



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 White Paper on levelling the playing field as regards foreign subsidies (*see below section on Trade / Export Controls*)
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission White Paper on levelling the playing field as regards foreign subsidies
- European Commission launches EU trade policy review
- European Commission Concept Paper on an international agreement to facilitate trade in healthcare products

Medicines, Medical Devices, and Personal Protective Equipment

- DG Health and Food Safety calls on stakeholders to join workshop on Pharmaceutical Strategy on 14-15 July 2020
- European Commission launches public consultation on Pharmaceutical Strategy for Europe
- European Commission Communication on EU Strategy for COVID-19 vaccines

Cybersecurity, Privacy & Data Protection

- Member States and European Commission agree on interoperability solution for mobile tracing and warning apps

COMPETITION & STATE AID

State Aid

European Commission White Paper on levelling the playing field as regards foreign subsidies (see [here](#))

See below section on Trade / Export Control.

EU approves new and amended Member State measures to support the economy (see [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:

- €9 million Polish scheme to support companies active in the primary agricultural sector affected by coronavirus outbreak
- €1.8 million Cypriot scheme to support farmers active in the primary agricultural sector affected by the coronavirus outbreak
- €59 million Lithuanian scheme to support companies active in the agricultural, food, forestry, rural development and fishery sectors
- €200 million Slovak rent compensation scheme to support companies affected by coronavirus outbreak
- €40 million Croatian guarantee scheme to support SMEs active in the field of culture and creative industries affected by coronavirus outbreak
- €7 million Luxembourg scheme to support audiovisual production companies affected by coronavirus outbreak
- €449 million Polish scheme to support research and development, testing and production of coronavirus relevant products
- €4 billion Slovak direct grant and guarantee schemes to support companies affected by coronavirus outbreak

TRADE / EXPORT CONTROL

European Commission White Paper on levelling the playing field as regards foreign subsidies (see [here](#))

On 17 June 2020, the European Commission issued a *White Paper on levelling the playing field as regards foreign subsidies*, proposing the adoption of new instruments to remedy distortions in the EU market arising from foreign subsidies. The proposed instruments include, in particular:

- a general instrument to capture distortive foreign subsidies provided to economic operators established or active in the EU market (“Module 1”);

- a mandatory notification and approval process for acquisitions of EU companies, if the acquirer benefits from financial support of a non-EU government (“Module 2”);
- in the context of EU public procurement procedures, a new ground of exclusion in relation to economic operators receiving distortive foreign subsidies (“Module 3”).

The White Paper underscores the importance of preserving a level playing field in the EU, even in exceptional economic circumstances. The Commission acknowledges that “*significant amounts of State aid*” are currently applied in the EU to combat the negative effects of the COVID-19 pandemic. Nonetheless, the Commission argues that this aid is “*indispensable*” to “*stabilise the economy and accelerate research in the coronavirus*”. The Commission, however, also stresses that all aid continues “*to be subject to EU State aid control... ensuring... its proportionality and minimising the potentially distortive effect on competition*”, and that the current assessment framework is “*temporary and limited in scope to crisis measures*”.

Additionally, the White Paper further includes several proposals on addressing the issue of foreign subsidies that give companies an unfair advantage in winning EU grants and funding.

Interested parties may comment on the Commission’s proposals through a [public consultation](#) until 23 September 2020.

European Commission launches EU trade policy review (see [here](#))

On 16 June 2020, the EU Commission announced the initiation of a major review of the European Union’s trade policy, including a public consultation seeking input from the European Parliament, Member States, stakeholders and civil society (e.g. NGOs, non-profits, etc.). The review aims at developing a new medium-term direction for EU trade policy, responding to new global challenges, including those arising from the coronavirus crisis.

The [public consultation](#) is open for comments until 15 September 2020. The results of this consultation will feed into a communication to be published towards end-2020.

European Commission Concept Paper on an international agreement to facilitate trade in healthcare products (see [here](#))

On 15 June 2020, the EU Commission published a Concept Paper on an international agreement to facilitate trade in healthcare products. The Paper includes ideas on facilitating trade in pharmaceutical and medical goods and avoiding trade disruptions in light of the ongoing challenges arising from the coronavirus pandemic. The Paper’s ideas could contribute to the creation of a new international agreement open to all WTO Members.

The Paper outlines the following potential elements of a future agreement:

- permanently eliminating tariffs on pharmaceutical and medical goods;
- developing a concept of “essential goods”, which would be subject to special trading conditions in times of crisis;
- establishing a global cooperation scheme during health crises, covering issues such as import and export restrictions, customs and transit, public procurement, and transparency in trade procedures.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

DG Health and Food Safety calls on stakeholders to join workshop on Pharmaceutical Strategy on 14-15 July 2020 (see [here](#))

On 19 June 2020, the European Commission's Directorate General for Health and Food Safety (DG Santé) called on stakeholders to join an upcoming online workshop (Workshop) to discuss the anticipated Pharmaceutical Strategy for Europe (Strategy). The planned Workshop takes place within the Commission's consultation on the Strategy, opened on 16 June 2020 (see below).

The Workshop, to be held on 14 and 15 July 2020, will allow interested parties to share their opinions on specific aspects of the Strategy. Representatives of industry, patients, public health organizations, healthcare professionals and researchers are invited to register until 3 July.

European Commission launches public consultation on Pharmaceutical Strategy for Europe (see [here](#))

On 16 June 2020, the European Commission launched a public consultation on the above-referred Pharmaceutical Strategy for Europe, anticipated to be adopted by end-2020.

Industry, competent authorities, patient associations, academics, and the general public are invited to submit their views via a questionnaire on issues of access, availability and affordability of medicines, environmental sustainability, and innovation in the field of pharmaceutical products until 15 September 2020. The consultation results will contribute to preparing the Pharmaceutical Strategy.

In particular, the consultation addresses, *inter alia*: (i) shortages of medicinal products; (ii) pricing; (iii) supporting R&D for innovative medicines to treat unmet medical needs and to tackle anti-microbial resistance; (v) risks and opportunities arising from the use of digital technologies and use of real world data.

The strategy outlined in the consultation addresses long-standing challenges and is linked to other Commission initiatives, such as the Industrial Strategy for Europe, as well as priorities outlined in the European Green Deal, the Beating Cancer Plan, and the Digital Strategy.

European Commission Communication on EU Strategy for COVID-19 vaccines (see [here](#))

On 17 June 2020, the European Commission adopted a Communication on EU Strategy for COVID-19 vaccines, addressed to the European Parliament, the European Council, the Council, and the European Investment Bank.

The Communication provides for a pan-European strategy to accelerate the development, manufacturing, and delivery of vaccines for COVID-19 in a timeframe between 12 and 18 months. It sets out three objectives to ensure: (i) vaccine quality, safety and efficacy, as well as (ii) prompt and (iii) affordable access to vaccination

The Communication aims at pursuing a sufficient supply of vaccines through Advance Purchase Agreements (Agreements) with manufacturers. The Commission will enter into Agreements on behalf of interested Member States. Upfront manufacturing costs will be partially financed via the Emergency Support Instrument (ESI), which currently has a budget of EUR 2.7 billion of EU resources, in exchange for the right to purchase vaccines based on predefined conditions. Vaccine doses will be allocated between Member States on a population-based approach.

Furthermore, the Communication clarifies that the Commission intends to revise the currently applicable regulatory framework in order to accelerate the development, authorization and availability of vaccines (e.g., temporarily derogate from specific provisions of the Directive on Genetically Modified Organisms (GMO) as concerns clinical trials for vaccines containing GMO and introduce certain flexibilities for labelling and packaging).

CYBERSECURITY, PRIVACY & DATA PROTECTION

Member States and European Commission agree on interoperability solution for mobile tracing and warning apps (see [here](#))

On 16 June 2020, with the support of the European Commission, Member States agreed on a set of technical specifications to ensure the safe exchange of information between national contact tracing apps launched by their respective governments.

Once deployed, the system will enable tracing apps to operate when users travel among the Member States, without the need to download different national apps. This will be particularly useful in the summer period, given greater anticipated movement within the EU for vacation travel.

Specific encryption mechanisms will prevent user identification, in line with the EU guidelines on data protection for apps issued by the European Data Privacy Board (EDPB) (see EDPB "*Guidelines no.4/20 on the use of location data and contact tracing tools in the context of the COVID-19*" [here](#), and EDPB "*Guidelines no. 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak*" [here](#)).

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