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

- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- EU and India launch the High-Level Dialogue on Trade and Investment, with a particular focus on COVID-19's impact
- EU adopts Joint Communication on new Agenda for the Mediterranean, particularly in view of Southern Neighbourhood recovery from the COVID-19 crisis
- The EU's Association Implementation Report on Georgia welcomes Georgia's commitment to continue its reform process, despite COVID-19's impact

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission and EMA update Guidance on management of clinical trials during the COVID-19 pandemic

Cybersecurity, Privacy & Data Protection

- Data protection measures clarified in European Commission and EMA updated Guidance on management of clinical trials during the COVID-19 pandemic

COMPETITION & STATE AID

State Aid

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:

- €4.9 billion Swedish guarantee scheme to support the economy in the context of the coronavirus outbreak.
- €300 million Austrian scheme for package travel organizers and facilitators of linked travel services in the context of the coronavirus outbreak.
- €255.5 million Danish scheme to compensate mink farmers affected by coronavirus measures.
- €1.18 billion Dutch scheme to support SMEs in the Netherlands affected by the coronavirus outbreak.
- €94.6 million Polish scheme to support non-governmental organizations and religious legal entities affected by the coronavirus outbreak.
- €20 million Slovenian scheme to support companies active in public transport sector affected by the coronavirus outbreak.

TRADE / EXPORT CONTROLS

EU and India launch the High-Level Dialogue on Trade and Investment, with a particular focus on COVID-19's impact (see here)

On 5 February 2021, the first meeting took place of the EU-India High-Level Dialogue on Trade Investment, which aims at enhancing EU-India bilateral trade and investment relations.

The meeting's Co-Chairs (European Commission Executive Vice-President and Commissioner for Trade Valdis Dombrovskis and India's Minister of Commerce and Industry Shri Piyush Goyal) discussed a broad range of trade and investment issues, particularly focusing on the COVID-19 pandemic's socio-economic impact, as well as vaccine production and distribution mechanisms, including value chain linkages.

The two sides also exchanged views on the state of play of EU-India bilateral trade and investment relations. The possibility of opening new areas of cooperation was also a focus point, for instance in relation to the resilience of global value chains and regulatory cooperation, notably in relation to new technologies.

Both sides also reiterated their commitment to further enhance their collaboration on WTO reform.

The next meeting of the High-Level Dialogue will discuss the findings of experts tasked by the Co-Chairs to examine the feasibility of resuming work on trade and investment agreements; new areas of cooperation (regulatory aspects and resilient value chains); as well as enhancing collaboration on

	WTO reform. These discussions will contribute to preparing the anticipated EU-India Leaders' Meeting.
EU adopts Joint Communication on new Agenda for the Mediterranean, particularly in view of Southern Neighbourhood recovery from the COVID-19 crisis (see here)	On 9 February 2020, the European Commission and Josep Borrell, High Representative of the European Union for Foreign Affairs and Security Policy/ European Commission Vice-President adopted a Joint Communication proposing an ambitious and innovative new Agenda for the Mediterranean. The Agenda includes a dedicated Economic and Investment Plan to spur long-term socio-economic recovery in the Southern Neighbourhood.* To implement the Plan, up to €7 billion for the period 2021-2027 is allocated under the new EU's Neighbourhood, Development and International Cooperation Instrument (NDICI), which could mobilize up to €30 billion in private and public investment in the region in the next decade. As stated by Commissioner for Neighbourhood and Enlargement Olivér Várhelyi, this initiative "*shows that Europe wants to contribute directly to a long-term vision of prosperity and stability of the region, especially in the social and economic recovery from the COVID-19 crisis."* The Plan includes preliminary flagship initiatives to strengthen resilience, build prosperity and increase trade and investment to support competitiveness and inclusive growth. The EU will carry out a mid-term review of the Joint Communication by 2024. * Includes: Algeria, Egypt, Israel, Jordan, Lebanon, Libya, Morocco, Palestine (*the Commission states that this designation shall not be construed as recognition of a State of Palestine and is without prejudice to the individual positions of Member States on this issue*), Syria, and Tunisia
The EU's Association Implementation Report on Georgia welcomes Georgia's commitment to continue its reform process, despite COVID-19's impact (see here)	On 9 February 2021, the European Commission published the European Union's annual Association Implementation Report on Georgia. The Report indicates that Georgia remains committed to the obligations and undertakings of the EU-Georgia Association Agreement, despite the COVID-19 related challenges. The Association Agreement, which entered into force in 2016, introduced a preferential trade regime to increase market access between the EU and Georgia based on better-aligned regulations. The EU is Georgia's largest trading partner. The Report indicates that Georgia has further aligned its legislation with EU standards, towards facilitating trade flows with the EU. In particular, Georgia intends to ensure an inclusive, green and sustainable recovery from the COVID-19 crisis and to make further progress on digitalization. Structural reforms will enhance Georgia's investment climate and trade potential and make its economy less vulnerable to external factors. Georgia's economy, however, entered a significant recession in 2020. In the first eleven months of 2020, the trade turnover between the EU and Georgia amounted to €2.1 billion, down by 12% compared to the same period in 2019. The EU has actively responded to support Georgia's efforts in tackling the COVID-19 pandemic, including reprogramming substantial grants to assist Georgia. As stated by Commissioner for Neighbourhood and Enlargement, Olivér Várhelyi: "*The EU has stood by the Georgian people since the start of the pandemic. We mobilised €183 million of grants for COVID-19 related assistance to Georgia last year, in addition to €150 million in macro-financial assistance.*"

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Commission and EMA update Guidance on management of clinical trials during the COVID-19 pandemic (see here)

On 4 February 2021, the European Commission and the European Medicines Agency (EMA) updated the guidance document on managing clinical trials conducted during the COVID-19 pandemic ("Guidance").

The Guidance expands the use and scope of remote source data verification ("rSDV") in clinical trials beyond those carried out for the treatment or prevention of COVID-19. As noted in the Guidance, rSDV can be justified in clinical trials, in view of the ongoing COVID-19 pandemic and the need to ensure the quality of clinical trial data and to protect the rights, safety and well-being of the trial participants in the EU/EEA.

The Guidance indicates that sponsors (entities sponsoring the research study) may now use rSDV in clinical trials investigating serious or life-threatening conditions, regardless of the trial phase or whether satisfactory alternatives exist on the market.

The use of rSDV in all other pivotal clinical trials is also now permitted under the Guidance, in situations where the absence of SDV for critical data *"may likely pose unacceptable risks to participants' safety or the reliability/integrity of trial results,"* as well as in trials "*involving particularly vulnerable participants such as children or those temporarily (e.g. trials in emergency situations) or permanently (e.g. trials in patients with advanced dementia) incapable of giving their informed consent*".

Sponsors are recommended to use rSDV only in agreement with investigators (the individual responsible for conducting the clinical trial at the trial site), who should not be unduly pressured to accept remote SDV and who should always prioritize the care given to trial participants and other patients.

In particular, rSDV should not be conducted in the absence of ensuring adequate data protection, including data security and protection of personal data (*for further details, see below Section on Cybersecurity, Privacy & Data Protection*).

CYBERSECURITY, PRIVACY & DATA PROTECTION

Data protection measures clarified in European Commission and EMA update Guidance on management of clinical trials during the COVID-19 pandemic (see here)

On 4 February 2021, the European Commission and the European Medicines Agency (EMA) updated the guidance document on managing clinical trials conducted during the COVID-19 pandemic ("Guidance"), expanding the use and scope of remote source data verification ("rSDV") in clinical trials (*for further details, see above Section on Medicines*).

In relation to data protection, the Guidance provides that rSDV must ensure adequate data protection, including data security and protection of personal data, even if pseudonymized. In this respect, Annex 1 of the Guidance provides for controls that, where applicable, can protect trial participants' rights while permitting rSDV.

Updates to Annex 1 of the Guidance, in particular, clarify that the principal investigator's institution and sponsors "*may be jointly responsible as controllers for ensuring information is safeguarded*", in line with the GDPR (EU General Data Protection Regulation).

Such data protection safeguards include, among others, ensuring that each trial participant or designated legal representative does not object to the remote review of the participant's records for trial purposes and that this process is documented in the trial participant's medical records. No rSDV will occur for a trial participant who objects to such remote review of their records.

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