

8 April 2020

Per E-MAIL

**To: Federal Ministry of Health
Health Ministries of the Länder**

By: S.D.D., Senior Manager Government Affairs and Health Policy

**Subject: IMPORTANT - EXPERIENCE OF PLASMA FOR THE PRODUCTION OF PLASMA PREPARATIONS
DURING SARS-COV-2-PANDEMIE**

Ladies and gentlemen,

PPTA (Plasma Protein Therapeutics Association) Deutschland e.V. is the representative of the private manufacturers of plasmatic medicines and their recombinant analogues. It represents 5 member companies in Germany as well as more than 60 plasma donation centres.

Although some important decisions have been taken at both European and national level on the importance of blood and plasma donations and plasma preparations, there is still serious concern about maintaining the supply of plasma preparations derived from human donor plasma, such as immunoglobulins and coagulating factors.

The World Health Organisation (WHO), the European Centre for Disease Prevention and Control (ECDC) and the European Commission's Directorate-General for Health and Food Safety (DG Santé) have identified plasma for transfusion and plasma for the production of medicinal products as relevant for supply. This ensures, on the one hand, the necessary transport of these goods within Europe and, on the other hand, means that both blood and plasma donation centres and facilities for the production of plasma iced medicinal products must be classified as relevant for supply.

In Germany, the Robert Koch Institute (RKI), the Paul-Ehrlich-Institut (PEI) and the Federal Centre for Health Education (BzgA) have published a joint call to continue to donate blood and plasma.

The increasingly intense media coverage of convalescent plasma for the treatment of COVID-19 sufferers is also likely to contribute to an increase in public awareness of plasma donation.

However, plasma donation centres are struggling with limitations that prevent the number of plasma donations from being kept at the pre-pandemic level:

The necessary safety measures, in particular the necessary compliance with the distance rules, mean that the plasma donation centres only work on appointments in order to prevent plasma donors from getting too close in the waiting areas.

These distance rules also result in a reduction in the number of donation places, so that fewer plasma donations can be made at the same time than before.

In addition, the operation can only be maintained in a self-contained manner if donors and staff in the centres are adequately protected.

From our point of view, the supply of protective equipment such as disinfectants, protective swearing, disposable gloves and mouth-nose protective masks is particularly critical to the plasma donation centers!

A possible obligation to wear protective masks in public, including for the general population, will exacerbate the difficult supply situation with protective equipment.

We therefore urge you to take measures to ensure that the blood and plasma donation centres are supplied with safety equipment, e.g. by giving blood and plasma donation facilities as well as clinics the highest priority in the supply of protective equipment!

At present, the supply of essential plasma preparations to patients is not at risk. However, if the expected decline in the number of plasma donations cannot be compensated by rapid measures, supply bottlenecks can occur in 7 to 12 months due to the long lead time in the production of e.g. immunoglobulins!

This would be very problematic especially at this time, when patients who rely on plasma preparations are among the most vulnerable at risk. COVID-19, especially those with a congenital immunodeficiency that means that patients without immunoglobulin preparations do not have sufficient protection against infection!

Last but not least, the production of convalescent plasma or SARS-CoV-2 – hyperimmunoglobulins for the treatment of COVID-19 patients is only possible if the operation can be maintained or possibly even intensified in the plasma dispensing facilities required for this purpose.

PPTA Germany is always available for an interview or questions.

With kind greetings



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