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Commissioner for Health and Food Safety
European Commission

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Commissioner for Internal Market
European Commission

Re: Disruptions in the API market

Brussels, 8th May 2020

Dear Commissioners,

I am writing to express concern over the clear intention of certain member states to intervene directly in the market for active pharmaceutical ingredients (API) during the Covid19 crisis. These policy actions create a serious risk of disruption for the manufacture and supply of medicines in critical and urgent need across Europe. These purchases of API are intended to secure supply at a time of massive demand surges – notably for intensive care unit (ICU) medicines for patients infected with Sars-Cov-2. This can, however, be very impactful on manufacturers of medicines as API suppliers will typically prioritise sales to states over manufacturers at a time of crisis.

These policies will create disruptions for manufacturers of medicines that are doing everything possible to comply with your request to produce more medicines for Europe (*3 April 2020 Letter to the pharmaceutical industry from Commissioner Kyriakides*). This is exacerbated by the fact that some of this state purchased API will not be transformed into medicine by specialised manufacturers. Instead, it will be transformed in hospital compounding centres or other facilities that will require time to re-engineer for this purpose. The EU is expected to ensure full compliance with GMP and other medicines regulations for all manufacturers and compounders of sterile medicines.

In addition, this policy will reduce the total productivity of the industry by transferring limited API availability to less productive units (compounding centres or re-engineered production units) than if the API has been sold to existing specialised manufacturing plants. This is an unfortunate policy at a time where the Commission has encouraged the industry to increase manufacturing speed and output to tackle the surge in demand related to Covid19. We are especially concerned that this diversion of API supplies will negatively impact the industry's efforts to plan for a possible second wave of the viral infection as initial information from manufacturers seems to confirm.

Medicines for Europe recommends that state interventions in the market are well considered and strictly limited to what is efficient in the future.

Yours respectfully,

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Medicines for Europe