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 issues Comfort letter on Cooperation at a Matchmaking Event – Towards COVID19 vaccines upscale production
- European Commission publishes Evaluation and follow-up measures on jurisdictional and procedural aspects of EU merger control
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- European Commission reinforces transparency and authorization mechanism for exports of COVID-19 vaccines
- EU-Canada pandemic recovery bolstered by Comprehensive Economic and Trade Agreement (CETA)

Medicines and Medical Devices

- European Commission hosts first Matchmaking Event - Towards COVID-19 vaccines upscale production
- EMA adopts recommendations to increase manufacturing capacity and supply of COVID-19 vaccines in the EU

Cybersecurity, Privacy & Data Protection

- *No noteworthy items for this issue*

COMPETITION & STATE AID

Competition

European Commission issues Comfort letter on Cooperation at a Matchmaking Event – Towards COVID19 vaccines upscale production (see here)

On 25 March 2021, the European Commission issued a "Comfort letter: Cooperation at a Matchmaking Event – Towards COVID19 vaccines upscale production."

The Comfort letter preceded the Commission's hosting of the first pan-European "matchmaking" event on 29 and 31 March 2021 to expand COVID-19 vaccine production capacities across Europe and to address production and supply chain bottlenecks.

The Matchmaking Event, open to any operator concerned with production capacity in the EU, seeks to accelerate connections between vaccine producers and service companies such as contract development and manufacturing organizations, equipment producers and others, towards improving planning for vaccine production in Europe.

The Comfort letter sets out guidance on how the matchmaking and exchanges between participating companies, including direct competitors, can take place in line with the EU competition rules. In particular:

- for matchmaking meetings between any companies (regardless of whether they are competitors or active at different levels of the supply chain), any exchange of confidential business information will be limited to what is indispensable for effectively resolving the supply challenges linked to the pandemic; and
- for matchmaking meetings between direct competitors:
  - companies will not share any confidential business information regarding their competing products, in particular information relating to prices, discounts, costs, sales, commercial strategies, expansion plans and investments, customers list, etc.; and
  - direct competitors will keep a record of topics discussed.

Should direct competitors consider that exchanging confidential business information in relation to competing products would be indispensable to finding solutions to boosting production or supply of COVID-19 vaccines, they should contact the Commission for guidance at least 24 hours before engaging in any such exchange in the context of the Matchmaking Event.

For specific cooperation initiatives with an EU dimension between competitors or non-competitors that require swift implementation in order to effectively tackle the pandemic, but which raise uncertainty about their compatibility with EU competition law, the Commission is ready to provide guidance to companies, associations and their legal counsel.

The Matchmaking Event is co-organized, on behalf of the European Commission, by Ecorys Europe EEIG-GEIE (main contractor and signatory for the consortium of the European Cluster Collaboration Platform (ECCP)) and SPI (a consortium partner responsible for the operational organization of the Matchmaking Event).

	For further details on the Matchmaking Event, see below Section on Medicines.
European Commission publishes Evaluation and follow-up measures on jurisdictional and procedural aspects of EU merger control (see here)	On 26 March 2021, the Commission published an Evaluation and follow-up measures on jurisdictional and procedural aspects of EU merger control. The Staff Working Document, "Evaluation of procedural and jurisdictional aspects of EU merger control," (see here) follows debates over the past years on the effectiveness of turnover-based jurisdictional thresholds of the EU Merger Regulation and, in particular, whether thresholds should be able to capture certain transactions involving firms that generate limited turnover at the time of the acquisition (an example frequently cited by the EU is Facebook's acquisition of WhatsApp in 2014). The EU claims a particular interest in expanding its jurisdictional scope in the digital economy and the pharmaceutical sector. The Commission argues that the outbreak of the COVID-19 pandemic has further heightened the importance of such considerations, as it holds that EU citizens and businesses have relied even more on digital services. The pandemic's impact on the health and economic well-being of EU citizens also highlights, in the Commission's view, the importance of fostering vigor and innovation in the EU economy, including in the pharmaceutical sector. The Commission further states that mergers should not be allowed to jeopardize the benefits of competitive dynamism, also in the aftermath of the pandemic and the recovery phase. The Evaluation focused on two topics in particular: (i) the effectiveness of the turnover-based jurisdictional thresholds in capturing concentrations that may have a significant impact on competition. The Evaluation reflects that the turnover-based jurisdictional thresholds, complemented with the referral mechanisms, have generally proved effective at this stage. However, regarding the above-mentioned market developments, the Commission believes that a transaction's value may not always be sufficiently correlated with the its potential competitive significance. In this respect, the Commission is of the opinion that encouraging and accepting more referrals under Article 22 of the Merger Regulation could give Member States and the Commission the flexibility to review mergers that it considers merit review at EU level, without imposing notification obligations on transactions that do not. In light of the Evaluation's results, the Commission adopted a Communication on 26 March 2021 providing guidance on the application of the referral mechanism between Member States and the Commission under Article 22 of the Merger Regulation (see here). (ii) the effectiveness of simplification measures introduced in 2013. The Evaluation states that the 2013 simplification measures have been effective in increasing the application of simplified procedures to unproblematic mergers and in reducing administrative burdens both for businesses and the Commission. Still, the Commission believes there is room for further simplification and targeting of the rules. It has launched a four-week impact assessment consultation (until 23 April 2021), seeking comments on its "Roadmap" (see

	here) on policy options for further targeting and simplification of merger procedures. In particular, the Roadmap notes that the Commission currently permits the electronic notification of mergers, due to COVID-19 restrictions, and that it would be beneficial to clarify the notification rules permanently in this respect to ensure safe, reliable and cost-efficient document transmissions. Finally, the Commission also launched a public consultation (until 18 June 2021, see here) on options for further targeting and simplifying merger review (in both simplified and non-simplified merger cases), without compromising effective merger enforcement.
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: • Modification of three Spanish schemes, including €10 billion budget increase for aid of limited amount, to further support economy in the context of the coronavirus outbreak – the first providing limited amounts of aid, guarantees on loans, subsidized loans and support for uncovered fixed costs to companies and the self-employed – the second providing support for research and development, testing and production of coronavirus relevant products as well as wage subsidies and deferrals of tax and social security contributions – the third is the Spanish recapitalization fund • €100 million support in favor of Greek oil and gas company Energean affected by the coronavirus outbreak • €270 million Italian measure to support rail freight and commercial passenger operators affected by the coronavirus outbreak • €20 million Cypriot subsidized loan scheme to support SMEs affected by the coronavirus outbreak • €9.9 million Estonian scheme to support companies active in tourism and directly related sectors affected by the coronavirus outbreak • modification of Belgian scheme (increase from €200 to €440 million) to support companies in Flanders affected by the coronavirus outbreak • €6.5 million Belgian scheme to support pig farmers affected by the coronavirus outbreak • Czech guarantee scheme for companies affected by the coronavirus outbreak and modification to existing guarantee scheme for loans to large exporting companies. These two measures can jointly generate loans with a nominal amount of up to approximately €19.3 billion

- Modifications to four Hungarian schemes to support companies in the context of the coronavirus outbreak
  - the first three schemes consist of limited budget increases and an extension of the deadline for the beneficiaries to submit applications
  - the fourth scheme consists of the extension of the scope of beneficiaries and an increase in the budget of the scheme, from approximately €315 million to approximately €625 million
- €400 million Dutch loan scheme to support companies providing package travel and linked travel arrangements in context of the coronavirus outbreak
- €22 million Czech scheme to support fairs and exhibitions sector in the context of the coronavirus outbreak
- Modifications of Bulgarian scheme to support employment in sectors most affected by the coronavirus outbreak:
  - the prolongation of the duration of the scheme until December 2021
  - the increase of the budget from BGN 40 million (approximately €20.5 million) to BGN 150 million (approximately €76.7 million)
  - amendments extending the scope of the eligible beneficiaries, employees and self-employed persons for which aid may be granted, as well as technical modifications

TRADE / EXPORT CONTROLS

European Commission reinforces transparency and authorization mechanism for exports of COVID-19 vaccines (see here and here)

On 24 March 2021, the Commission announced new measures to address ongoing shortfalls in timely access to COVID-19 vaccines for EU citizens.

Executive Vice-President and EU Trade Commissioner, Valdis Dombrovskis, highlighted that the EU remains the biggest global exporter of vaccines and is the only OECD producer that continues to export vaccines to countries having their own production capacities. However, when these countries do not export to the EU, there is no reciprocity. Furthermore, while the EU's epidemiological situation remains very serious, it continues to export significantly to countries with situations less serious than the EU's, or with greater vaccination roll-out than in the EU.

To address these imbalances, the Commission has adopted a new Implementing Regulation to adapt the EU's export authorization mechanism for vaccines, introducing two changes to the existing scheme:

(i) In addition to assessing the impact of a planned export on the ability to satisfy the EU's Advance Purchase Agreements (APAs) with vaccine manufacturers, Member States and the Commission now should also consider:

- Reciprocity, e.g., whether the destination country restricts its own exports of vaccines or their raw materials, either by law or other means; and

	– Proportionality, e.g., whether the conditions prevailing in the destination country are better or worse than the EU's, in particular its epidemiological situation, its vaccination rate, and its access to vaccines. (ii) To provide a full view of the vaccine trade, the new Regulation now encompasses 17 countries previously exempted* from the export authorization scheme. Commissioner Dombrovskis also emphasized that unconditional exemptions from the export authorization mechanism will continue to apply to exports to low- and middle-income countries, supplies through COVAX (the global procurement mechanism to ensure rapid and fair access to COVID-19 vaccines for all countries), and exports to EU overseas countries and territories. Since the launch in January 2021 of the EU vaccine export mechanism, 380 out of 381 export requests to 33 different destinations have been granted for a total of some 43 million doses. The largest export destinations include the UK (approximately 10.9 million doses), Canada (6.6 million), and Japan (5.4 million). * *List of countries: Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Georgia, Israel, Jordan, Iceland, Lebanon, Libya, Liechtenstein, Montenegro, Norway, North Macedonia, Serbia and Switzerland.*
EU-Canada pandemic recovery bolstered by Comprehensive Economic and Trade Agreement (CETA) (see here)	On 25 March 2021, the EU and Canada held the second CETA (Comprehensive Economic and Trade Agreement) Joint Committee Meeting, led by Co-Chairs, Executive Vice-President and EU Trade Commissioner Valdis Dombrovskis and Canadian Minister of Small Business, Export Promotion and International Trade the Honourable Mary Ng. Launched in 2017, the CETA is a trade agreement between the EU and Canada to lower tariffs and facilitate the export of goods and services between the EU and Canada.* CETA is a core component of the political, trade and economic partnership between the EU and Canada. Subsequent to CETA, EU-Canada trade had increased by 25% until the start of the pandemic. And despite COVID-19's unprecedented impact on international trade, EU-Canada trade flows in 2020 remained 15% higher in 2020 than before CETA's provisional entry into force. Responding to the economic impact of the COVID-19 pandemic, the Co-Chairs reviewed measures taken by both the EU and Canada to facilitate the continuation of preferential trade during the pandemic. These include increased flexibility and further administrative cooperation on the verification of origin. The Co-Chairs also highlighted the importance of ongoing efforts to address remaining regulatory and other market access issues to enable exporters in the EU and Canada to maximize benefits under CETA. The third meeting of the CETA Joint Committee is scheduled to take place in Canada in Autumn 2022. * *CETA entered into force provisionally on 21 September 2017. National parliaments in EU countries – and in certain cases, regional ones as well – must approve CETA before it can take full effect.*

MEDICINES AND MEDICAL DEVICES

European Commission hosts first Matchmaking Event - Towards COVID-19 vaccines upscale production (see here and here)	On 29 and 31 March 2021, the Commission's Task Force for the Industrial Scale-up of COVID-19 vaccine production hosted the first pan-European "matchmaking" event. This initiative seeks to expand COVID-19 vaccine production capacities across Europe, address production and supply chain bottlenecks, and improve planning strategy for current and future vaccine production. *For further details on the Matchmaking Event, see above Section on Antitrust.* The Matchmaking Event, open to any operator concerned with production capacity in the EU, gathered over 300 participating companies from 25 Member States. As explained by Commissioner Thierry Breton, responsible for the Internal Market: "*The matchmaking event is all about fostering new connections and partnerships across the production and supply chain. I encourage the many companies involved in the vaccine manufacturing process to make the most of the matchmaking opportunities*." The Matchmaking Event was organized with the support of the European Cluster Collaboration Platform (ECCP), in collaboration with the Council of European BioRegions (CEBR) and the European Cluster Alliance (ECA).
EMA adopts recommendations to increase manufacturing capacity and supply of COVID-19 vaccines in the EU (see here)	On 26 March 2021, the European Medicines Agency (EMA) published a summary of recommendations adopted by its Committee for Medicinal Products for Human Use (CHMP), aimed at increasing manufacturing capacity and supply of the COVID-19 vaccines in the EU. In particular, the CHMP issued a positive opinion concerning the approval of new manufacturing sites for producing: – the active substance of the AstraZeneca's COVID-19 vaccine (in Leiden, the Netherlands); – the active substance and finished product of Comirnaty, the COVID-19 vaccine developed by BioNTech and Pfizer (in Marburg, Germany); – the active substance and finished product intermediates for Moderna's COVID-19 vaccine (in Visp, Switzerland). The CHMP also provided a positive opinion on the transportation and storage of vials of Comirnaty at the temperature of standard pharmaceutical freezers (i.e., between -25 to -15˚C), for a one-time period of two weeks, as an alternative to the already authorized long-term storage at a temperature of between -90 and -60˚C. The CHMP issued additional positive opinions concerning certain changes to the manufacturing processes for Moderna's vaccine, also aimed at ramped-up production capacity.

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