



# COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

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This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

## LATEST KEY DEVELOPMENTS

### Competition & State Aid

- Air Canada and Transat withdraw from proposed merger after European Commission rejects remedy package – Remarks from Executive Vice-President and Competition Commissioner Vestager on COVID-related concerns
- European Systemic Risk Board advocates more targeted COVID support to foster financial stability
- EU approves new and amended Member State measures to support the economy

### Trade / Export Controls

- European Parliament INTA Committee meeting to discuss trade aspects of COVID-19
- European Commission reports further increases in EU agri-food trade, despite pandemic
- European Commission publishes updated list of Member State authorities overseeing authorization mechanism for vaccine exports

### Medicines and Medical Devices

- European Commission seeks feedback on Roadmap on “Evaluation and revision of general pharmaceutical legislation”
- European Commission launches public consultation on Health Emergency Preparedness and Response Authority (HERA)

### Cybersecurity, Privacy & Data Protection

- European Data Protection Board and European Data Protection Supervisor adopt Joint Opinion on Proposal for Digital Green Certificate

## COMPETITION & STATE AID

### Competition

**Air Canada and Transat withdraw from proposed merger after European Commission rejects remedy package – Remarks from Executive Vice-President and Competition Commissioner Vestager on COVID-related concerns (see [here](#))**

On 2 April 2021, Executive Vice-President and Competition Commissioner Margrethe Vestager commented on Air Canada and Transat's withdrawal from their proposed merger. The Commission had opened an in-depth investigation on 25 May 2020 of Air Canada's proposed acquisition of Transat and entered into remedy discussions.

Commissioner Vestager, in particular, elicited the Commission's COVID-related concerns regarding the proposed merger. She emphasized that EU merger control rules and policy shall also apply during times of severe economic shock. While the coronavirus outbreak had tremendously impacted the airline sector, she stated that a rapid and strong recovery would require safeguarding competitive market structures.

Commissioner Vestager indicated that the Commission had sought to determine the extent of the coronavirus crisis' impact on Air Canada, Transat, and their competitors' operations. The Commission stated that Air Canada and Transat are the two leading airlines with an extensive network of routes between Europe and Canada. According to the Commission's preliminary conclusions, in the long-run, both Air Canada and Transat would likely remain actual or potential competitors on the vast majority of the routes between the European Economic Area and Canada, which they both operated before the pandemic.

The in-depth investigation led to the Commission's preliminary findings that the proposed transaction would raise competition concerns on a large number of transatlantic routes. Commissioner Vestager argued that in the Commission's view, discussions with the parties and the proposed remedy package had not adequately addressed the Commission's competition concerns.

### State Aid

**European Systemic Risk Board advocates more targeted COVID support to foster financial stability (see [here](#))**

On 25 March 2021, the General Board of the European Systemic Risk Board ("ESRB") held its 41<sup>st</sup> regular meeting and further discussed the impact of the coronavirus pandemic on financial stability in the EU.

The ESRB, established in 2010, is tasked with overseeing the financial system of the EU and preventing and mitigating systemic risk. Its General Board, chaired by President of the European Central Bank (ECB), Christine Lagarde, is the ESRB's decision-making body.

At the meeting, the General Board reiterated that the main source of systemic risk in the EU arose from the pandemic's impact on economic activity, including through growing pressure on the solvency of non-financial corporations ("NFCs," i.e., principally engaging in the production of non-financial goods and services) and household indebtedness. Such pressure could possibly spill over to the financial system. The General Board noted that NFCs in several sectors continued to suffer from a very significant fall in revenues, while already facing depleted cash buffers and difficulties in rolling over maturing debt.

The General Board noted the key need to continue extraordinary public support measures until recovery is firmly in place. However, it also highlighted that in rebuilding the economy, current public support measures should also become more targeted as the crisis evolved. In this respect, it also saw merit in increasingly complementing liquidity support with equity support, possibly including quasi-equity and subsidies, for viable but overindebted businesses. The General Board noted, in particular, that success in containing solvency pressures in the NFC sector was crucial to minimizing the spillover effects of the COVID-19 crisis on the financial sector.

The ESRB's current assessment of systemic risks in the EU is summarized in its latest risk dashboard, published on 6 April 2021 (see [here](#)). The risk dashboard is a set of quantitative and qualitative indicators of systemic risk in the EU financial system.

**EU approves new and amended Member State measures to support the economy (see [here](#) and [here](#))**

Since the onset of the coronavirus outbreak, the European Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the Temporary Framework.

The most recent measures adopted to support the economy and companies affected by coronavirus outbreak include:

- €500 million Portuguese top-up insurance scheme to support domestic trade credit in the coronavirus outbreak
- €200 million Belgian subsidized loans scheme to support economic activity in Wallonia in the context of coronavirus outbreak
- €4 billion French measure to recapitalize Air France
- €35 million Portuguese scheme to support companies in Azores region in the context of the coronavirus outbreak
- €60 million Irish scheme to support SMEs affected by the coronavirus outbreak
- Modification of an existing Swedish scheme to support tenants operating in several sectors affected by the coronavirus outbreak, including an increase in the budget, from approximately €453 million to approximately €795 million and the extension of the scope of the measure
- €24 million Italian scheme to support mooring companies affected by the coronavirus outbreak

## TRADE / EXPORT CONTROLS

**European Parliament INTA Committee meeting to discuss trade aspects of COVID-19 (see [here](#))**

On 15 April 2021, the INTA (European Parliament Committee on International Trade) meeting will address trade aspects of COVID-19.

The Committee, in particular, will discuss the first draft of the own-initiative Report, dated 19 March 2021, on the trade related aspects and implications of the pandemic (see [here](#)). The draft Report is one facet of INTA's assessment of the role of trade as a tool for sustainable recovery and for attaining open strategic autonomy under the European Commission's earlier-announced Trade Policy Review (see *Jones Day COVID-19 Update No. 37 of 24 February 2021*).

The draft Report focuses on the areas of Trade and sustainable development; Fair, resilient and green value chains; Trade policy for critical health products: lessons learned from the COVID-19 crisis; and Multilateralism and Europe's geopolitical place in the world.

Previously, INTA's meetings of 17-18 March 2021 included a public hearing addressing topics such as resilient, fair and sustainable supply chains, as well as a presentation on "Post Covid-19 value chains: options for reshoring production back to Europe in a globalised economy" (see *Jones Day COVID-19 Updates Nos. 41 and 42 of 17 and 24 March 2021*).

**European Commission reports further increases in EU agri-food trade, despite pandemic (see [here](#))**

On 31 March 2021, the Commission released a report on "Monitoring EU Agri-Food Trade: Developments January – December 2020," indicating further increases in EU27 agri-food trade,\* despite the difficulties of the pandemic.

The report stated that during 2020, EU27 agri-food trade (exports and imports) attained a total value of €306.5 billion (i.e., 1% greater than in 2019). In this respect, EU27 exports increased to €184.3 billion, while EU27 imports rose to €122.2 billion.

Concerning exports, in 2020, the highest increases in export values compared to 2019 were recorded in trade with China (+€3216 million, +22%), primarily driven by a rise in EU exports of pig meat (+€2439 million, +74%).

However, significant reductions in EU exports in value terms also occurred in sectors most affected by the COVID-19 lockdowns and economic crises. Exports of spirits and liqueurs (-€ 1582 million, -19%) and wine (-€1223 million, -8%) continued to show the sharpest decline, related both to COVID and punitive US tariffs.

\* "EU27" does not include the UK which left the EU on 31/01/2020. Trade with the UK is reported as trade with a third country in the report, for the current period and the reference periods, although single market conditions still applied to the UK.

**European Commission publishes updated list of Member State authorities overseeing authorization mechanism for vaccine exports (see [here](#))**

On 31 March 2021, the Commission published an updated list of Member State authorities competent for overseeing the transparency and authorization mechanism for COVID-19 vaccine exports.

To recall, the vaccine export mechanism, covering exports outside the EU of COVID-19 vaccines subject to Advance Purchase Agreements ("APAs"), was extended from 12 March 2021 to 30 June 2021. This extension responds to continuing delays in vaccine deliveries to the EU (see *Jones Day COVID-19 Update No. 40 of 17 March 2021*).

## MEDICINES AND MEDICAL DEVICES

**European Commission seeks feedback on Roadmap on "Evaluation and**

On 30 March 2021, the Commission launched a call for feedback on the Roadmap on the "Evaluation and revision of the general pharmaceutical legal framework." Such legal framework concerns Directive 2001/83/EC on the Community code relating to medicinal products for human use, as well as Regulation (EC) No 726/2004 laying down Community procedures for the

**revision of general pharmaceutical legislation” (see [here](#))**

authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency).

With the goal of ensuring access to affordable medicines in the EU, the evaluation and revision of the legal framework seeks to support innovation and strengthen supply security, while adapting to new scientific and technological developments and lessening regulatory burden where possible. This process will draw on lessons from the COVID-19 pandemic, towards building a future-proof and crisis-resistant pharmaceuticals system.

This revision of the general pharmaceutical legislation is complementary to other ongoing initiatives, such as the EU Health Emergency Preparedness and Response Authority (HERA) (*see also below on HERA public consultation*) and the European Health Data Space (EHDS), which aims to provide high-quality healthcare while embracing digital health.

Feedback on the Roadmap may be provided until 27 April 2021. The Commission will take such feedback into account for further development and fine-tuning of the initiative. The Commission will compile feedback received in a synopsis report, explaining how such input will be integrated and, if applicable, why certain suggestions cannot be taken up.

A public consultation will follow, anticipated in the last quarter of 2021. The revised legal framework is expected in the last quarter of 2022.

**European Commission launches public consultation on Health Emergency Preparedness and Response Authority (HERA) (see [here](#))**

On 31 March 2021, the Commission opened a public consultation on HERA (the Health Emergency Preparedness and Response Authority). HERA is one component of the EU's response to the COVID-19 pandemic and pursuit of a robust European Health Union, seeking to improve Europe's ability to respond to cross-border health threats and emergencies (*see also Jones Day COVID-19 Update No. 37 of 24 February 2021*).

As stated by Stella Kyriakides, Commissioner for Health and Food Safety: *“COVID-19 has revealed gaps in our collective preparedness and response. The Health Emergency Preparedness and Response Authority, EU's HERA, is a fundamental part of the solution that we need for the next health crisis to prepare better and respond more swiftly, together....To ensure that [HERA] meets current and future challenges as swiftly as possible, we will listen very carefully to stakeholders' views.”*

The public consultation focuses on issues such as the EU's framework to develop, manufacture and deploy medical countermeasures; anticipatory threat and risk assessments; and market dynamics and supply chain intelligence.

The public consultation will run until 12 May 2021, with the Commission also holding discussions in parallel with Member States and stakeholders. Later this year, a legislative proposal will set out the precise remit of HERA.

## CYBERSECURITY, PRIVACY & DATA PROTECTION

**European Data Protection Board and European Data Protection Supervisor adopt**

On 6 April 2021, the European Data Protection Board (“EDPB”) and the European Data Protection Supervisor (“EDPS”) adopted a Joint Opinion on the Proposal for a Digital Green Certificate (“Joint Opinion”).

The proposed Digital Green Certificate is set out in two proposals:

**Joint Opinion on Proposal for Digital Green Certificate (see [here](#))**

- a draft Regulation on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (i.e., applicable to EU citizens); and
- a draft Regulation on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic.

These two proposals seek to require all EU Member States to use the Digital Green Certificate framework and issue certificates for the purpose of facilitating the exercise of the right to free movement within the EU during the COVID-19 pandemic.

In their Joint Opinion, the EDPB and EDPS stress that the Digital Green Certificate must comply with EU personal data protection legislation and in particular, with the principles of necessity, proportionality and effectiveness.

In addition, according to the Joint Opinion, the use of Digital Green Certificates should not result in the direct, or indirect, discrimination, of individuals.

Finally, the Joint Opinion indicates that the proposal should contain appropriate safeguards to ensure the security of personal data. For instance, any access to, and subsequent use of, individuals' data by EU Member States should not extend beyond the end of the pandemic.

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