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## Antitrust: Impact of COVID-19 on Life Sciences

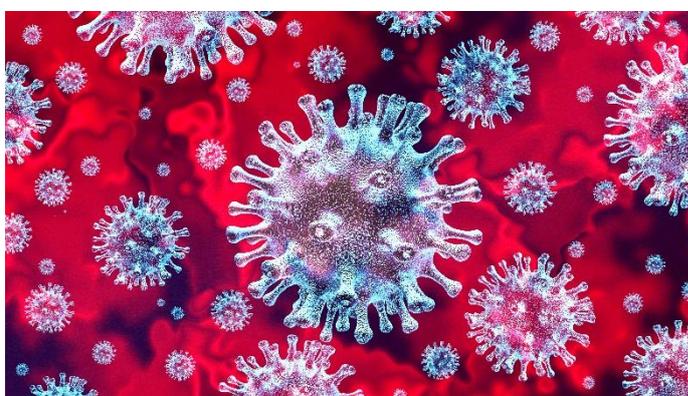
In light of the unprecedented public emergency caused by the COVID-19 pandemic, pharmaceutical and medical devices companies are under enormous pressure to support the efforts of national governments to tackle this global crisis. Most significantly, the race is on to identify, test and (ultimately) mass produce a vaccine against COVID-19. Similarly, the race is on to develop, manufacture and supply COVID-19 testing kits, trial drugs, ventilators and personal protective equipment (i.e. PPE) given shortages that have arisen as a result of stockpiling, lockdown of factories or third parties supplying the EU due to quarantine measures, logistical issues caused by border control and export bans.

Given the complexity and the amount of financial and technical resources as well as know-how required to meet such objectives; the logical, most expedient and efficient course of action would be for companies in the life sciences sector to work closely on such measures (e.g. to adapt production, monitor stock levels, co-ordinate the distribution of key medicines, share commercially sensitive information and research to develop a vaccine, etc.). However, such collaborative actions between competitors would generally be at risk of contravening UK and EU competition law rules.

Fortunately, there has been a general relaxation of the usually strict competition regulations in both the EU and UK, especially vis-à-vis companies operating in the life sciences sector, recognising that extraordinary times may require extraordinary measures to permit certain types of collaborations that would otherwise ordinarily be caught and sanctioned by the competition rules.

Yet both the European Commission ("**Commission**") and the Competition & Markets Authority ("**CMA**") have still made it clear that the present situation must not be exploited by companies – "*no free pass*"

has been given, for instance, to enter into cartel type arrangements or abuse a dominant position in the market.



### EU Developments

#### European Commission's Communication on Business Cooperation

The Commission recently published on 8 April 2020 a Communication on the Temporary Framework for assessing issues related to business cooperation in response to COVID-19 which helps provide guidance to businesses on the application of competition law rules as a result of the pandemic ("**Communication**")<sup>1</sup>. Prior to publishing the Communication, the Commission had received numerous notifications from Member States that they were already experiencing shortages of medicines used to treat patients with COVID-19 or that they would be expecting such shortages to occur very soon. Similarly, the Commission also received a large number of queries from businesses contemplating entering into collaborative arrangements to meet this shortfall.

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<sup>1</sup> Communication from the Commission: Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak (2020/C 116 I/02) Published on 8 April 2020. Available at: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0408\(04\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020XC0408(04))

## New Guidance

The Communication, in essence, permits various forms of cooperation between undertakings in order to ensure the supply and adequate distribution of essential products and services during the COVID-19 outbreak.<sup>2</sup> This includes medicines and medical equipment that are used to test and treat COVID-19 patients, or else are necessary to mitigate and possibly overcome the outbreak.

As such, the Communication provides clarification to businesses on what form of cooperation may be permitted during this pandemic. While companies will still need to self-assess whether schemes they are contemplating would be compliant with EU competition law, the Communication will be helpful for businesses to consult when making such a determination.

The Communication provides a non-exhaustive list of activities which, during the present crisis, would likely be permissible provided that they are subject to certain safeguards (e.g. no flow of individualised company information back to competitors, etc.).<sup>3</sup> Such activities would include entrusting a trade association or independent advisor to:

- a) Coordinate joint transport for input materials;
- b) Contribute to identifying those essential medicines for which, in view of forecasted production, there are risks of shortages;
- c) Aggregate production and capacity information, without exchanging individual company information;
- d) Work on a model to predict demand on a Member State level, and identifying supply gaps; and
- e) Share aggregate supply gap information, and request participating undertakings, on an individual basis and without sharing that information with competitors, to indicate whether they can fill the supply gap to meet demand (either through existing stocks or increase of production).<sup>4</sup>

Moreover, aside from these specific examples, other forms of collaborative actions which would entail the

exchange of sensitive information and coordination will also be permissible (or, at least, would not give rise to an enforcement priority for the Commission) to the extent that such measures are:

- a) Designed and objectively necessary to actually increase output in the most efficient way to address or avoid a shortage of supply of essential products or services, such as those that are used to treat COVID-19 patients;
- b) Temporary in nature;<sup>5</sup> and
- c) Not in excess of what is strictly necessary to achieve the objective of addressing or avoiding the shortage of supply.<sup>6</sup>

For all schemes being contemplated under these criteria, the Commission has advised businesses to document all exchanges and agreements between themselves, and to be in a position to provide this information to the Commission upon request.

This approach has also been endorsed by the International Competition Network ("**ICN**"), a global body whose members represent national competition authorities. The ICN has indicated in a statement<sup>7</sup> that competition authorities should accommodate collaboration between competitors in order to address the COVID-19 issues all countries are facing. The ICN is encouraging companies to act responsibly and fairly to ensure that products and services are available at competitive prices.

## Comfort Letters

As a further means of providing clarity to businesses on an expedited basis, the Commission has also indicated in its Communication that it is prepared, at its own discretion, to issue *ad hoc* "comfort letters" that had previously been abolished in 2003. This will allow companies to receive bespoke guidance from the Commission in relation to specific projects and attain a degree of legal certainty where they are unsure whether their proposed arrangements comply with relevant EU competition rules. However, comfort letters will only be administrative in nature and will not be binding. The Commission has already issued such a comfort letter to *Medicines for Europe*<sup>8</sup> in relation to a specific voluntary cooperation project among pharmaceutical producers – both members and non-members of the association – that targets

<sup>2</sup> Depending on the evolution of the crisis, the Commission might amend or supplement this Communication in order to cover other forms of cooperation.

<sup>3</sup> These are set out in the Commission's Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (2011/C 11/01) Published on 14 January 2011. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52011XC0114%2804%29>

<sup>4</sup> See paragraph 12 of the Communication.

<sup>5</sup> In other words, only applicable for as long as there is a risk of shortage or, in any event, for as long as the COVID-19 crisis lasts.

<sup>6</sup> See paragraph 14 of the Communication.

<sup>7</sup> See the ICN Steering Group Statement: Competition during and after the COVID-19 Pandemic published April 2020, and available at: <https://www.internationalcompetitionnetwork.org/wp-content/uploads/2020/04/SG-Covid19Statement-April2020.pdf>.

<sup>8</sup> Formerly known as the European Generics Medicines Association.

the risk of shortage of critical hospital medicines for the treatment of coronavirus patients.

The Commission has allocated significant resources to informally answer questions relating to cooperation between companies, including in the life sciences sector. This includes a dedicated email address for queries and the setting up of a dedicated website where guidance/information can be accessed easily.<sup>9</sup>

### European Competition Network – Joint Statement



A further point to note on developments at the EU level is that the European Competition Network (“**ECN**”), the organisation consisting of the competition authorities of all EU Member States, has issued a joint statement mirroring the Commission’s position.<sup>10</sup> That is to say, the ECN has similarly clarified that it will not actively intervene against necessary and temporary measures put in place in order to avoid a shortage of supply of essential products and equipment. Such measures are unlikely to be problematic in the present situation under Article 101 of the Treaty on the Functioning of the European Union (“**TFEU**”), or else would generate such efficiencies that would most likely outweigh any such restriction and therefore be permissible under Article 101(3) of the TFEU. That said, the ECN has also clarified that it will not allow the present situation to be exploited by companies who may seek to collude or price-fix under the pretence of supplying essential products to organisations and consumers.

The ECN recommends that businesses with doubts about the compatibility of any cooperation initiatives

seek informal guidance from the Commission or relevant national competition law authority.

## UK Developments

### Healthcare Order

One of the main actions taken in this area in the UK has been the passing of a new healthcare order (“**Order**”)<sup>11</sup> by the UK government that came into force on 28 March 2020 with retrospective effect from 1 March 2020. The Order represents an exemption to the Competition Act 1998 (“**CA 1998**”). Schedule 3 of the CA 1998 allows the government to specify certain activities as being exempt from the Chapter I prohibition if there are exceptional and compelling reasons of public policy to do so.

The Order allows the NHS to engage with independent healthcare companies in order to provide extra capacity for the treatment of patients during the COVID-19 pandemic. In so doing, it is likely that commercially sensitive information will need to be shared between the NHS bodies and independent providers, and amongst independent providers themselves. To that end, the Order specifies five types of collaborative arrangements (known as “qualifying activities”) that will, subject to the approval of the Secretary of State, be permissible under UK competition law. These are:

- 1) Sharing information about capacity to provide certain services;
- 2) Coordinating on the deployment of staff;
- 3) The sharing or loan of facilities;
- 4) Joint purchasing of goods, facilities or services; and
- 5) The division of activities (including agreements to limit or expand the scale or range of services supplied by one or more providers).

Furthermore, agreements falling under the above criteria must be notified to the Secretary of State for approval within 14 days of the agreement being made. In doing so, parties must provide: (i) the names of undertakings or bodies that are parties to the agreement; (ii) a description of the nature of the

<sup>9</sup> See:

<https://ec.europa.eu/competition/antitrust/coronavirus.html>.

<sup>10</sup> Joint statement by the European Competition Network (ECN) on application of competition law during the Corona crisis. Available at: [https://ec.europa.eu/competition/ecn/202003\\_joint-statement\\_ecn\\_corona-crisis.pdf](https://ec.europa.eu/competition/ecn/202003_joint-statement_ecn_corona-crisis.pdf)

<sup>11</sup> The Competition Act 1998 (Health Services for Patients in England) (Coronavirus) (Public Policy Exclusion) Order 2020. Available at: <http://www.legislation.gov.uk/ukxi/2020/368/made>

agreement; (iii) the date the agreement was made and date it was, or will be, implemented; and (iv) the products or services to which the agreement relates.

Importantly, the Order does not permit the sharing of any information relating to costs, prices or future business plans. These forms of anti-competitive behaviours are still prohibited under Chapter I of the CA 1998.

### COVID-19 Taskforce

In addition to the passing of the Order, the CMA has indicated that it will be carefully scrutinising any behaviour that could be harmful to consumers. As a signal of its intent, the CMA launched a COVID-19 taskforce ("**Taskforce**") on 20 March 2020 in order to police the actions of companies during the pandemic.<sup>12</sup> The Taskforce will scrutinise market developments to identify harmful practices (e.g. predatory or excessive pricing), warn companies suspected of exploiting the exceptional circumstances presented by COVID-19 and take enforcement action if there is any evidence that companies have breached competition and/or consumer protection laws.



### Open Letters

In a similar vein, the CMA has also written an open letter to the pharmaceutical and food and beverages industries to both remind them of their importance to the lifeblood of the UK economy and to warn them against exploiting the present situation for their own benefit.<sup>13</sup> The CMA is, therefore, sending a clear message that it will not hesitate to take enforcement action against any companies found to be engaging

in anti-competitive practices during this time of crisis. Pharmaceutical and medical devices companies need to be particularly careful about their pricing, given the various recent findings of excessive pricing in this sector and ensure that any cooperation with other competitors is done in a compliant manner.

### Conclusion

Whilst the general relaxation of the usually strict EU and UK competition law rules is a very welcome development for the life sciences sector and one which will play a crucial role in tackling the present crisis to ensure that key medical supplies and services continue to be provided, companies should also be warned of the risks in engaging in anti-competitive practices purely for their own benefit, as opposed to the mutually beneficial outcome in fighting COVID-19. Both the Commission and the CMA have made it very clear that they will be monitoring collaborations closely and that any attempt to circumvent the strict frameworks put in place will be punished accordingly.

### Contact us

If you are uncertain whether any arrangements you are entering into are compliant with the EU and UK competition rules, Stephenson Harwood's Competition Team would be happy to discuss.



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<sup>12</sup> See <https://www.gov.uk/government/news/cma-launches-covid-19-taskforce>.

<sup>13</sup> The Competition & Markets Authority. *An open letter to the pharmaceutical and food and drinks industries*. Published on 20 March 2020. Available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/874240/COVID\\_19\\_Open\\_letter\\_to\\_pharmaceutical\\_and\\_food\\_and\\_drink\\_industries2.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874240/COVID_19_Open_letter_to_pharmaceutical_and_food_and_drink_industries2.pdf)