Plasma Protein Therapeutics Association

Date: 23 July 2020
By email

To:

Stella Kyriakides	**European Commissioner, Health and Food Safety**
Andrzej Rys	**Director for health systems, medical products and innovation**
Sylvain Giraud	**Head of Unit, European Commission, DG SANTE, Dir. B4**
Agnes Mathieu-Mendes	**Deputy Head of Unit, European Commission, DG SANTE, Dir. B4**
Stefaan Van der Spiegel	**Head of Sector, European Commission, DG SANTE, Dir. B4**

From: Maarten Van Baelen, Executive Director Europe, PPTA

SUBJECT: Use of the EU Emergency Support Instrument for the collection of COVID-19 convalescent plasma.

Dear Ms Kyriakides,

We thank the European Commission for considering setting up an Emergency Support Instrument with the purpose of increasing the collection of COVID-19 convalescent plasma (CPP) to address the acute phase of the COVID-19 pandemic. The therapeutic use of plasma during the current pandemic highlights once more the importance of strengthening the infrastructure needed to collect more plasma in Europe and the growing clinical need for treatment with plasma-derived medicinal products.

Convalescent plasma is usable for transfusion purposes to treat acute medical conditions, but can also be used for the development of specific, licensed medicinal products, namely hyperimmune immunoglobulins which can be used both curatively and preventatively. Hyperimmune immunoglobulins for the treatment of COVID-19 contain a high content of anti-SARS-CoV-2 antibodies if manufactured from plasma collected from donors recovered from COVID-19.

Convalescent plasma collected from various donors is not a standardized product: the levels of SARS-CoV-2 specific antibodies in the product vary from donor-to-donor and the levels of other plasma proteins vary as well. Hyperimmune immunoglobulins on the other side are manufactured from pooled plasma from a large number of donors (100-1000) under highly controlled condition resulting in highly purified Ig product with consistent antibody levels from vial-to-vial.

PPTA member companies and their partners are currently investing significant resources in the development and manufacturing of COVID-19-specific hyperimmune immunoglobulins from

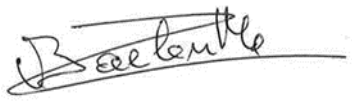
COVID-19 convalescent plasma[1]. In the medium- and long-term this therapy represent a promising treatment option against COVID-19. The supply of convalescent plasma is critical to develop COVID-19-specific hyperimmune immunoglobulin. In the current situation the Member States shall focus on securing sufficient supply of COVID-19 convalescent plasma but furthermore it will be essential to allow producers of plasma-derived medicinal products to collect normal source plasma in all Member States and not only in Austria, Czech Republic, Germany and Hungary. That will reduce the dependency from the USA , also with regard to Covid-19 convalescent plasma.

The collection of plasma for manufacturing of plasma-derived medicinal products for licensure in the European Union requires significant expertise. Due to the complexity of sourcing, manufacturing as well as regulatory requirements the majority of source plasma (plasma collected through plasmapheresis) in Europe today is collected by the private sector. PPTA and EPA are representing this sector and our members are open for sharing their expertise in this field.

Provided that the COVID-19 convalescent plasma is collected appropriately, in compliance with industry standards[i],[ii] and the regulatory requirements in the European Union[iii,iv,v,vi,vii,viii,ix,x,xi,xii] the plasma collected by the public sector, with the purpose of using it for transfusion, can also be used to produce COVID-19-specific hyperimmune immunoglobulins, as well as human normal immunoglobulin products used to treat patients with immunodeficiencies.

In conclusion, PPTA members are open to provide support to increase the collection of convalescent plasma in Europe and to ensure that the collected plasma can also be used to manufacture life-saving plasma-derived medicines, including normal human and hyperimmune immunoglobulins, for patients who rely on them. In addition, we are eager learn about, and provide further input in the future on, the details and conditions of this European Support Instrument.

Respectfully,



Maarten Van Baelen

Executive Director, PPTA Europe

MVanBaelen@pptaglobal.org

[1] https://www.grifols.com/en/view-news/-/news/grifols-continues-to-lead-initiatives-to-combat-covid-19-with-the-development-of-the-first-specific-drug; https://www.kedrion.com/coronavirus-plasma-anti-covid-19-treatment; https://www.takeda.com/covid-19-information-center/covig-19-plasma-alliance/

Annex:

[i] IQPP PPTA standards - http://www.pptaglobal.org/safety-quality/standards/iqpp
[ii] QSEAL PPTA standards - http://www.pptaglobal.org/safety-quality/standards/qseal
[iii] Guideline on plasma-derived medicinal products/ EMA/CHMP/BWP/706271/2010/ 21 July 2018.
[iv] DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use.
[v] DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.
[vi] EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines, Annex 14: Manufacture of Medicinal Products Derived from Human Blood or Plasma. 2011.
Medicinal Products Derived From Human Blood and Human Plasma – Product Specific Guidelines European Pharmacopoeia (Ph. Eur.):
[vii] Monograph 0853 “Human Plasma for Fractionation” of current Ph. Eur.
[viii] Human normal immunoglobulin for intramuscular administration (0338) of current Ph. Eur.
[ix] Human normal immunoglobulin for subcutaneous administration (2788) of current Ph. Eur.
[x] Human normal immunoglobulin for intravenous administration (0918) of current Ph. Eur.
[xi] Technical guide for the ELABORATION AND USE OF MONOGRAPHS AND GENERAL CHAPTERS ON HUMAN PLASMA DERIVED PRODUCTS. Ph. Eur. (2015).