

Opinion on the draft of the

Ordinance to ensure the supply of medical products to the population in the epidemic caused by the coronavirus SARS-CoV-2

(Medical Needs Supply Security Ordinance-MedBVSV)

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.

Below are our comments and suggestions to complement the draft:

2 Procurement and submission by federal authorities

Here, the procurement process by the Federal Government or the bodies commissioned by the Confederation (Section 2 paragraph 1) is not explicitly described here. Unfortunately, it remains unclear who the "commissioned bodies" will be and how the procurement will take place.

3 Exceptions to the Medicines Act and the Medicines Trade Ordinance for procurement and distribution in accordance with Section 2

Since the provisions of the Drug Price Ordinance are not to apply in accordance with Section 3 (1), we assume that price negotiations will take place in the event of contact by the authorised authorities, also in view of the fact that no obligation on the part of the manufacturers is required to pay.

In this context, we would like to point out that the availability of medicines that could be considered is already limited. Plasma preparations manufactured by our member companies have a significant part of the contractual obligations that must be met in order to be able to treat chronic patients in approved indications. The care of these patients must not be jeopardised under any circumstances.

Section 5 Exceptions to the Transfusion Act

We expressly welcome the flexibilisations described in Section 5 paragraph 1, which can certainly help to ensure a necessary level of blood and plasma donation.

In our view, however, this will not be enough and propose a further measure to keep the number of plasma donations as close as possible to the pre-pandemic level at the moment under the conditions of the Corona pandemic.

As already described elsewhere, the necessary safety measures, in particular the necessary compliance with the distance rules, lead to work in the plasma donation centres only 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.

We currently see a decrease in donations compared to the previous year. As the pandemic progresses, we have to assume that the normal donation process will be reduced by about 30%-50%, especially due to the reduced number of donation places in the donation centres, as fewer donations can be accepted than usual.

A countermeasure to ensure the long-term supply of plasma for the production of plasma preparations would be to extend the opening hours of plasma donation centres.

In order for longer opening hours to be introduced in the donation centers, however, aber more staff is needed, especially the presence of a doctor is required.. It is difficult to find sufficient medical staff even under normal conditions. An extension of the opening hours is therefore precluded by Section 4 paragraph 3 of the Transfusion Act, which requires the presence of a medical person when making the donation. As a result, due to acute shortages of doctors in donation centres, infolgedessen opening hours cannot be extended as desirable.

One possible solution could be to allow donation centers for a limited time to allow well-known, medically well-managed and controlled permanent donors whose last donation is no more than 2 to 4 weeks ago, to allow a donation appointment even at times when no doctor is present in the center. And this only if the medical person connected to the centre or the senior medical person is available in the background for any queries. The suitability for donation would be determined here by qualified members of the senior health and nursing service on the basis of an anamnesis sheet and collection of vital parameters according to strictly standardized requirements according to RiLiBÄK.

We would like to emphasize explicitly that this deviation should only be limited to already registered and pre-examined plasma donors, which come to a subsequent donation or regular donation. For first-time donors or donors of COVID-19 convalescent plasma, personal medical supervision and control remains indispensable!