PPTA
Plasma Protein Therapeutics Association

13 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** **President & CEO**
Maarten Van Baelen **Executive Director Europe**

SUBJECT: WARNING ON THE NEED TO COLLECT PLASMA DURING NOVEL CORONAVIRUS OUTBREAK TO ENSURE CONTINUED ACCESS TO PLASMA DERIVED MEDICINAL PRODUCTS

☒ 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 analog 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 conditions[1]. 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 share with you, as members of the coronavirus response team and the EU executive steering group on shortages of medicines, our serious and imminent concerns about the potential impact of measures related to the Coronavirus pandemic on patient access to PPTs, in particular PPTs derived from human donated plasma (Plasma Derived Medicinal Products - PDMPs).

First of all, we would like to stress that donor screening and testing, and viral reduction steps in the manufacturing process are ensuring that PDMPs are safe for the patient. These viral reduction steps also eliminate the SARS-CoV-2, meaning that there is no concern for the safety margins of plasma protein therapies manufactured by PPTA member companies.

Whilst we acknowledge the need for measures to be put in place to avoid the spread of the novel coronavirus (SARS-CoV-2), we are deeply concerned about the impact these measures might have on the availability of human donated plasma for manufacturing of PDMPs, and how certain measures such as export bans might affect the global supply chain and eventually also the availability of PDMPs.

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% of the plasma used for fractionation, while the commercial sector collects 38%[2]. However, only four European countries (Austria, Czech Republic, Germany, and Hungary) are able to contribute to the total of privately collected 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.

As further global spread of the Coronavirus is likely, more people will become ill and increased public health measures will be put in place to counteract the spread (for instance, restriction of movement/or quarantine). PPTA expects that this likely could lead to a decrease in global plasma availability. Lower donor availability, blood and plasma donor deferrals, donation centre staff actions (lower staff occupation), decreased access to donation centres (restriction to movement of both donor centre staff and donors) and the unavailability of devices, equipment, & goods will likely lead to a significant decrease in plasma collection globally.

Public blood collection services are urgently calling for blood donations to prevent shortages of blood supply, and as such also supply of plasma, due to the coronavirus[3]. In Italy on the other side, the National Blood Centre decided to suspend donations for 14 days from those who return from China, those who have been exposed to an infected person and those who have had the virus[4].

Presently, Europe is heavily and disproportionally reliant on plasma coming from the U.S and the four European countries (DE, AT, CZ, HU) as the majority of other countries have put in place restrictive policies for the private industry to collect plasma. Therefore, any decrease in plasma collection in the European plasma-contributing countries (which we are expecting due

[2] The Market Research Bureau, 2017 data

[3] Germany: https://www.blutspendedienst-west.de/magazin/gesundheit/ruhig-blut-blutspenden-zeiten-des-coronavirus-sars-cov-2; France: https://dondesang.efs.sante.fr/information-concernant-linfection-covid-19-coronavirus-sars-cov2-actualisation-13032020; United States: https://www.redcross.org/about-us/news-and-events/press-release/2020/red-cross-urges-healthy-individuals-to-give-blood-amid-coronavirus-concerns.html - http://www.aabb.org/advocacy/regulatorygovernment/Pages/Statement-on-Coronavirus-and-Blood-Donation.aspx

[4] Italy: https://www.centronazionalesangue.it/node/838

to the above-mentioned reasons) or an export ban of plasma from DE, AT, CZ, HU as well as the U.S will lead to a decreased availability of PDMPs for European patients who rely on these life-saving medicines.

Plasma protein therapies are manufactured by only a few companies in the world. This is because of the time, expertise and significant investment necessary to manufacture plasma protein therapies. While some plasma protein therapies may reach patients within 7 to 12 months from the time plasma is collected from a human donor, other products, 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 bans of intermediates and materials could bring effects much sooner.

We therefor strongly advise the Commission to utilize all its policy and legal tools to reaching that member state measures and decrees, which limit the movement of people, should expressly recognise medicines (including life-saving medicines such as PDMPs), starting materials such as plasma, medical devices, intermediate products and the logistics of those as essential to avoid a disruption in the global supply chain of medicines.

In addition, PPTA recommends to the European Commission, National ministries and competent authorities the urgent adoption of policies, such as an EU-wide contingency plan on the collection of plasma to ensure availability of PDMPs for patients in Europe. The recent evaluation of the European Blood Directive identified the presence of contingency planning in times of crisis as a shortcoming in many Member States. Further to this, PPTA recommends to the European Commission to provide support to both public and private sector actors to run crucially important, comprehensive plasma donation awareness campaigns.

PPTA respectfully asks the European Commission to acknowledge that national self-sufficiency measures, like those in place for the collection of blood for transfusion, cannot be applied likewise to the collection of plasma in order to mitigate the current shortfall in EU plasma collection and avoid any potential future shortfalls in plasma and PDMP supply for European patients. PPTA therefore asks that future European policies, at the Member State or EU level, should consider the important differences between blood and plasma collection as well as differences between transfusable blood products and PDMPs. Any measure or new policies addressing plasma collection should be both patient- and donor-centred, based on strong science, and focused on meeting the growing clinical need and the globality of the resource plasma. These policies should also promote coexistence by acknowledging the valuable contributions of both the public and private sectors to blood and plasma collection.

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

Respectfully,

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