

[REDACTED]  
Pharmaceuticals B-5  
DG SANTE  
B – 1040 Brussels

Brussels, 9 December 2020

Ref: NM/PT/67.885

Dear [REDACTED]

### **Labelling and Packaging Flexibilities for COVID-19 Therapeutics**

As representatives of most of the world's developers of COVID-19 vaccines, we have welcomed the publication of the Memorandum of Understanding (MOU) on September 27, 2020 (SANTE.DDG1.B.5/AL/FI mmc(2020)5727730), which calls for labelling and packaging flexibilities for COVID-19 vaccines that are much needed to support their streamlined distribution. With this letter, we would like to request that a **similar Memorandum of Understanding** is drawn up for the COVID-19 therapeutics that will be submitted soon for regulatory assessment.

As agreed under the ACT-Accelerator and widely accepted by clinical experts and epidemiologists, the successful management of the pandemic will require the availability of **both** vaccines and therapeutics to address the overall burden of disease and hospitalisation of patients with COVID-19. To meet the considerable unmet medical need and the changing nature of the epidemic, manufacturing and packaging of COVID-19 therapeutic candidates will have to begin at risk. Our request is that the regulatory flexibilities granted across the EU for COVID-19 vaccines (detailed in the **Questions and answers on labelling flexibilities for COVID-19 vaccines**, published by the European Medicines Agency (EMA) <sup>1</sup> on 27 November 2020) are extended to COVID-19 therapeutics.

---

<sup>1</sup> EMA/616718/2020

We believe that requiring packaging in the different EU national languages could significantly delay production and therefore availability of COVID-19 therapeutics for patients. The EMA questions and answers on labelling flexibilities for COVID-19 vaccines allow for information on the immediate and outer packaging to be limited to English, with translations of the product information electronic annexes to be provided in all EEA languages, as per standard post-opinion procedure. For the package leaflet, the majority of EEA countries have agreed to grant a temporary exemption from the obligation to provide the printed package leaflet in their national language(s). Package leaflets can be printed in English only, provided that translations in the national language(s) are made available through alternative ways (e.g. via a QR code). The approval of information on the immediate packaging, outer packaging and leaflet should be available as early as possible and in advance of the marketing authorization. This would allow manufacturers to initiate packaging activities before authorization and hence, if the product is approved, to be able start distribution as soon as marketing authorisation is granted. Finally, to ensure supply flexibility across EEA, we would also welcome collaboration between EU institutions and Member States to ensure acceptance of the Global Trade Item Number (GTIN) standard by all Member States and the exemption of country-specific blue box requirements.

If not yet done, we would like to encourage the European Commission to initiated discussions in these regards for the COVID-19 therapeutics with the Members of the Pharmaceutical Committee, the Members of the Heads of Medicines Agencies (HMA), the Members of the CMDh and the leadership of the EMA. We encourage action as soon as possible and remain available to discuss this request further.

Thank you in advance for your time and kind consideration.

Best wishes,

