism allows for transmitting documents to the Commission’s Directorate General for Competition by post or by hand delivery (e.g., in exceptional circumstances, for example, where transmissions exceed 10 gigabytes in size; or where required electronic delivery or signing is technically not possible).

The Commission’s webpage on [merger simplification](#) provides further details, including a [practical information section](#), with guidance on, e.g.,

- [eTrustEx](#) (Trusted Document Exchange), the platform for secure transmission of documents between DG Competition and external stakeholders.
- [eRFI](#) (electronic Request for Information (RFI)) provides respondents with a secure web-based workspace to (co-)draft, and submit their replies to the Commission.
- Key templates such as a model power of attorney for notifications; and table for turnover data for notifications.

Looking ahead. As stated in the above-referred Merger Policy Brief, the Commission expects that by broadening and clarifying the categories of simplified cases, some 10% of cases previously requiring notification under the ordinary procedure will now be reviewed under the simplified procedure. Thus, the Commission anticipates that at least 80% of all notified cases will be reviewed under the simplified procedure going forward.

By substantially alleviating the procedural burdens within merger control for unproblematic cases, the Commission expects that this will enable a more focused examination of cases deemed as warranting closer scrutiny.

Executive Vice-President and Competition Commissioner Vestager temporarily withdraws from the European Commission's work (see [here](#))

Commission President von der Leyen granted unpaid leave, as announced on 5 September 2023, to Executive Vice-President and Competition Commissioner Margrethe Vestager during her campaign for the position of President of the European Investment Bank (EIB),* following Commissioner Vestager's nomination as an official candidate by the Danish government (see also [Jones Day EU Emergency Response Update No. 104 of 10 July 2023](#)).

During the period of Commissioner Vestager's temporary withdrawal from the Commission's work, President von der Leyen has assigned her work as follows:

- Vice-President for Values and Transparency Věra Jourová will be responsible for the steering and coordination of "A Europe Fit for the digital age"; and
- Justice Commissioner Didier Reynders will be responsible for Competition.

Commissioner Vestager, as reported in the press, has notably resolved to take more risk at the EIB if becoming its president, contending that the EIB's conservative approach will not suffice for the green transition and reconstruction of Ukraine.

* *The EIB, the lending arm of the European Union, is the world's largest multilateral financial institution (balance sheet of over €544 billion) and one of the largest providers of climate finance.*

TRADE / EXPORT CONTROLS

European Commission President Ursula von der Leyen announces initiation of anti-subsidy investigation into EU imports of electric vehicles from China (see [here](#))

During her 2023 State of the Union speech on 13 September 2023, European Commission President Ursula von der Leyen announced the initiation of an EU anti-subsidy investigation into EU imports of electric vehicles (EV) from China, stating:

"[The electric vehicles sector] is a crucial industry for the clean economy, with a huge potential for Europe. But global markets are now flooded with cheaper Chinese electric cars. And their price is kept artificially low by huge state subsidies. This is distorting our market."

According to press reports, the Commission is initiating the investigation on an *ex officio* basis (i.e., upon the Commission's own initiative, under Regulation (EU) 2016/1037 on protection against subsidised imports from countries not members of the European Union, Article 10(8)), rather than following a formal complaint by members of the relevant industry. While it appears that a number of EU Member States and some EU EV manufacturers support the Commission's decision to investigate, others reportedly oppose eventual anti-subsidy measures.

Initiating EU trade defense investigations on an *ex officio* basis is less common than following the filing of a formal complaint. However, they are subject to the same legal and evidential requirements as those applicable to complaints. Thus, the Commission may only initiate an *ex officio* investigation if it has sufficient evidence of dumped imports causing injury to the European industry.

Next steps: the initiation of the investigation will be formalized with the publication of a notice of initiation (NOI) in the Official Journal of the EU. The NOI should include more detailed information on the investigation itself, including the exact EV imports from China that are concerned.

The anti-subsidy investigation could stretch beyond the term of the current European Commission, ending in summer 2024. The investigation may lead to the EU adopting countervailing duties* on covered imports of Chinese EVs, which could include EVs produced by EU companies in China and imported into the EU.

** Countervailing duties are most commonly set on an ad valorem basis, for a period of five years (fixed rate duties, minimum import prices, or price undertaking measures are also possible).*

European Commission publishes Guidance on enhanced due diligence to shield against Russia sanctions circumvention (see [here](#))

On 7 September 2023, the European Commission issued Guidance providing an overview of enhanced due diligence expectations to avoid the circumvention of EU sanctions on Russia. The Guidance presently focuses mainly on export-related sanctions.

In announcing the Guidance, Mairead McGuinness, Commissioner for Financial Services, Financial Stability and Capital Markets Union, stated: *“EU sanctions are having a real impact on Russia's ability to wage war, and therefore Russia is desperately searching for ways to circumvent them. The lengths that Russia will go to get around our restrictions are increasingly complex and opaque. This practical guidance will help EU exporters spot red flags and reduce the risk of sanctions evasion.”*

As EU operators* now face increased risk of finding themselves in a position where they may facilitate prohibited activities involving Russia, the Guidance notes that this calls for the development of an enhanced due diligence model, in particular for high-risk sectors and complex supply chains.

The Guidance notably sets out:

- Successive steps that EU operators should undertake to carry out a strategic risk assessment to mitigate their exposure to potential sanctions circumvention schemes (e.g., identifying main and emerging techniques used by Russian actors to circumvent sanctions; risk analysis; mitigation measures);
- Guidelines for implementing enhanced due diligence, including best practices for EU operators in assessing business partners, transactions, and the goods themselves (e.g., is there any proven business record; who is the end user);
- Best practices to address typologies of sanctions circumventions (e.g., how to prevent possible diversion to Russia and/or Belarus from third countries, for example, by including contractual clauses with third-country business partners prohibiting re-exports to Russia and Belarus; specific guidance for the banking and finance sectors, noting the need for additional vigilance regarding the use of correspondent accounts); and
- A circumvention red flag list related to businesses and customers (e.g., indirect transactions (such as those using intermediaries, shell companies) that make no or little economic sense).

The Guidance further reminds that the [EU sanctions whistleblower tool](#) enables sharing information in a fully anonymous way about possible EU sanctions violations, in view of increasing the effectiveness of EU sanctions.

** EU operators incorporated or constituted under the law of an EU Member State are directly required to comply with EU sanctions law. However, non-EU entities are also required to comply in certain circumstances, including in relation to any transaction or business done in whole or in part on EU territory.*

MEDICINES AND MEDICAL DEVICES

European Commission creates Advisory Committee on Public Health Emergencies ([here](#))

On 12 September 2023, the European Commission announced the establishment of the Advisory Committee on Public Health Emergencies (“Committee”), which will provide advice in the event of serious cross-border threats to public health in view of filling a serious gap identified in this area during the COVID-19 pandemic.

The Committee will help the Commission and Member States to determine when a public health emergency formally exists, advise on measures to be taken in response to the epidemic, and when these should be lifted. Composed of a group of experts from different disciplines and sectors, the Committee will advise on public health, biomedical, behavioral, social, economic, cultural and international issues in the event of a health crisis.

The Committee is established under the Regulation on Serious Cross-Border Health Threats (Regulation (EU) 2022/2371) ([here](#)) (see also [Jones Day COVID-19 Update No. 90 of 28 October 2022](#) and [No. 95 of 9 January 2023](#)). Its creation is an important step towards strengthening the response to cross-border health threats, as part of building a robust European Health Union (see also [Jones Day COVID-19 Update No. 27 of 18 November 2020](#)).

Looking ahead. A call for experts will be launched in the coming weeks, and the Committee is due to start work in Spring 2024.

European Commission authorizes adapted COVID-19 vaccine for Member States’ autumn vaccination campaigns ([here](#))

On 1 September 2023, the Commission authorized the Comirnaty XBB.1.5-adapted COVID-19 vaccine, developed by BioNTech-Pfizer, for Member States’ autumn vaccination campaigns.

In announcing this authorization, Stella Kyriakides, European Commissioner for Health and Food Safety stated: “*I welcome this very timely authorisation of the updated COVID vaccine, which will target emerging and spreading variants. COVID-19 will circulate in parallel to seasonal influenza during the upcoming autumn and winter season, and we need to be ready...*”.

The vaccine was authorized after an evaluation by the European Medicines Agency (EMA) under the accelerated assessment mechanism (see also [Jones Day . COVID-19 Update No. 7 of 8 May 2020](#)).

The vaccine is adapted to target the SARS-CoV-2 Omicron strain XBB.1.5, in line with the [ECDC-EMA statement](#) on updating the composition of COVID-19 vaccines for new SARS-CoV-2 variants. The vaccine is also expected to increase the breadth of immunity against current dominant and emerging variants. This is the third adaptation of this vaccine to respond to new COVID-19 variants.

To recall, the Commission aims to accelerate the development, manufacturing and deployment of vaccines against COVID-19 under the EU Vaccines Strategy, which also serves as a reference point for Member States when devising their national vaccination strategies ([here](#)) (see also [Jones Day COVID-19 Update No. 13 of 19 June 2020](#)).

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission designates first gatekeepers under Digital Markets Act (see [here](#))

On 6 September 2023, the Commission designated the six first gatekeepers under the Digital Markets Act (“DMA,” see [here](#)).

To recall, the DMA entered into force in November 2022 and became applicable in May 2023. The DMA was a priority initiative under the Joint Declaration on EU Legislative Priorities for 2022 (see [Jones Day Alert No. 72 of 10 January 2022](#)), which aimed at guiding the EU’s recovery from the COVID-19 crisis.

The DMA aims to prevent the imposition of unfair conditions on businesses and end users by those designated as “gatekeepers” (i.e., large digital platforms deemed as significantly impacting the internal market, serving as an important gateway for business users to reach their end users, and which enjoy, or will foreseeably enjoy, an entrenched and durable position) that provide a “core platform service” (e.g., online search engines; online social networking services, web browsers, virtual assistants) (see also [Jones Day EU Emergency Update No. 102 of 3 May 2023](#)).

The Commission’s newly designated gatekeepers (including companies such as Amazon and Microsoft) together provide a total of 22 core platform services identified by the Commission, such as Windows PS OS and LinkedIn.

Looking ahead. Following their designations as gatekeepers, the companies have six months to comply with obligations under the DMA and submit a detailed compliance report outlining how they comply with each obligation. However, certain obligations start to apply as of designation (e.g., obligation to inform the Commission of any planned concentration).

With respect to data protection, in particular, where consent for collecting, processing, cross-using and sharing of personal data is required to ensure compliance with the DMA, a gatekeeper shall take the necessary steps either to enable business users to directly obtain the required consent to their processing, where such consent is required under the GDPR or ePrivacy Directive 2002/58/EC, or to comply with EU data protection and privacy rules and principles in other ways, including by providing business users with duly anonymized data where appropriate.

In case of non-compliance with DMA obligations, a gatekeeper is subject to fines of up to 10% of the company’s total worldwide turnover (or up to 20% in case of repeated infringement). In addition, the Commission may also adopt additional remedies in case of systemic non-compliance.

For additional information on the DMA, see [Jones Day White Paper “Digital Markets Act: European Union Adopts New “Competition” Regulations for Certain Digital Platforms”](#), August 2022.

European Commission proposes Critical Infrastructure Blueprint (see [here](#))

On 6 September 2023, the Commission proposed a Council Recommendation for a Critical Infrastructure Blueprint, which aims at reinforcing the EU's coordination in response to attempted disruptions of critical infrastructure.

The Commission notes that critical infrastructure operates against the backdrop of the highly volatile geopolitical context of Russia's war against Ukraine, increased hybrid attacks, and sabotage of the Nord Stream gas pipelines. Critical infrastructure also provides vital services to all sectors of society (e.g., healthcare, finance, energy, transport, etc.).

In responding to any significant critical infrastructure incident, the draft Blueprint aims at achieving the following key objectives:

- Strengthen shared situational awareness by better understanding the significant critical infrastructure incident in the Member States, its origins, and its potential consequences.
- Ensure coordinated public communication, in particular, in view of tackling disinformation and minimizing discrepancies in public communications after a critical infrastructure incident.
- Provide effective response, notably through better cooperation between Member States and EU bodies, which will contribute to mitigating the effects of a significant critical infrastructure incident.

The draft Blueprint would become applicable where an incident results in:

- significant disruptive effect to or in six or more Member States; or
- significant disruptive effect in two or more Member States, and timely policy coordination in the response at Union level is required, due to the incident's broad-ranging and significant technical or political impact.

The draft Blueprint would also notably complement existing EU crisis instruments, such as in the area of cybersecurity (e.g., Commission Recommendation 2017/1584 of 13 September 2017 on coordinated response to large-scale cybersecurity incidents and crises ([Cyber Blueprint](#))).

Next steps. The Council of the European Union will discuss the proposed Blueprint.

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