COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 12 | 12 June 2020

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 consults Member States on proposal to expand State aid Temporary Framework to further support micro, small and start-up companies and incentivize private investments
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- *No noteworthy developments for this issue*

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission requests opinion on "*A new framework for the organisation of health and social care following the COVID-19 pandemic*"
- EMA Guidance on remote GCP inspections during the COVID-19 pandemic
- EMA action for supporting availability of medicines during COVID-19 pandemic
- EMA to review *remdesivir* application for a conditional marketing authorization

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

COMPETITION & STATE AID

State Aid

EU consults Member States on proposal to expand State aid Temporary Framework to further support micro, small and start-up companies and incentivize private investments (see here)

On 12 June 2020, the European Commission sent a draft proposal for Member State consultation to extend the scope of the State aid Temporary Framework. In particular, the European Commission proposes to:

(i) Enable Member States to support certain micro and small enterprises, including start-ups that were already in difficulty before 31 December 2019. The proposed amendment would apply to all micro and small companies, unless such companies are in insolvency proceedings, have received rescue aid that remains unrepaid, or are subject to a restructuring plan under State aid rules.

(ii) Adapt the conditions for recapitalization measures under the Temporary Framework where private investors contribute to the capital increase of companies together with the State. Notably, the proposed changes would:

- allow companies with an existing State shareholding to raise capital similar to private companies, whilst maintaining the same safeguards to preserve effective competition in the Single Market, and
- encourage capital injections with significant private participation in private companies as well, limiting the need for State aid and the risk of competition distortions.

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:

- €3.7 billion Swedish scheme to compensate companies for damages suffered due to coronavirus outbreak
- €286 million Finnish measure to recapitalise Finnair
- €1.2 billion Portuguese urgent liquidity support to TAP
- €30.5 million Lithuanian scheme to support bovine animal and milk producers affected by the coronavirus outbreak
- €155 million Hungarian “umbrella” direct grant scheme to support the economy in the coronavirus outbreak
- €33 million Cypriot scheme deferring payment of VAT to support companies affected by coronavirus outbreak
- Polish recapitalisation scheme to enable up to €1.65 billion of capital support to SMEs and large enterprises affected by the coronavirus outbreak

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

European Commission requests opinion on "*A new framework for the organisation of health and social care following the COVID-19 pandemic*" (see here)	On 10 June 2020, the European Commission (Commission) requested the Expert Panel on Effective Ways of Investing in Health to provide an opinion on "*A new framework for the organisation of health and social care following the COVID-19 pandemic*" (Opinion). The Expert Panel is an interdisciplinary and independent group established by the Commission to provide non-binding advice on matters related to healthcare systems aimed at supporting the Directorate-General for Health and Food Safety. It gathers 17 experts appointed for 3 years from December 2019, following an open call for applications addressed to independent scientists with over 10 years of professional and multi-disciplinary experience in the health area. In the context of the COVID-19 pandemic, the Commission requested the Expert Panel to provide an analysis and issue recommendations on: (i) building blocks for improving care organization and criteria to be used for a continuous evaluation of the appropriateness of service delivery capacity of primary care, outpatient specialist and hospital/social care; (ii) the elements and conditions for capacity building in primary care, outpatient specialist and hospital/social care to strengthen overall robustness against unpredictable events; (iii) sustaining healthcare for vulnerable patient groups with urgent needs for care; and (iv) criteria, methodologies and models to resilience-test health systems for unpredictable high-pressure scenarios. The Opinion is due by November 2020.
EMA Guidance on remote GCP inspections during the COVID-19 pandemic (see here)	On 10 June 2020, the European Medicines Agency (EMA) issued Guidance on remote good clinical practice (GCP) inspections during the COVID-19 pandemic (Guidance). The Guidance is the first in a series of EMA documents published on remote inspections for verifying compliance with EU and international standards during the pandemic. It outlines requirements and specificities of GCP inspections. The Guidance highlights that, even during this pandemic, the inspection team should always perform a case-by-case assessment of whether a remote GCP inspection is considered appropriate, although remote inspections of investigator sites are not feasible. The Guidance also provides recommendations on the actual conducting of remote inspections, once considered feasible. The Guidance emphasizes that inspectors must be able to review the electronic trial master file, audit trails, activity logs, metadata, as well as access to electronic case report form systems.
EMA action for supporting availability of medicines during	On 8 June 2020, the EMA published the results of the meeting on 3 June 2020 of the EU Executive Steering Group on Shortages of Medicines Caused by Major Events (Steering Group). This group is a body composed of EMA, European Commission and national competent authorities (NCAs) established

COVID-19 pandemic (see here)	to tackle the impact of COVID-19 on the supply of medicinal products in the EU. The Steering Group decided to task an ad hoc working group within the EMA, composed of experts appointed by NCAs, with developing a framework for collecting and sharing demand data in the EU. The working group will identify the medicinal products that fall under its remit, including products beyond those used in intensive care units, for which an immediate need was identified during the pandemic. At the end of its mandate, the working group will issue a reflection paper summarizing best practices derived from national forecasting models and proposing practical recommendations for a harmonized approach.
EMA to review *remdesivir* application for a conditional marketing authorization (see here)	On 8 June 2020, the EMA received Gilead's application for a conditional marketing authorisation (CMA) relevant to *remdesivir* for the treatment of COVID-19. The EMA notes that *remdesivir* is an infusion viral RNA polymerase inhibitor initially developed for treating Ebola and which also showed broad in vitro activity against different COVID-19. Concerning the application process, the EMA indicated that the Committee for Medicinal Products for Human Use's (CHMP) opinion could be issued within weeks, depending on the robustness and completeness of the data submitted. Certain data were already assessed during the first cycle of the rolling review, at the end of which the CHMP invited Gilead to submit additional data. Moreover, the Paediatric Committee (PDCO) already issued its opinion on the paediatric investigation plan. Notably, *remdesivir* is already used for the treatment of patients affected by COVID-19 in the context of clinical trials and compassionate use programmes. In this context, the EMA published a brief visual guide on fast-track procedures for COVID-19 treatments and vaccines (here).

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