

16 March 2020

BY E-MAIL

MEMO

TO: The coronavirus response team

- Commissioner Janez Lenarčič
- Commissioner Stella Kyriakides
- Commissioner Ylva Johansson
- Commissioner Adina Vălean
- Commissioner Paolo Gentiloni

EU Executive Steering Group on shortages of medicines caused by major events

CC: DG SANTE:

- Anne Bucher, Director General
- Martin Seychell, Deputy Director-General
- Andrzej Rys, Director
- Agnes Mathieu-Mendes, Deputy Head of Unit
- Stefaan Van Der Spiegel, Head of Sector, Substances of Human Origin

EMA: Guido Rasi, Executive Director.

**FROM: Amy Efantis
Maarten Van Baelen**

**President & CEO
Executive Director Europe**

SUBJECT: RECOGNITION OF PLASMA AND PHARMACEUTICAL INTERMEDIATES AS ESSENTIAL

Urgent Handle & Confirm Review & Comment FYI As Requested

Dear members of the coronavirus response team and EU Executive Steering Group on shortages,

The Plasma Protein Therapeutics Association (PPTA – www.pptaglobal.org), a global industry trade association, represents the private sector manufacturers of plasma-derived and recombinant analogue therapies, collectively known as plasma protein therapies (PPTs) and the collectors of source plasma used for fractionation. Millions of people use PPTs worldwide to treat a variety of rare and chronic and/or genetic diseases and serious, often life-threatening medical conditions¹. For individuals with these conditions, PPTs replace their missing or deficient proteins. Without these treatments, many patients would either not be able to survive or would have a substantially diminished quality of life and productivity.

¹ More patients across the European Union are diagnosed every year with life-threatening plasma protein related disorders, such as Hemophilia and other bleeding disorders, immune deficiencies, Hereditary Angioedema, and Alpha 1-Antitrypsin Deficiencies. In many cases, PDMPs are the only treatment option for these rare diseases. New indications, improved diagnostic techniques, greater use in emerging markets, and an increased use in cancer treatment-induced secondary immunodeficiency are further contributing to the growing clinical need for PDMPs.

PPTA would like to thank the European Commission for the recently published "[Guidelines for border management measures to protect health and ensure the availability of goods and essential services](#)". We recognise the importance of such a guideline to ensure availability across Europe of essential products such as medicines and medical devices and to be able to prioritise essential products when needed (e.g. via "green lanes"). However, we would like to call the European Commission to add plasma from human origin as a key starting material for the production of medicines and pharmaceutical intermediates to that list of essential products. These products are essential for the development of PPTs derived from human donated plasma (Plasma Derived Medicinal Products - PDMPs).

Proposed amendment:

6. Member States should **preserve the free circulation of all goods**. In particular, they should guarantee the **supply chain of essential products** such as medicines and related starting materials including plasma from human origin, medical equipment, pharmaceutical intermediates, essential and perishable food products and livestock.

Plasma can be obtained from whole blood (resulting in recovered plasma) or collected directly through a process called plasmapheresis (resulting in source plasma). Currently, Europe is reliant on the U.S. for 37% of its plasma. Out of the 63% of plasma which is collected in Europe for European patients, the non-profit public sector collects 62%² of the plasma used for fractionation, while the commercial sector collects 38%³. However, only four European countries (Austria, Czech Republic, Germany, and Hungary) are able to contribute to the total of privately collected source plasma in Europe. These four countries allow the coexistence of public and privately-owned collection centres and compensate donors for expense and inconvenience related to the donation. It is critical that the transport of source plasma collected in these countries, but also recovered plasma collected in other EU Member States, can get un-hindered to those countries where the plants are located which manufacture/fractionate PDMPs.

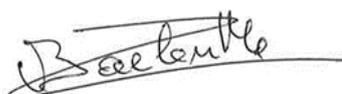
Plasma fractionation and further manufacturing takes place in Austria, Belgium, France, Germany, Hungary, Italy, Spain, Sweden and UK,. It is therefore needed that plasma and pharmaceutical intermediates are able to cross borders without delays or interruptions in order to ensure continuity of manufacturing of PMDPs. While some plasma protein therapies may reach patients within 7 to 12 months from the time plasma is collected from a human donor, for other products it can take up to 2 years to reach the patients. Such particularities on the time scale with a high public health impact require utmost consideration and make it critical that sufficient plasma volumes are always available for fractionation. This specific and lengthy supply chain makes that the response on availability of PDMPs might only be noticed in the medium term. However, the potential transport interruptions of plasma and intermediates could bring effects much sooner.

PPTA is at your disposal for any questions, comments, or concerns you may have.

Respectfully,



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Maarten Van Baelen
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² 17% via plasmapheresis programs, 45% collection via recovered plasma

³ The Market Research Bureau, 2017 data