



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 extends Member State ability to implement certain aid without prior notification to support resilient recovery from pandemic
- European Commission opens public consultation on revising Communication on short-term export credit insurance
- European Commission approves new and amended Member State measures to support the economy

Trade / Export Controls

- Updated list of FDI screening mechanisms notified by Member States
- Latest Eurostat data – A rise in exports, imports, and intra-euro area trade as compared to May 2020

Medicines and Medical Devices

- European Commission releases 2020 Annual Report on Monitoring the application of European Union law, including sustaining key supply chains for medical supplies
- European Medicines Agency starts rolling review of Sanofi Pasteur COVID-19 vaccine candidate
- European Medicines Agency approves Spikevax for youth aged 12 to 17

Cybersecurity, Privacy & Data Protection

- European Commission issues Communication to facilitate use of EU Digital COVID Certificates during air travel
- European Commission releases 2020 Annual Report on Monitoring the application of European Union law, including enhancing data protection

COMPETITION & STATE AID

State Aid

European Commission extends Member State ability to implement certain aid without prior notification to support resilient recovery from pandemic (see [here](#))

On 23 July 2021, the Commission adopted an extension of the General Block Exemption Regulation (“GBER”) to allow Member States to implement certain aid measures, without prior Commission scrutiny, by:

(i) streamlining the interplay between EU State aid rules and EU funding rules under the new EU “budget” (i.e., the EU Multiannual Financial Framework (“MFF”)). This simplification is intended to, in particular, allow Member States to rely on the assessment of projects already carried out under certain EU-programmes (e.g. for Research, Development and Innovation (RD&I)), instead of conducting separate assessments for State aid purposes when combining with national funding or funding under shared management programmes; and

(ii) broadening the ability to provide State aid to support sustainable and resilient economic recovery from the coronavirus pandemic. The new aid categories to be exempted from the notification obligation fall under high EU priority policy areas for the twin green and digital transition, such as aid for publicly accessible electric recharging and hydrogen refueling infrastructure for road vehicles, as well as aid for fixed broadband networks and 4G and 5G mobile networks.

In addition to this extension of the GBER’s scope, the Commission has also launched a new revision of the GBER aimed at further streamlining State aid rules in light of the Commission priorities in relation to the twin transition. Consultations with Member States and stakeholders will be forthcoming on the draft text of this new amendment, which the Commission is expected to adopt during Q4 2021 (see [here](#)).

European Commission opens public consultation on revising Communication on short-term export credit insurance (see [here](#))

On 22 July 2021, the Commission launched a public consultation on a proposed revision of the Communication on short-term export credit insurance (“STEC”). Export credit insurance shields sellers against risks raised by export credit used by foreign buyers to defer payment of goods and services.

The Commission regulates State aid in the area of short-term export-credit insurance both among exporters in different Member States and export-credit insurers operating in the EU. In this respect, the STEC is meant to ensure that State support to export credits does not distort competition among private and public or publicly-supported export credit insurers, and its purpose is to safeguard a level-playing field among exporters in different Member States.

Under the STEC, trade within the EU and nine non-EU countries, with a maximum risk period of up to two years, entails marketable risks and, in principle, should not be insured by the State or State supported insurers. As private insurers may offer such insurance, the Commission considers that the State should not offer similar insurance.

However, with the coronavirus crisis and resulting insufficiency of private insurance capacity for exports to all countries, the Commission decided on

27 March 2020 to temporarily remove all countries from the list of “marketable risk” countries under the STEC. This derogation, running until 31 December 2021, has enabled Member States to make available public short-term export credit insurance.

The STEC is set to expire on 31 December 2021, and its anticipated revision principally entails a small number of mainly technical amendments, such as the following:

- STEC’s application would continue beyond 2021;
- risks incurred by small and medium-sized enterprises, with a total annual export turnover not exceeding EUR 2.5 million (*i.e., a proposed increase from current €2 million threshold*), are temporarily non-marketable for exporters in the notifying Member State; and
- Member States would be required to publish annual reports on risks considered as non-marketable and covered by State insurers.

The public consultation runs until 23 September 2021. The Commission and Member States will discuss the draft revised STEC in September 2021, with its adoption anticipated in Q4 2021.

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

- €650,000 Latvian scheme to support companies active in microgreen production, fishery and aquaculture sectors affected by the coronavirus outbreak.
- €200 million Belgian scheme to support micro, small and medium-sized businesses affected by the coronavirus outbreak.
- €9 million Spanish scheme to compensate Spain’s regional airline Air Nostrum for the damage suffered due to the coronavirus outbreak.
- €9.5 million Irish scheme to support not-for-profit entities affected by the coronavirus outbreak.
- €110 million Greek scheme to compensate Athens International Airport S.A., the operator of Athens International airport, for the damage suffered due to the coronavirus outbreak.
- €800 million Italian scheme to compensate airports and ground-handling operators for the damage suffered due to the coronavirus outbreak.

TRADE / EXPORT CONTROLS

Updated list of FDI screening mechanisms notified by Member States (see [here](#))

On 14 July 2021, the European Commission published the updated list of screening mechanisms notified by Member States pursuant to the regulatory framework for the screening of foreign direct investments (“FDI”) into the European Union (Regulation (EU) 2019/452 of 19 March 2019). The list indicates that the following 18 Member States currently have a screening mechanism in place: Austria, Czech Republic, Denmark, Finland, France,

Germany, Hungary, Italy, Latvia, Lithuania, Malta, The Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, and Spain.

Notably, various Member State measures were taken in response to the COVID-19 crisis (e.g., FDI screening provisions notified by Italy, Poland and Slovenia) following relevant guidance by the European Commission. To recall, in March 2020, the Commission issued guidelines addressing FDI screening in the context of the coronavirus pandemic. This guidance, in particular, calls upon Member States without such screening to set up a full-fledged mechanism to enable, *inter alia*, the review of transactions posing a risk to EU critical health infrastructures (see *Jones Day Alert, "New European Commission Guidance Calls for Increased Scrutiny of Investments Amid COVID-19 Crisis", March 2020*, see [here](#)).

Latest Eurostat data – A rise in exports, imports, and intra-euro area trade as compared to May 2020 (see [here](#))

On 16 July 2021, the European Commission published the latest Eurostat data on international trade.

The first estimate for euro area* exports of goods to the rest of the world in May 2021 was €188.2 billion, an increase of 31.9% compared with May 2020 (€142.7 billion). These statistics of last May were significantly impacted by the Member States' COVID-19 containment measures. Imports from the rest of the world stood at €180.7 billion, a rise of 35.2% compared with May 2020 (€133.7 billion).

As a result, the euro area recorded a €7.5 billion surplus in trade in goods with the rest of the world in May 2021, compared with +€8.9 billion in May 2020.

Intra-euro area trade rose to €181.5 billion in May 2021, an increase of 45.4% compared with May 2020.

As regards extra-EU** exports, in the period between January and May 2021, these rose to €957.9 billion (an increase of 13.3% compared with January-May 2020), and imports rose to €878.2 billion (an increase of 12.7% compared with January-May 2020). Furthermore, all Member States saw large increases in extra-EU exports, with the highest increases in Greece (+68.0%), Portugal (+62.6%) and Romania (+60.8%).

Extra-EU imports reflect a similar trend. In May 2021 compared to May 2020, all Member States increased extra-EU imports, above all in Latvia (+104.7%), Lithuania (+87.3%) and Slovakia (+83.0%).

* *The euro area (EA19) includes Belgium, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Austria, Portugal, Slovenia, Slovakia and Finland.*

** *The EU (European Union) includes Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland and Sweden.*

MEDICINES AND MEDICAL DEVICES

European Commission releases 2020 Annual Report on

On 23 July 2021, the Commission adopted the Annual Report on Monitoring the Application of EU Law, detailing the Commission's monitoring and enforcement EU law in 2020, and how Member States performed in various policy areas. The report, in particular, takes into consideration the COVID-19

<p>Monitoring the application of European Union law, including sustaining key supply chains for medical supplies (see here)</p>	<p>pandemic and the Commission's actions to safeguard individuals and businesses across the EU (<i>for further details, see below Section on Cybersecurity</i>).</p> <p>The Report emphasized that the application of EU law remains paramount in times of crisis. The pandemic has emphasized the need to sustain the proper functioning of the single market, which proved crucial to keeping key supply chains intact, including for medical supplies and food.</p> <p>Indeed, serious disruptions to supply chains and the aggravated shortage of essential products were raised by many unilateral Member State actions in response to the pandemic to introduce export restrictions for medicines, protective equipment, and other COVID-19-relevant products, particularly between March and May 2020. Other restrictions supported domestic producers, for instance, in the food sector.</p> <p>The Report noted the real risk of a domino effect in the first half of 2020 among Member States who felt compelled to adopt similar protectionist measures. In response, the Commission undertook various measures, including:</p> <ul style="list-style-type: none"> – bringing urgent infringement procedures against certain restrictions imposed in reaction to the pandemic; – frequent exchanges with Member States on the harm brought by such restrictions to the free movement of goods; and – convincing Member States to avoid adopting, or to repeal, national laws restricting the free movement of COVID-relevant medicines and medical devices in the EU. <p>The Commission has presented an annual report on monitoring the application of EU law since 1984, following a request by the European Parliament. The Parliament then adopts a resolution on the Commission's report.</p>
<p>European Medicines Agency starts rolling review of Sanofi Pasteur COVID-19 vaccine candidate (see here)</p>	<p>On 20 July 2021, the European Medicines Agency (EMA) started the rolling review of Vicprevtyn, the COVID-19 vaccine candidate developed by Sanofi Pasteur.</p> <p>The rolling review mechanism enables the EMA to evaluate pre- and clinical data as they become available in order to speed up the regulatory procedure for obtaining a market authorization. The EMA's decision to start the review of the Sanofi Pasteur's vaccine candidate is based on promising non-clinical data and early clinical studies suggesting that the product triggers the production of antibodies targeting SARS-CoV-2 virus.</p> <p>The rolling review will continue until robust evidence is available for the purposes of submitting a formal marketing authorization application.</p>
<p>European Medicines Agency approves Spikevax for youth aged 12 to 17 (see here)</p>	<p>On 23 July 2021, the EMA recommended granting an extension of indicated use for the COVID-19 vaccine Spikevax (previously COVID-19 Vaccine Moderna) to also include use in youth aged 12 to 17 years.</p> <p>The recommendation was granted following a pediatric study that showed that Spikevax produced an antibody response in 12- to 17-year-olds comparable to that seen in young adults aged 18 to 25 years. Moreover, none of the children receiving the vaccine developed COVID-19.</p>

CYBERSECURITY, PRIVACY & DATA PROTECTION

European Commission issues Communication to facilitate use of EU Digital COVID Certificates during air travel (see [here](#))

On 22 July 2021, the Commission published guidance to EU Member States on facilitating use of the EU Digital COVID Certificate during air travel (*Communication on Reaping the full benefits of EU Digital COVID Certificates: Supporting free movement of citizens and the recovery of the air transport sector through guidelines and recommendations for EU Member States*).

To recall, on 1 July 2021, the European Commission announced the entry into force of the EU Digital COVID Certificate Regulation (*see Jones Day COVID-19 Update No. 54 of 6 July 2021*). The non-mandatory Certificate indicates whether a person has been vaccinated against COVID-19, has a recent negative test result, or has recovered from the infection.

Air travel will be particularly impacted by the verification process for Certificates, given rising passenger numbers, notably during the summer season. To avoid duplicative Certificate checks, the Commission's guidance recommends a "one-stop" verification process prior to departure, in coordination with authorities, airports, and airlines.

The Communication further emphasizes the Commission's view that the Certificate's trust framework ensures the highest level of data protection, in line with the General Data Protection Regulation ("GDPR"). Any processing of personal data must comply with the GDPR, i.e., only to verify and confirm the holder's vaccination, test result or recovery, and personal data shall be limited to what is strictly necessary and shall not be retained.

For example, the Communication recommends verification of Certificates during the airline online check-in process. According to the Communication, this offers the advantage of checking passenger health-related documents in one place and prior to arriving at the departure airport, without requiring overly complex technical implementation.

The Communication further indicates that its guidance should be gradually taken up by other transport modes as well (e.g. ferries, cruise ships, rail and road transport).

European Commission releases 2020 Annual Report on Monitoring the application of European Union law, including enhancing data protection (see [here](#))

On 23 July 2021, the Commission adopted the Annual Report on Monitoring the Application of EU Law, detailing the Commission's monitoring and enforcement EU law in 2020, and how Member States performed in various policy areas. The report, in particular, takes into consideration the COVID-19 pandemic and the Commission's actions to safeguard individuals and businesses across the EU (*for further details, see above Section on Medicines*).

The Report noted that the COVID-19 pandemic highlighted the need for an effective data protection regime to build trust and innovative digital solutions. In light of this goal, for instance, the Commission issued guidance on contact tracing apps in April 2020, which provided key data protection principles.

On the enforcement side, the Commission pursued infringement proceedings against Slovenia and Germany failing to transpose the Data Protection Law Enforcement Directive. In late 2020, the Commission decided to refer

Slovenia to the European Court of Justice.

The Commission has presented an annual report on monitoring the application of EU law since 1984, following a request by the European Parliament. The Parliament then adopts a resolution on the Commission's report.

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