EUROPEAN COMMISSION
DG COMPETITION

The Director-General

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Medicines for Europe,
Mr Adrian van den Hoven
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1000 Brussels, Belgium
By email: adrian@medicinesforeurope.com

Subject: Comfort letter: coordination in the pharmaceutical industry to increase production and to improve supply of urgently needed critical hospital medicines to treat COVID-19 patients

Dear Sir,

I refer to your submission of 6 April 2020 regarding the consultation mentioned in reference and the explanations you have provided before and after this submission.

On behalf of Medicines for Europe ('MfE'), you have requested from the European Commission a letter providing comfort under Article 101 TFEU 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. MfE is making this request on behalf of its members and other pharmaceutical manufacturers that are, or may in the future be, participating in the cooperation.[1]

The cooperation practices concerned aim at improving supply and increasing production in the most expedient and effective manner, and possibly also at improving distribution.

The Commission understands that the pharmaceutical industry is currently acting to adapt its stock and production capacity to the sudden, pan-European surge in demand for certain COVID-19 hospital medicines, leading to an acute risk of medicine shortages in the EU.

[1] Since the entry into force of Council Regulation (EC) No 1/2003, undertakings can no longer notify their agreements to the Commission in order to receive an individual exemption from Article 101 TFEU, but they are responsible for assessing themselves the legality of their agreements and practices. Notwithstanding, in view of the unprecedented challenges faced by undertakings and consumers due to the COVID-19 pandemic, the Commission has decided to exceptionally provide undertakings with ad hoc feedback or comfort on the legality of cooperation initiatives that need to be swiftly implemented in order to effectively tackle the COVID-19 pandemic, see Communication from the Commission of 8 April 2020, "Communication on a Temporary Framework for assessing antitrust issues related to business cooperation in response to urgency situations stemming from the current COVID-19 outbreak".

The situation of medicine shortages is aggravated by an uncertainty about the modalities of the further spread of the COVID-19 pandemic.

As a result, health care providers or distributors may be either under-estimating or over-estimating the demand in the EU, notably for intensive care medicines. As a consequence, the Commission understands there is a risk of precautionary orders for large quantities of medicines used to treat COVID-19 patients and significant stock-piling. This, in turn, risks aggravating shortages in the EU. The situation would be further exacerbated by the exponential growth of demand for COVID-19 medicines worldwide.

According to MfE's submission and your analysis of the spreading of the COVID-19 outbreak, you suggest that to meet the health care needs of COVID-19 patients across Europe, the production capacity to produce COVID-19 medicines would need to increase very significantly. This includes products such as deep sedatives, neuromuscular blockers, strong analgesics, vasopressors, antibiotics and adjuvants. COVID-19 intensive care patients require a particularly high amount of these medicines, given that they are ventilated.

The risk of shortages has been identified also by the Commission, with the support of the European Medicines Agency. For instance, on 2 April 2020 Commissioners Kyriakides and Breton called upon innovators, generic, over-the-counter and chemical producers to increase production capacity for all medicines facing increased demand in the context of COVID-19. The letter also invited these players to work together to address the increased demand for those medicines, including by identifying alternatives.

In light of the above, pharmaceutical manufacturers producing relevant COVID-19 medicines intend to engage in a cooperation to model demand for these medicines. The cooperation envisages further to identify production capacity and existing stocks, and to adapt or to reallocate, based on projected or actual demand, production and stocks, and to potentially also address the distribution of COVID-19 medicines.

The Commission understands that this cooperation further needs to coordinate available industry production capacity throughout Europe and identify means to optimise the use of resources available in the industry. In particular, the coordination may need to include cross-supply of API(s) (active pharmaceutical ingredient(s)), possibly including intermediates, and jointly identifying where to best switch production of a certain production site to a certain medicine and/or to increase capacity, so that not all firms focus on one or a few medicines, whilst others remain in under-production. The cooperation also envisages, where medicines are being under-supplied or where over-supply exists, to rebalance and adapt capacity utilisation, production and supply (including possibly distribution), on an ongoing basis.

After considering the matter on the basis of the information and the factual circumstances described by you, and subject to the considerations and conditions set out below, the Commission considers that in the present exceptional circumstances the cooperation practices as set out above do not raise concerns under Article 101 of the Treaty on the Functioning of the European Union.

The Commission has based its assessment notably on the following circumstances:

- The Commissioner for Health and Food Safety and the Commission's Directorate-General for Health and Food Safety ('DG SANTE') requested pharmaceutical undertakings in relation to shortages of COVID-19 hospital medicines to engage in

exchanges about the above-mentioned cooperation. The Commission is providing a forum for these exchanges and will have a steering role in the process.[2]

- The cooperation has the overall purpose to expeditiously and effectively increase supply and production of urgently needed COVID-19 medicines. Based on the facts explained in MfE's submission, the cooperation is necessary to achieve the increases in production and to improve the supply of those urgently needed COVID-19 medicines across the EU in the most efficient way. MfE accepts to put in place certain safeguards:
    - First, the cooperation will be open to any pharmaceutical manufacturer willing to participate.
    - Second, minutes of all meetings will be created and kept, and copies of any agreement entered into between undertakings in the context of this cooperation will be shared with the Commission.
    - Third, the exchange of confidential business information among manufacturers will be limited to what is indispensable for effectively achieving the aims set out above. The Commission will make available to the undertakings a controlled forum for exchanging sensitive information to the extent its discussion is necessary to achieve these aims. The Commission will provide input, also, as relevant, with the involvement of the European Medicines Agency and national health systems. Information from undertakings will either be gathered by MfE or by an external third party that the Commission understands MfE has appointed, and be made available to the participating undertakings in aggregated form only.
    - Fourth, the cooperation will be limited in time until the risk of shortages, including in a possible second wave of the COVID-19 epidemic, is overcome. The Commission may inform MfE, when this is the case.

This comfort letter does not cover any discussion of prices or any other possible coordination on issues which are not strictly necessary for effectively achieving the aims set out above. This comfort letter is also subject to participating undertakings not unduly increasing prices beyond what is justified by possible increases in costs, which you have accepted. Conduct amounting to opportunistically seeking to exploit the crisis as a 'cover' for non-essential collusion or other anticompetitive behaviour will continue not to be tolerated by the Commission.

In light of these considerations, the cooperation set out in MfE's submission of 6 April 2020 does not raise concerns under Article 101 TFEU. In reaching this conclusion, we have consulted also the National Competition Authorities that together with the European Commission constitute the European Competition Network.

Yours faithfully,

Olivier GUERSENT

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[2] This intervention is of course without prejudice to the powers of the Member States laid down in Article 168 of the TFEU.