

Via E-MAIL

**To: Federal Ministry of Social Affairs, Health, Care and Consumer Protection
Att. Mr. Rudolf Anschober, Minister of Health**

**cc. S7 Team
Federal Chancellery Vienna**

From: Karl Petrovsky, PPTA, Director Health Policy Europe

Brussels , 14 April 2020

Dear Minister Anschober, Ladies and Gentlemen in the crisis team,

The PPTA (Plasma Protein Therapeutics Association) represents the interests of the private manufacturers of plasma derived medicinal products and their recombinant analogues, as well as the private operators of plasma donation facilities, with a strong presence in Austria. After previous correspondence with the Ministry, PPTA addresses the following concerns:

Although important decisions have been made in both at European level and in Austria regarding the classification of plasma donation facilities as critical infrastructure, there is still cause for concern about the ability for continued plasma donation operations. This is of paramount importance for the continuity of the production of life-saving medicinal products made from human donor plasma, e.g. immunoglobulins, coagulation factors.

In this context, PPTA welcomes the express clarification of the Ministry in its letter dated March 30, 2020 that plasma donation facilities are part of the critical infrastructure and can remain open if certain safety measures are taken. PPTA requested this referring to the guidelines of the European Center for Diseases and Prevention Control (ECDC)¹, the EU Commission², the WHO, since 3 weeks ago almost all plasma centers were closed down as a consequence of the corona pandemic spread. The mentioned clarification by the Ministry meanwhile resulted in the fact that 11 of the 18 plasma centers have been reopened and the remaining ones hopefully going soon into operation.

As a consequence of the security measures taken by the Authorities, there is a significant decrease in plasma donations, which remain massively below the level before Covid 19 even after the centers re-opening. In addition, the plasma collection centers need sufficient protective equipment to ensure the safety of both, donors and personnel, but are currently facing considerable supply problems.

In order to bring the plasma donation volume at least to pre-Covid level as soon as possible, PPTA urges you, dear Minister and Coronavirus crisis team, to take all measures without delay to ensure:

- Priority access to adequate care for plasma donation centers includes:
 - Face shields
 - Mouth-nose masks, as well
 - Disposable gloves and disinfectants

- An explicit call from the Ministry and relevant institutions should be directed to the population on the need o for plasma donation, necessary than ever.

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

² EU Commission “*COVID-19 and Substances of Human Origin Cross-Border shipments of SoHO as essential goods and services*”

Giving course to the mentioned concerns represents a decisive contribution to ensuring continuity of the plasma application, because:

Continuous plasma application is fundamentally important for the complex and lengthy manufacturing process of plasma protein therapies, the duration of which is between 7 -12 months, from the time of the plasma donation to the finished PDMP. This means that sufficient plasma volumes for production / fractionation must be available at all times in order to maintain the production volumes. Any interruption in the plasma collection today impacts approx. 6-7 months later on a correspondingly reduced production output, with negative effects on the treatment of the patients whom urgently need these life-saving plasma protein therapies.

The mandatory anti-Covid 19 security measures , in particular the required compliance with the social distancing rules, have led to that the plasma donation centers only work upon scheduled donation appointments to avoid that plasma donors get too close in the waiting areas. Likewise, the distance rules also result in a reduction in donation places, so that fewer plasma donations can be carried out at the same time than before.

It should be noted, however, that the decline in plasma donations is not only determined by the reduction in donor places, but in particular also by the greatly reduced willingness to donate.

In addition, appropriately maintaining the plasma collection operations depend of course of the fact that donors and staff in the centers are adequately protected. The above-mentioned ECDC guideline explicitly states that plasma donation facilities should have priority access to the supply of personal protective equipment, such as face shields, masks, gloves, etc. (which expressly is not covering the special equipment required in hospital settings with Covid patients).

With regard to the call for plasma donations to the population, which has not yet taken place in Austria, PPTA refers to the ECDC guideline mentioned which recommends to the EU states to call the population to explicitly go for plasma donation. This is reinforced by specific actions in EU member states, such as in Germany the recent call by the Paul Ehrlich Institute and the Robert Koch Institute to the population to go also donating plasma as well as similar calls in France and Italy.

Finally, the application of convalescent plasma in plasma donation facilities, respectively the production of SARS-CoV-2 - hyperimmunoglobulins for the therapy of COVID-19 patients is only possible if the operation in the plasma donation facilities is maintained or possibly even intensified.

In conclusion, taking into account above arguments and being fully aware of the related challenges, PPTA urges you, dear Minister, Ladies and Gentlemen of the crisis team:

- to ensure the priority access of plasma donation facilities to purchasing protective equipment as soon as possible, and
- to issue an explicit call to the population to donate plasma as soon as possible.

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

Respectfully,

Karl Petrovsky
PPTA, Director Health Policy Europe