

## COMPETITION AND REGULATED MARKETS

# COVID-19 Practical Considerations: European Commission's comfort letter on pharmaceutical sector cooperation

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On 29 April 2020, the European Commission published a letter providing comfort under EU competition law rules for certain cooperation practices aiming at responding effectively to challenges regarding shortages of medicines in the EU as a result of the COVID-19 outbreak. This briefing examines the Commission's letter and what it means for pharmaceutical companies operating in Europe.

## Background

Competition/antitrust laws generally require competitors to operate on the market independently of each other and only permit cooperation in limited circumstances where it can be demonstrated that the resulting efficiencies and consumer benefits outweigh any restriction on competition. However, in light of the COVID-19 crisis and calls for the relaxation of competition laws to help businesses deal with the fall-out, competition authorities have provided additional guidance on the application of competition law during the pandemic, including:

- On 23 March 2020 the European

Competition Network ("ECN")<sup>1</sup> issued a joint statement clarifying how competition rules apply in the context of the crisis.<sup>2</sup>

- On 25 March 2020, the Competition and Consumer Protection Commission of Ireland ("CCPC") published the ECN joint statement on its website, signalling that it will approach competition enforcement in the context of the crisis in line with the principles set out in the joint statement.<sup>3</sup>
- On 8 April 2020, the Commission published a communication on a Temporary Framework for assessing antitrust issues related to business cooperation in response to the current COVID-19 outbreak (the "Antitrust Temporary Framework").<sup>4</sup>

The Antitrust Temporary Framework recognises that measures taken by undertakings may contribute to bridging the gap between supply and demand during the current COVID-19 outbreak. The supply and adequate distribution of essential scarce products and services during the outbreak is of critical importance and any shortages may be avoided through business cooperation

projects. Scarce products of particular focus are critical medical goods and medical equipment used to test and treat COVID-19 patients.

Indeed, the Antitrust Temporary Framework specifically recognises that cooperation in the health sector may need to go further than other sectors to overcome critical supply shortages. Under the Temporary Framework, any measures taken to identify essential medicines at risk of shortage, aggregate production and capacity information, work on models to predict demand at a Member State level and share aggregate supply gap information will not raise antitrust concerns, provided these measures are subject to sufficient safeguards.

As it stands, the Commission operates a system of self-assessment whereby undertakings are themselves responsible for assessing the legality of their agreements and practices. However, in an effort to provide guidance to companies cooperating in urgent situations connected to the COVID-19 outbreak, the Commission has implemented a temporary process whereby ad hoc written comfort to undertakings can

1 The ECN is a network of the Directorate General for Competition of the European Commission and the 27 national competition authorities across the EU, including the Competition and Consumer Protection Commission of Ireland. The ECN provides a forum for discussion and cooperation of European competition authorities and ensures the effective and consistent application of EU competition rules.

2 See ECN Joint Statement on the 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)

3 See CCPC Press Release on ECN joint statement, available at <https://www.ccpc.ie/consumers/2020/03/25/covid-19-european-competition-law-joint-statement/>

4 Communication from the European Commission on a Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak, C(2020) 3200, available at [https://ec.europa.eu/info/sites/info/files/framework\\_communication\\_antitrust\\_issues\\_related\\_to\\_cooperation\\_between\\_competitors\\_in\\_covid-19.pdf](https://ec.europa.eu/info/sites/info/files/framework_communication_antitrust_issues_related_to_cooperation_between_competitors_in_covid-19.pdf)

be provided in relation to specific and well-defined cooperation projects.<sup>5</sup> The first such "comfort letter" from the Commission under the Antitrust Temporary Framework was issued to Medicines for Europe on 8 April 2020.

### The Medicines for Europe comfort letter

The comfort letter refers to certain cooperation practices aimed at addressing the risk of acute shortages in medicines used to treat COVID-19, which has been caused by a sudden exponential growth in the demand for such medicines, difficulties in accurate order forecasting and stockpiling measures. The proposed cooperation is extensive and envisages pharmaceutical manufacturers cooperating to model demand, to identify production capacity and existing stocks and to adjust or reallocate production and stocks based on projected or actual demand. In addition, the cooperation foresees more extensive coordination to ensure optimal use of resources, including:

- Cross-supply of active pharmaceutical ingredients, possibly including intermediates;
- Joint identification of where to switch or increase capacity or production with a view to ensuring an adequate supply of all relevant materials; and
- Measures to rebalance and adapt capacity utilisation, and production and supply, possibly also including distribution, where medicines are being over- or under-supplied.

The Commission considered that these measures do not raise concerns under EU competition law, based on two primary circumstances. First, the proposed cooperation followed a request from the

EU Commissioner for Health and Food Safety and the Commission's Directorate General for Health and Food Safety, DG SANTE, for pharmaceutical companies to work together to address issues regarding the supply of medicines. This reflects guidance in the Antitrust Temporary Framework that the role of public authorities in encouraging cooperation will be a relevant factor to be taken into account in considering the compatibility of any cooperation measures under EU competition law. Second, in line with the Antitrust Temporary Framework, the cooperation is aimed at addressing a scarcity of supply of medicines that are critical to the treatment of COVID-19 and is necessary to achieve the aim of ensuring security of supply by increasing production and improving supply in an efficient way.

However, the comfort letter is also subject to the following safeguards:

- The cooperation will be open to any pharmaceutical manufacturer interested in participating.
- Minutes of all meetings will be created and kept, and copies of any agreement entered into in the context of the cooperation will be shared with the Commission.
- The exchange of confidential business information among manufacturers will be limited to what is indispensable for effectively achieving the aims set of the cooperation, and the Commission will make available to the participants a controlled forum for exchanging sensitive information to the extent its discussion is necessary to achieve these aims.
- The cooperation will be limited in time until the risk of shortages has passed, and the Commission will inform

Medicines for Europe when this is the case.

In addition, the comfort letter makes explicitly clear that it does not cover coordination on issues that are not strictly necessary for achieving the aims described above. Furthermore, the comfort letter is subject to the participants' agreement not to increase prices beyond what is justified by possible increases in the underlying costs of the relevant products.

### Helpful clarification on cooperation in the pharmaceutical sector

The comfort letter provides helpful clarifications on the approach of the Commission under the Antitrust Temporary Framework to cooperation measures in the pharmaceutical sector during the COVID-19 crisis, and envisages a wide range of measures that may be undertaken in compliance with competition law rules. However, any such cooperation measures must be strictly limited to those necessary to achieve the aims as set out above and must be subject to the relevant safeguards as outlined by the Commission. The Arthur Cox Competition and Regulated Markets team is available to help you ensure that in this context the steps you take to handle the impact of the crisis do not give rise to competition law risks.

*Please contact a member of the team for further guidance including any guidance on engaging with the European Commission on potential cooperation projects.*

<sup>5</sup> Communication from the European Commission on a Temporary Framework for assessing antitrust issues related to business cooperation in response to situations of urgency stemming from the current COVID-19 outbreak, reference above. The Commission has also set up a dedicated webpage and a dedicated mailbox that can be used to seek informal guidance on specific initiatives.

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