



# 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

- European Commission ramps up home searches of employees of companies suspected of potential competition breaches
- European Commission comments on state of competition law in context of pandemic
- European Commission approves new and amended Member State measures to support the economy

### Trade / Export Controls

- European Commission releases Report by Wise Persons Group on Reform of EU Customs Union

### Medicines and Medical Devices

- ECDC and EMA issue advice on fourth doses of mRNA COVID-19 vaccines
- EMA starts rolling review of COVID-19 Vaccine HIPRA (PHH-1V)
- European Commissioner for Health and Food Safety answers question from Member of European Parliament on transparency of COVID-19 vaccine contracts

### Cybersecurity, Privacy & Data Protection

- Council of European Union authorizes Member States to sign protocol to Convention on Cybercrime
- European Commission adopts EU Digital COVID Certificate equivalence decisions for Colombia and Malaysia

## COMPETITION & STATE AID

### Competition

**European Commission ramps up home searches of employees of companies suspected of potential competition breaches (see [here](#))**

On 5 April 2022, Maria Jaspers (Director of Cartel Directorate, DG Competition, European Commission) spoke of the Commission's intention to ramp up home searches of employees of companies implicated in potential anticompetitive activities.

This heightened focus on home inspections, according to Jaspers, responds to the shift to increased remote working during the pandemic and the greater likelihood of keeping (and deleting) relevant evidence at home.

In this respect, Jaspers noted that "*for the first time in many years,*" the Commission had recently searched the home of an employee of a company suspected of competition breaches, in parallel to conducting inspections at the company's business premises. To shield the individual's privacy, the Commission did not issue a press release, nor will it do so for future home inspections.

Jaspers further commented that in combating anticompetitive conduct, the Commission's whistleblower tool had triggered more EU and national-level investigations. Launched in 2017, this electronic whistleblowers' tool seeks to enable the Commission to gather information on anticompetitive activities, while protecting whistleblower anonymity (see also [Jones Day COVID-19 Update No. 65 of 25 October 2021](#)).

**European Commission comments on state of competition law in context of pandemic (see [here](#))**

On 25 March 2022, Executive Vice-President and Competition Commissioner Margrethe Vestager provided remarks on the state of competition law, including in the context of the pandemic. In this respect, she highlighted the following:

"Fracturing" the Single Market may arise particularly in times of disruption by businesses attempting to create unfair opportunities, for example, by restricting sales or impeding trade across the EU's internal borders. Commissioner Vestager cited the ongoing investigation of the clothing market (launched in January 2022) to determine the potential breach of EU competition rules by Pierre Cardin and its licensee the Ahlers Group by restricting cross-border and online sales of Pierre Cardin-licensed products, as well as sales of such products to specific customer groups.

The tremendous volume of State aid work since the pandemic has resulted in over 1200 Commission decisions and amendment decisions since February 2022, with the Commission approving some 900 national measures notified by 27 Member States under the COVID Temporary Framework.

Commissioner Vestager further noted that according to the Commission's latest survey results, State aid disbursements remained proportionate to the impact of the pandemic crisis measures and that no single Member State had completely outspent others. As the COVID situation has improved, the Commission's discussion with Member States is now focused on how quickly such crisis measures can be phased out.

## State Aid

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

Since the onset of the coronavirus outbreak, the 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 Temporary Framework, adopted in March 2020, is currently applicable until 30 June 2022.

- €4 million Lithuanian scheme to support accommodation service providers and tour operators in the context of the coronavirus pandemic.
- €2.2 million Italian scheme to support the cruise ships sector in the context of the coronavirus pandemic.
- €1 million Romanian scheme to support airlines starting operations at Arad airport in the context of the coronavirus pandemic.
- €3 million Cypriot scheme to support companies and the self-employed of certain sectors affected by the coronavirus pandemic.
- Latvian scheme to support companies in the primary agricultural production sector affected by the coronavirus pandemic, re-introducing a measure that expired on 31 December 2021, including €1.5 million budget increase.
- €815 million Greek scheme to support the economy in the context of the coronavirus pandemic.
- €2 million Estonian scheme to support cultural events and concert organizers affected by the coronavirus pandemic.
- €280 million Hungarian investment support scheme towards a sustainable recovery in the tourism sector in the context of the coronavirus pandemic.
- Extension of French scheme to support companies affected by the coronavirus pandemic by providing public guarantees to investment funds that acquire equity loans or subordinated bonds, towards encouraging long-term private financing to viable small and medium-sized enterprises and mid-cap companies that engage in an investment plan. Originally authorized until 30 June 2022, the scheme is now extended until 31 December 2023, while leaving the budget and all other application criteria unchanged.
- €7.5 million Croatian scheme to support the maritime, transport and transport infrastructure sectors affected by the coronavirus pandemic.
- Italian scheme to support companies active in road passenger transport by bus affected by the coronavirus pandemic, re-introducing a measure that expired on 31 December 2021.

## TRADE / EXPORT CONTROLS

### European Commission releases Report by Wise Persons Group on Reform of EU Customs Union (see [here](#))

On 31 March 2022, the European Commission released the Report by the Wise Persons Group (WPG) on Reform of the EU Customs Union.

The WPG, an independent high-level group (comprised of 12 members from government, industry, and academia), is tasked with proposing innovative solutions to the most urgent issues confronting the Customs Union.

The Report considers that the Customs Union is not “*fit for purpose*,” with dangerous, non-compliant products entering the EU market, as well as billions of uncollected customs duties and taxes. It indicates that the Customs Union needs urgent structural change, with three root challenges at issue:

- (i) major increase in trade volumes and technology developments (e.g. sharp rise in e-commerce and the “*unmanageable flow*” of millions of small packages to be processed at the EU borders);
- (ii) managing customs' growing range of tasks that extend beyond revenue collection (e.g. safeguarding safety, health, security, human rights); and
- (iii) absence of common implementation of customs-related rules and procedures (e.g. different control practices across border entry points, both within and across Member States, differences in control priorities, and variances in addressing and sanctioning non-compliance).

In particular, with COVID-19, EU customs faced a massive increase of traffic of sub-standard and dangerous goods in the health area, from personal protective equipment to medicines and medical devices. Now, EU customs faces the challenge of the war in Ukraine at the European border, including the implementation of sanctions while supporting humanitarian efforts.

The Report's recommendations include, for instance:

- A new approach to data that reduces reliance on customs declarations, while focusing on gathering more robust data from commercial sources and providing businesses with a single data entry point for customs formalities.
- A comprehensive framework for cooperation, including data sharing between EU customs, as well as market surveillance authorities, law enforcement bodies, and tax authorities, in view of comprehensive risk management at EU level.
- Establishing a European Customs Agency to complement the Commission's role and support Member State efforts.

The WPG's recommendations are now under discussion with the European Parliament and the Member States. Based on these contributions and wider stakeholder consultations, the Commission aims to present a Customs Union reform package by end-2022, which intends to revise EU customs legislation and governance of the Customs Union.

This reform package will build on ongoing initiatives, such as the Union Customs Code (UCC) evaluation (see also recent *Opinion on the UCC by the Fit for Future Platform for simplification of EU law*, [Jones Day COVID-19 Update No. 75 of 1 February 2022](#)).

The EU customs reform package is targeted for implementation by 2030.

## MEDICINES AND MEDICAL DEVICES

### **ECDC and EMA issue advice on fourth doses of mRNA COVID-19 vaccines (see [here](#))**

On 6 April 2022, the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) issued advice on a fourth dose of mRNA COVID-19 vaccines, and in particular, indicated the following:

- It is premature to consider using a fourth dose in the general population;
- A fourth dose (or second booster) can be administered to adults 80 years or above after reviewing data on the increased risk of severe COVID-19 in this age group and the protection given by a fourth dose;
- If the current epidemiological situation changes and new information emerges, it may become necessary to consider a fourth dose in adults with normal immune systems aged 60 to 79 years;
- Thus far, studies on additional boosters have not raised safety concerns.

As re-vaccination campaigns could begin in the autumn, authorities will consider the best timing for additional mRNA COVID-19 vaccines doses, possibly taking advantage of updated vaccines.

The ECDC and EMA will continue to review available evidence on the effectiveness of COVID-19 vaccines and accordingly update their recommendations.

### **EMA starts rolling review of COVID-19 Vaccine HIPRA (PHH-1V) (see [here](#))**

On 29 March 2022, the Human Medicines Committee (CHMP) of the EMA announced the start of a rolling review of COVID-19 Vaccine HIPRA (also known as PHH-1V).

The HIPRA vaccine, a protein-based vaccine developed by HIPRA Human Health S.L.U, is intended as a booster vaccine for adults already fully vaccinated with a different COVID-19 vaccine.

The CHMP's decision to start the rolling review is based on preliminary results from laboratory studies (non-clinical data) and clinical studies in adults. These studies suggest that the immune response with the HIPRA vaccine may be effective against SARS-CoV-2, including variants of concern such as Omicron.

The EMA will evaluate data as they become available, with the rolling review continuing until enough evidence is available for a formal marketing authorization application (MAA).

Upon such eventual MAA and because of work done during the rolling review, the EMA expects that it should take less time than normal to evaluate the HIPRA vaccine for compliance with the usual EU standards for effectiveness and safety.

### **European Commissioner for Health and Food Safety answers**

On 29 March 2022, Stella Kyriakides, Commissioner for Health and Food Safety, answered a Parliamentary question concerning the transparency of the Commission's contracts with pharmaceutical companies for procuring COVID-19 vaccines on behalf of EU Member States (see [here](#)).

**question from Member of European Parliament on transparency of COVID-19 vaccine contracts (see [here](#))**

The Parliamentary question notes that the Commission has only published redacted contracts, and asks, in particular, why the Commission has not released unredacted contracts to the public and whether it intends to do so.

Commissioner Kyriakides replied that the contracts will not be fully disclosed to the public due to contractual obligations to uphold confidentiality and legal obligations towards the companies. In this respect, she noted:

- Vaccine manufacturers will continue to market their vaccines on a worldwide basis and have heavily invested in research and in production capacity, such that these companies have a legitimate interest in not publicly disclosing all terms of contracts with the EU.
- EU rules on public access to documents provide that access to certain contract provisions shall be refused where their disclosure is liable to undermine the protection of legitimate commercial interests of third parties.

Nonetheless, Commissioner Kyriakides indicated that the Commission is preparing less-redacted versions of the contracts, in view of disclosing certain additional elements of the contracts.

## CYBERSECURITY, PRIVACY & DATA PROTECTION

**Council of European Union authorizes Member States to sign protocol to Convention on Cybercrime (see [here](#) and [here](#))**

On 5 April 2022, the Council adopted a Decision authorizing Member States to sign, in the interest of the EU, the Second Additional Protocol to the Convention on Cybercrime on enhanced co-operation and disclosure of electronic evidence of the Council of Europe ("Protocol") (see [here](#)). The EU cannot sign the Protocol, as only states can be parties to it.

To recall, the Protocol supplements the Convention on Cybercrime ("Budapest Convention") of 2001 and aims to further enhance cooperation on cybercrime, in particular, by offering criminal justice authorities the ability to collect evidence in electronic form for specific criminal investigations or proceedings related to computer systems and data, while safeguarding the use of sensitive data (see also [Jones Day COVID-19 Update No. 68 of 22 November 2021](#)).

The Explanatory Report to the Protocol notes that since the Convention was opened for signature in 2001, the exploitation of technology for criminal purposes has significantly increased. In particular, during the COVID-19 pandemic, countries observed significant pandemic-related cybercrime, including attacks on hospitals and medical facilities developing vaccines against the virus; misuse of domain names to promote fake vaccines and treatments; and other types of fraudulent activity.

The Council has sent the Decision to the European Parliament for its approval. The Protocol is expected to be opened for signature on 12 May 2022. Member States are encouraged to sign the Protocol during the signing ceremony on that day, or as soon as possible after that.

At present, 66 countries are party to the Budapest Convention, including 26 EU Member States.

**European Commission adopts EU Digital COVID Certificate equivalence decisions for Colombia and Malaysia (see [here](#))**

On 4 April 2022, the Commission adopted two new equivalence decisions certifying that COVID-19 certificates issued in Colombia and Malaysia are equivalent to the EU Digital COVID Certificate (see also [Jones Day COVID-19 Update No. 78 of 14 March 2022](#) for the latest preceding Commission Equivalence Decisions).

In practice, this means that these two countries will be connected to the EU's system and that COVID certificates issued by this country will be accepted in the EU under the same conditions as the EU Digital COVID Certificate.

In return, the two countries have accepted EU Digital COVID Certificates for travel to their countries.

As a result of these two decisions, 64 countries are now connected to the EU's system (see overview of all decisions [here](#)).

The equivalence decisions entered into force on 2 April 2022.

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