Confidential

Pfizer Inc.
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Valdis Dombrovskis, Executive Vice President and Commissioner for Trade
Stella Kyriakides, European Commissioner for Health and Food Safety
Thierry Breton, European Commissioner for the Internal Market

5th February 2021

Subject: Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation

Dear Commissioner,

I am writing to you with urgency and concern in regard to EU's new Implementing Regulation (2021/111), which was published and entered into force on 30th January.

As you are aware, Pfizer is operating a tightly-calibrated supply chain to ensure we are able to supply vaccines at speed to patients in Europe and the world. While we continue to have systemic concerns regarding the measure as a whole, we wanted to draw your attention to specific issues related to its design and execution that have become apparent in the days since the Regulation entered into force. We hope you will be able to give these concerns your prompt attention, given the potentially significant consequences of manufacturing and supply being impacted.

Our experience to date with the administration of the Regulation is that it imposes a cumbersome administrative burden on companies and customs authorities alike, and creates ambiguity in the approval timeline and process. As you are aware, Pfizer is planning to significantly scale up its manufacturing, including exports, in the coming weeks, and other companies across Europe may be doing the same. It will be absolutely critical to Pfizer that both the Commission and Member State competent authorities have in place resources and procedures to be able to manage submissions without delay, also given ultra-cold chain requirements. For many individual export countries, there will be tens or hundreds of 'final destinations'. Pursuant to the Regulation, each shipment requires a separate authorisation, resulting in a separate individual customs authorization number. To address these concerns, we urge the Commission to create a system for automatic approval of these critical medical goods. Such a system would be consistent with the Commission's stated goal of ensuring transparency, while avoiding unnecessary export delays.

Secondly, we would like to alert you to one aspect of the measure's design and execution that requires immediate attention to avoid impacts on supply, including to patients in the EU. We learned on Tuesday that batch-testing samples were being held by a Member State's customs authorities due to the new legislation. Having promptly raised the matter with relevant authorities, Pfizer was informed that "*it was not the intention of the implementation Regulation to cover the samples for batch testing or the investigational medicinal products used in clinical trials used in the context of the clinical trials for the marketing authorisation of the Pfizer vaccines*". While these sample shipments have been cleared for export, to ensure that future sample shipments are not subject to authorisation, the Commission must provide clear guidance in writing to all EU customs authorities on the treatment of such shipments and make this guidance available to all affected stakeholders. To emphasise, batch-testing samples and clinical trial supply are critical components of our wider development and manufacturing operations, in accordance with legal requirements. The samples held and subsequently authorised yesterday were destined for US facilities that provide quality testing for our vaccines manufactured in Europe. Disruption to such supply could have serious and immediate impact on our ability to manufacture, with consequences for patients in Europe and the world.

To that end we would ask the Commission to immediately resolve this by revising the Regulation to add such a clarification, or by issuing appropriate guidance to Member State customs authorities. Given the wider scale up of manufacturing across Member States to which vaccines producers are all committed, it is essential that the clarification or guidance is applied in a uniform manner across all Member States.

Finally, we wish to emphasise the importance of open, global supply chains. Global supply chains for medicines and vaccines have long-benefited Europe, as the world's largest exporter of finished medicines and a major hub for life sciences investment. More pressingly, the flexibility for import and export globally has greatly benefitted the EU over the course of the pandemic, with supply for our ICU (intensive care unit) medicines re-directed from both Americas and Asia-Pacific to the benefit of Covid-19 patients in the EU.

Our commitment to patients in Europe, and globally, remains unwavering, and we call for swift action to support our shared goal of tackling this pandemic together.

Sincerely,

Pfizer Global Supply

cc: Michael Hager, Head of Cabinet of Commissioner Dombrovskis
George Rossides, Head of Cabinet of Commissioner Kyriakides
Valère Moutarlier, Head of Cabinet of Commissioner Breton

Sabine Weyand, Director-General for Trade
Sandra Gallina, Director-General for Health and Food Safety
Kerstin Jorna, Director-General for Internal Market