Plasma Protein Therapeutics Association

16 April 2020 **BY E-MAIL**

Minister of Health - Adam Vojtěch
Deputy Minister of Health – Roman Prymula
Chief Hygienist of Czech Republic: Jarmila Rážová

SUBJECT: NATIONAL CONTINGENCY PLAN ON THE COLLECTION OF PLASMA AND BLOOD

Dear Minister Vojtěch,

The Plasma Protein Therapeutics Association (PPTA) wishes to ensure that you have considered the collection of blood and plasma (including convalescent plasma) to be essential activities during national COVID-19 outbreak contingency planning. In accordance to guidelines of the ECDC this would mean that plasma and blood collection centres are listed on the list of essential services; that national policies and guidance prioritise the supply of personal for collection centres; that there is communication to the general public about the need to regularly donate blood and plasma[1]. PPTA would like to encourage national authorities to step up on the two latter objectives.

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 Plasma Derived Medicinal Products (PDMPs) worldwide to treat a variety of rare and chronic and/or genetic diseases and serious, often life-threatening medical conditions[2]. For individuals with these conditions, PDMPs 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.

Over the past weeks PPTA collection centres have experienced that donation numbers have been decreasing due to the spread of the Coronavirus. Any decrease in plasma collection can lead to a decreased availability of PDMPs for patients in the future. The manufacturing of plasma protein therapies is a very complex and lengthy process. The production cycle lead time for PDMPs is between 7-12 months. This means that PDMPs may reach patients within 7 to 12 months from the time plasma is collected from a human donor. 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. To illustrate this: any decrease in plasma collection *today* will have an impact on decreased PDMP production output with a delay of ca 6-7 months.

[1] ECDC - *Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU/EEA* – 20 March 2020
[2] 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.

The European Center for Disease prevention and Control (ECDC) and the European Commission[3] have classified blood and plasma, along with other Substances of Human Origin, as essential. The ECDC guide specifically mentions that national policies and guidance should prioritise the supply of personal protective equipment (PPE), such as face masks, face shields, gloves and disinfectants for collection centres, considering that personal protective measures in the donation area of a SoHO establishment should not be as stringent as in settings where staff take care of infected or potentially infected patients. PPTA learned that some progress has been reached in the supply of such PPEs also to plasma collection centres, but there still are significant irregularities and bottlenecks in the supply. Whilst we acknowledge the challenges in obtaining supply of PPEs from the global market and while we agree that frontline healthcare workers should be supplied first, we would like to ensure that explicitly also blood and plasma collection centres are included in the priority list for receiving above identified PPEs to ensure continuity of operations.

Next to ensuring that our donors are safe with the use of PPEs, our centres have also taken other measures to reduce the spreading of Covid-19, as indicated in the ECDC guideline. The centres have introduced a variety of measures such as social distancing measures between donors, performing a temperature control checks prior to entering the facilities, the need to make appointment prior to donations, creating specific donor health questionnaires etc. We would therefor like to ask you to communicate to the general public and donor community about the need to regularly donate blood and plasma and the possibility of doing so during national COVID-19 outbreak contingency planning.

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

Respectfully,

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[3] European Commission note: *"COVID-19 and Substances of Human Origin Cross-Border shipments of SoHO as essential goods and services"*