

## PPTA and IPFA request staff of Blood establishments to be included in priority groups for COVID-19 vaccination

Plasma-derived medicinal products (PDMPs) are medicinal products manufactured from human plasma donated by healthy donors. PDMPs are essential for around 300,000 European patients who rely on these essential medicines<sup>1</sup> to treat a variety of rare, chronic, and potentially life-threatening conditions, which are often genetic in origin.<sup>2</sup> Without these treatments, many patients would either not be able to survive or would have a substantially diminished quality of life.

The Plasma Protein Therapeutics Association (PPTA) and the International Plasma Fractionation Association (IPFA) are requesting European Union Member States to include staff of blood establishments as priority groups for COVID-19 vaccination, especially those who are in close contact with donors, when making priority decisions for vaccination campaigns. This staff is critical to the functioning of blood establishments and should also be considered as essential health care workers who are at an increased risk of being infected.

### Background

The European Commission's recent publication on "*Preparedness for COVID-19 vaccination strategies and vaccine deployment*" as well as the "*WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*" encourage and support countries in developing a roadmap for public health strategies and recommend to target priority groups for COVID-19 vaccination, given that different levels of vaccine availability and epidemiologic settings in various countries are expected.

### COVID-19 and critical substances of human origin (SoHo)

In context of the COVID-19 pandemic, the European Centre for Disease Control and Prevention (ECDC) defines blood and blood components as "critical" Substances of Human Origin (SoHO) and plasma for the manufacturing of medicinal products is considered an "essential" SoHO. In the most recent version of the relevant ECDC publication, "*Coronavirus disease - 2019 (COVID-19) and supply of substances of human origin in EU/EEA*", the potential exposure of blood establishment staff to the novel coronavirus (SARS-CoV-2) has been acknowledged. The blood/ plasma donation procedure requires some blood/ plasma centre staff to be in close contact with the donor.

### COVID-19 affects plasma collections

Plasma can be obtained from whole blood donations (resulting in recovered plasma) or collected directly through a process called plasmapheresis (resulting in source plasma). COVID-19 poses a risk to sufficiency and availability of blood and plasma by reducing donor availability, the capacity of the collection establishment to accommodate donors due to physical distancing measures, affecting staff

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<sup>1</sup> WHO model list of essential medicines - 21st list, 2019 -

<https://www.who.int/publications/i/item/WHOMVPEMPIAU2019.06>

<sup>2</sup> More patients across the European Union are diagnosed every year with life-threatening plasma protein related disorders, such as immune deficiencies, immune-mediated peripheral neuropathies, Hereditary Angioedema, Alpha 1-Antitrypsin Deficiencies, Hemophilia and other bleeding disorders. In many cases, PDMPs are the only treatment option for these rare diseases. PDMPs are also widely used in hospital intensive care of critically ill patients. 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.

at blood and plasma collection centres, changing the demand for blood and blood components, and limiting the provision or distribution of critical materials and equipment required for blood establishments.<sup>3</sup>

Most countries in the European Union have experienced a marked decline in the number of blood and plasma donations due to COVID-19. Donors could not donate because they have been infected, have been quarantined due to exposure to a confirmed case or were practising recommended physical distancing. Other factors resulting in decreasing the number of donors in the EU are COVID-19-related restrictions in public transportation, impact on work commitments, the need to care for family members (through for instance closure of schools and/ or childcare facilities) or a reluctance to donate due to fear of being infected.<sup>4</sup>

Considering that manufacturing of plasma-derived therapies is complex and can take up to seven to 12 months, any decline in plasma donations could negatively impact EU patients' ability to access their lifesaving therapies.<sup>5,6</sup> There is a risk that the current decline in plasma collections could cause significant supply and access challenges in the months to come.

### About PPTA

The Plasma Protein Therapeutics Association (PPTA – [www.pptaglobal.org](http://www.pptaglobal.org)), a global industry trade association, represents the private sector manufacturers of PDMPs and recombinant analogue therapies, collectively known as plasma protein therapies (PPTs), and the collectors of source plasma used for fractionation. PPTA's global members include Biotest, BioProducts Laboratory Ltd., CSL Behring, Grifols, Kedrion, and Takeda. Millions of people use PPTs worldwide to treat a variety of diseases and serious medical conditions. PPTA also administers standards and programs that help ensure the quality and safety of PPTs, donors, and patients.

### About IPFA

The International Plasma and Fractionation Association (IPFA) is an international association for not-for-profit plasma fractionators and national blood services. IPFA supports the activities of its member organisations in their goal to ensure and sustain reliable access to lifesaving plasma-derived medical products in their communities and to be their recognised international advocate. The activities of IPFA and its members are built on the commitment and generosity of donors and accordingly advocate policies for recruitment and incentives which avoid their exploitation. As an umbrella association, IPFA represents its members in negotiations and meetings with competent authorities, medicines agencies, regulatory agencies, political officials, patient organisations, donor associations, commercial counter parts, and other interested parties in the field. IPFA arranges scientific and educational events and workshops related to the field of plasma donation and fractionation.

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<sup>3</sup> ECDC - Coronavirus disease - 2019 (COVID-19) and supply of substances of human origin in EU/EEA – More info here: <https://www.ecdc.europa.eu/en/publications-data/coronavirus-disease-2019-covid-19-and-supply-substances-human-origin>

<sup>4</sup> Wang Y, Han W, Pan L, Wang C, Liu Y, Hu W, et al. Impact of COVID-19 on blood centres in Zhejiang province China. *Vox Sang.* 2020 Aug;115(6):502-6.

<sup>5</sup> Hartmann J, Klein HG, "Supply and demand for plasma-derived medicinal products - A critical reassessment amid the COVID-19 pandemic." *Transfusion.* 2020 Aug 28;10.1111/trf.16078. doi: 10.1111/trf.16078.

<sup>6</sup> Prevot J, Jolles S, "Global immunoglobulin supply: steaming toward the iceberg?" *Curr Opin Allergy Clin Immunol.* 2020, 20:000–000 DOI:10.1097/ACI.0000000000000696