COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 15 | 3 July 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 expands the Temporary Framework to further support micro, small and start-up companies and incentivize private investments
- EU prolongs EU State aid rules to mitigate impact of COVID-19
- Portugal increases shareholding in TAP Air Portugal
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- EU Commission's second review of steel safeguards takes account of difficult market situation due to coronavirus crisis
- Programme for Germany's Presidency of the Council outlines trade priorities in the context of COVID-19 crisis

Medicines, Medical Devices, and Personal Protective Equipment

- European Commission grants the first (conditional) marketing authorization for the treatment of COVID-19
- European Commission Pharmaceutical Committee meeting
- Statement on COVID-19 clinical trials issued by International Coalition of Medicines Regulatory Authorities (ICMRA)
- Update to the Guidance for medicine developers and companies on COVID-19
- EMA revises guidance on Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials

Cybersecurity, Privacy & Data Protection

- *No noteworthy developments for this issue*

COMPETITION & STATE AID

State Aid

EU expands the Temporary Framework to further support micro, small and start-up companies and incentivize private investments (see here)

On 29 June 2020, the European Commission adopted a third amendment to the Temporary Framework for State aid measures to support the economy in the COVID-19 outbreak. This amendment further extends the Framework to:

(i) Enable Member States to provide public support to all micro, small and start-up enterprises, including those already in difficulty on 31 December 2019. This excludes companies in insolvency proceedings, those that received rescue aid that remains unrepaid, or those subject to a restructuring plan under State aid rules.

(ii) Incentivize private investors to participate in COVID-19 related recapitalization aid measures. The European Commission has therefore adapted the conditions for recapitalization measures where private investors and the State together contribute to the capital increase of companies.

In the context of this amendment, the European Commission clarified that aid should not be conditioned on relocating the beneficiary's production activity or another activity from one country within the European Economic Area (EEA) to the territory of the Member State granting the aid, since such condition would be particularly harmful to the internal market.

EU prolongs EU State aid rules to mitigate impact of COVID-19 (see here)

On 2 July 2020, the European Commission prolonged the validity of certain State aid rules due to expire at the end of 2020. In particular, the European Commission granted:

(i) A **one-year extension (until 2021)** for the Guidelines on (a) regional State aid for 2014-2020, (b) State aid to promote risk finance investments, (c) State aid for environmental protection and energy, as well as (d) the Communication on the execution of important projects of common European interest (IPCEI), and (e) the Communication on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to short-term export-credit insurance (STEC); and

(ii) A **three-year extension (until 2023)** for the General Block Exemption Regulation (GBER), the *de minimis* Regulation, and the Guidelines on State aid for rescuing and restructuring non-financial undertakings in difficulty**.**

The European Commission also adopted targeted adjustments to the prolonged rules, as well as to the Framework for State aid for research and development and innovation. These adjustments address, in particular:

(i) **Undertakings in difficulty**. Companies that entered into difficulty following the coronavirus outbreak, and that do not have access to certain types of aid under the existing rules, will remain eligible to receive aid under the GBER and other sets of rules (*i.e.* the Guidelines on regional State aid for 2014-2020, the Framework for State aid for research and development and innovation, the Guidelines on State aid for environmental protection and energy, and the IPCEI Communication), for a certain period of time during and after the crisis.

	(ii) **Job relocations**. Job losses that a company may incur due to the COVID-19 outbreak will not be considered as relocations and hence a breach of any commitment not to relocate in the coming years (commitments that companies may have undertaken upon receiving regional investment aid falling under the GBER). In addition to these adjustments, the European Commission proposes to amend the *de minimis* Regulation to allow undertakings that entered into difficulty because of the COVID-19 outbreak to remain eligible for *de minimis* aid for a limited period of time.
Portugal increases shareholding in the TAP Air Portugal (see here)	On 2 July 2020, Portugal announced that it would increase its shareholding in TAP Air Portugal. The government will invest €55 million ($62 million) in the airlines, increasing its ownership stake from 50% to 72.5%. Executive Vice-President Margrethe Vestager had earlier expressed support for nationalizations and partial-nationalizations to help European companies recover from the COVID-19 crisis and to avoid takeovers by, *inter alia,* Chinese investors. A few months ago, TAP Air Portugal was reportedly in negotiations to obtain substantial credit lines with two State-owned Chinese banks (see here).
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: • €200 million Slovenian scheme to compensate large companies for damages suffered due to coronavirus outbreak • €160 million Dutch scheme to compensate companies that offer special transport services which suffered due to coronavirus outbreak • €600 million Slovenian scheme to support companies affected by the coronavirus outbreak • €102 million Bulgarian scheme to support medium-sized companies affected by the coronavirus outbreak • €1.4 billion Dutch scheme to support small and medium-sized enterprises affected by the coronavirus outbreak • €207 million French wage subsidy regime to support the economy in the context of the coronavirus pandemic • €80 million Croatian loan guarantee scheme for companies in the maritime, transport, travel and infrastructure sectors affected by the coronavirus outbreak • €30 billion French subordinated loan scheme to support companies affected by the coronavirus outbreak • €145 million Luxembourgish reinsurance scheme to support trade credit insurance market in coronavirus outbreak

	• €800 million Romanian scheme to support companies affected by the coronavirus outbreak • €6.3 million Cypriot incentive scheme towards airlines affected by coronavirus outbreak
TRADE / EXPORT CONTROL	
EU Commission's second review of steel safeguards takes account of difficult market situation due to coronavirus crisis (see here)	On 30 June 2020, the Commission published the results of its second review of the EU's safeguard measures on imports of steel products. The Commission implemented the following main changes to the measures, also taking into account the difficulties faced by the EU steel industry due to the pandemic: • Country-specific quotas will be made available in quarterly, rather than annual, allotments. • Introduction of a new country-specific quota for hot-rolled flat (category 1) steel. • For countries that have exhausted their country-specific quota, accessing the residual quota will be permitted only to the extent necessary to respond to demand. • Update of the list of developing countries excluded from the measures on the basis of the most recent stable statistical data (2019). These changes took effect as of 1 July 2020.
Programme for Germany's Presidency of the Council outlines trade priorities in the context of COVID-19 crisis (see here)	On 1 July 2020, Germany took over the six-month Presidency of the Council of the EU. Its Programme highlights that a key priority will be to overcome the social and economic consequences of the COVID-19 pandemic. In this context, the Programme outlines a number of principles that will guide the German Presidency's approach to EU trade policy: • Strive to keep markets open and to strengthen trade and investment on the basis of international, enforceable rules. • Act to correct market distortions caused by state-controlled and subsidized companies from third countries. In the context of the COVID-19 crisis, this also applies to protecting European companies that could be takeover targets. • Propel a modernization agenda for the World Trade Organization (WTO) and progress in ongoing trade negotiations with, *inter alia*, MERCOSUR, Mexico, New Zealand and Australia. • Promote a more level playing field In trade relations with China. • Open up procurement markets in third countries. • Improve international investment protection regulations and drive forward efforts to create a Multilateral Investment Court.

	• Continue to review the EU's foreign trade and investment policy tools to put EU businesses on equal footing when engaging in international competition with companies from third countries.
MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT	
European Commission grants the first (conditional) marketing authorization for the treatment of COVID-19 (see here)	On 3 July 2020, the European Commission authorized the first medicinal product for the treatment of COVID-19 on the grounds of the positive opinion issued by the Committee for Human Medicinal Products (CHMP) on 25 June 2020 (here). In particular, the Commission granted Veklury (*remdesivir*) a conditional marketing authorization (MA) for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen. Under this conditional MA, the Marketing Authorization Holder must provide comprehensive clinical data after one year. Following the review of such additional data by the European Medicines Agency (EMA), the conditional MA can be converted into a "standard" MA.
European Commission Pharmaceutical Committee meeting (see here)	On 2 July 2020, the European Commission Pharmaceutical Committee held its 88th meeting, which addressed, *inter alia*: • Orphan and pediatric-related legislation, focusing on three key aspects: (i) unmet medical needs; (ii) availability and accessibility of orphan and pediatric medicines; and (iii) technological and scientific developments. A Staff Working Document (SWD) summarizing the meeting's findings will be published this summer. • The Committee's update on the Vaccine Strategy (here) excluded the possible use of a vaccine prior to granting a marketing authorization. It emphasized, however, the possibility of coordinated and harmonized scientific assessment at European level to foster vaccine development. Such coordinated approach would be facilitated by the European Medicines Agency (EMA). A specific vaccine development model is currently under preparation and will soon be presented to the Member States. Finally, the Committee noted that both the EMA and Commission are seeking greater flexibility in vaccine labelling and packaging requirements, such as easing language requirements, use of multi-dose vials, etc. • The recently published Roadmap on Pharmaceutical Strategy is open to consultation until 15 September 2020 (here). It 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; and (v) risks and opportunities arising from the use of digital technologies and use of real world data.
Statement on COVID-19 clinical trials issued by International Coalition of	On 1 July 2020, the International Coalition of Medicines Regulatory Authorities (ICMRA) issued a statement on the prioritization of COVID-19 clinical trials. The statement sets out the key clinical trials features that are most likely to generate the evidence required for accelerated approval of potential medicinal

Medicines Regulatory Authorities (ICMRA) (see here)	products and vaccines against COVID-19. It also cautions sponsors in relation to commencing new trials where there is a scarcity of recruitable patients. In such cases, priority should be given to completing trials already underway. Finally, the statement encourages investigators to provide full and prompt accessibility to results, both for the subjects enrolled in the trials and the general public. This ICMRA statement was immediately endorsed by the EMA (here).
Update to the Guidance for medicine developers and companies on COVID-19 (see here)	On 1 July 2020, the European Commission, the Heads of Medicines Authorities (HMA), and the EMA issued an update to the joint *Questions and Answers document on regulatory expectations for medicinal products amid the coronavirus disease (COVID-19) pandemic* (Q&A). The Q&A gives marketing authorization holders certain flexibility in deviating from their management of pharmacovigilance corrective and preventive actions (CAPAs) on the grounds of justified reasons related to the pandemic. It provides that deviations must duly recorded, limited in time, and terminated as soon as possible. The Q&A also recommends that regulators follow a risk-based approach when considering postponing pharmacovigilance audits. Remote audits should be preferred over deferment, when appropriate and feasible. Finally, the Q&A clarifies that sites located outside the European Economic Area (EEA) cannot receive an automatic extension for changes in the scope of the good manufacturing practice (GMP) certificate. On the same day, the European Commission, the HMA, and the EMA published an update to the document on *Questions and Answers on regulatory expectations for medicinal products for veterinary use during the COVID-19 pandemic to cover pharmacovigilance inspections* (here).
EMA revises guidance on Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials (see here)	On 29 June 2020, following a four-week public consultation, the EMA revised the guidance on *Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials*. The revised guidance expands the scope of pandemic-related measures that should be included in sponsors' data collection, such as dates and duration of lockdowns, travel restrictions and other measures affecting trial sites. It also emphasizes the importance of maintaining trial integrity and stresses that risk assessments should be based on blinded data and conducted by independent committees, if trial integrity is at risk. Furthermore, the revised guidance advises to promptly seek scientific advice from the EMA if substantial amendments to protocols are considered necessary.

LAWYER CONTACTS

Renato Antonini
Partner, Government Regulation; Antitrust & Competition Law
Brussels
rantonini@jonesday.com
+32.2.645.14.19

Kaarli H. Eichhorn
Partner, Antitrust & Competition Law; Government Regulation; Technology
Brussels
keichhorn@jonesday.com
+32.2.645.14.41

Dr. Jörg Hladjk
Partner, Cybersecurity, Privacy & Data Protection; Government Regulation; Technology
Brussels
jhladjk@jonesday.com
+32.2.645.15.30

Cristiana Spontoni
Partner, Health Care & Life Sciences; Government Regulation
Brussels
cspontoni@jonesday.com
+32.2.645.14.48