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HEALTH AND FOOD SAFETY

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Dear Mrs Svarcaite,
Dear Mrs Moll,
Dear Mrs Saykali,
Dear Mr van den Hoven,
Dear Mrs de Azero,

As the coronavirus pandemic escalated in Europe, the European Commission swiftly engaged with your associations and their member companies with the objective of proactively preventing shortages of essential medicines at such a critical moment. Our weekly telephone conferences are examples of much needed cooperation between the pharmaceutical sector and the Commission in times of crisis.

During our last call on 27 March 2020, it was reported that there is an imminent risk of shortages of critical hospital medicines used to treat COVID-19 patients. Since then, several Member States have indeed reported to the European Medicines Agency (EMA) that they only have one week's stock of such critical medicines.

With my colleague Commissioner Thierry Breton, we therefore call on the EU pharmaceutical industry, whether research-based, generic, OTC or API producers and as a matter of extreme urgency, to increase their production of medicines used to treat seriously ill COVID-19 patients.

During these exceptionally challenging times, we are relying on you and your sense of responsibility and solidarity to ensure that patients in Europe will have access to the medicines they need. It is of utmost importance to give immediate priority to increasing the production of medicines attached in the Annex to this letter and ensure supply to the countries in need.

The Commission will continue to closely engage with you on finding optimal solutions for the challenges at hand. We count on you to discourage unethical commercial behaviour.

The Commission will spare no effort to ensure the free movement of goods, including medicines across Europe, for example via engagement with Member States on export restrictions, the recently published guidelines on “green lanes” and facilitating air cargo operations.

EMA is currently finalising a list of essential medicines going beyond the list of medicines used in the ICU setting that will be shortly communicated.

In addition, a number of medicines under development and medicines currently authorised for other diseases are used to treat patients with COVID-19, under clinical trials or national early access schemes. The EU pharmaceutical industry should also increase production of these medicines to respond to the needs of EU Member States, so as to prevent shortages for patients that rely on some of them for the treatment of other pre-existing diseases. In light of the lockdown and continued restrictions in India, there is also a clear need to increase paracetamol production in the EU, where possible.

We strongly recommend that you engage with national authorities, so Member States can each ensure a centralised distribution of medicines used to treat COVID-19 patients and that they can safeguard an equitable distribution for patients most in need.

We are also engaging actively with the Indian government, so as to allow shipments to reach the EU.

At this time of unprecedented crisis, we all have a moral and societal responsibility to pool and maximise our efforts and exhaust all possibilities so as to prevent shortages of critical medicines. We trust we can count on you, the EU pharmaceutical industry, to fulfil your legal obligations and show your commitment to protecting public health and the lives of European patients.

Yours sincerely,



Stella Kyriakides

TO:

- Mrs Jurate Svarcaite, Director General - The Association of the European Self-Care Industry (AESGP)
- Mrs Nathalie Moll, Director General - The European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Mrs Maggie Saykali, Director Resins and Fine Chemicals - CEFIC Specialty Chemicals
- Mr Adrian van den Hoven, Director General - Medicines for Europe
- Mrs Magdalena de Azero, Executive Director - Vaccines Europe

CC :

- Professor Guido Rasi, Executive Director - European Medicines Agency (EMA)

ANNEX (attached): Status report on shortages of ICU medicines (per therapeutic class)