

ANNEX

References

- 1 WHO Action framework to advance universal access to safe, effective and quality assured blood products <https://apps.who.int/iris/rest/bitstreams/1269101/retrieve> Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells <https://eur-lex.europa.eu/eli/dir/2004/23/oj> DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:033:0030:0040:EN:PDF>
- 2 Statista 2021 <https://www.statista.com/statistics/1055411/plasma-collection-centres-in-the-eu/>;
- 3 The Economist Vein attempts, 2018.
- 4 Europe needs to collect more plasma – PPTA Position paper 2019 https://www.pptaglobal.org/images/patientaccess/eu/EU_Position_paper_Europe_needs_to_collect_more_plasma.pdf
- 5 Compensation can be considered as a voluntary unpaid donation. It is conceptually recognised as such by analogy in the EU Tissue and Cells Directive, it is reflected in the EU Commission Report on implementation of VUD Principle, and it is recognised by the Council of Europe Committee on Bioethics. In addition, different types of incentives and compensation are used by the public sector as well for the collection of whole blood. The Market Research Bureau, collection data of 2017; Statement from the European Commission “Coronavirus: European Commission strengthens support for treatment through convalescent plasma”. More info here: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1435 MRB Report data 2019; EU Directive 2002/98/EC; EU Directive 2004/23/EC (article 12); EU Commission staff working document 2016 on implementation of VUD principle in EU member States; Committee on Bioethics (DH-BIO) - Guide for the implementation of the Principle of Prohibition of Financial Gain with respect to the human body and its parts, as such, from living or deceased donors (article 23, 24) More information: Commission staff working document on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution, 2016. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0130&qid=1616462768503&from=EN>
- 6 Professors Macis & Lacetera, Johns Hopkins University and the University of Toronto (The Source Winter Issue, 2017)
- 7 Reported by countries in the EC 2nd Report on Voluntary and Unpaid Donation of Blood and Blood Components https://ec.europa.eu/health/sites/health/files/blood_tissues_or_gans/docs/blood_reportdonationen.pdf
- 8 Requirement of Hungary National Blood Service (OVSZ): Government Decree No. 439/2015 (XII. 28.) §10 (1a) on the rules of the management of the national blood stock.
- 9 https://www.vintura.com/wp-content/uploads/2020/03/White-paper-key-economic-and-value-considerations-for-plasma-derived-medicinal-products-PDMPs-in-Europe_Vintura-and-PPTA.pdf * Vintura analysis. Manning R and Grabowski H: Key economic and value considerations in the U.S. market for plasma protein therapies. 2018. Available online: <https://www.bateswhite.com/newsroom-insight-197.html> Bonilla FA et al: International Consensus Document (ICON): Common Variable Immunodeficiency Disorders. J Allergy Clin Immunol Pract. 2016 Jan-Feb;4(1):38-59. Mejia-Carvajal C et al: Life expectancy in haemophilia outcome. J Thromb Haemost. 2006 Mar;4(3):507-9. Manco-Johnson MJ et al: Prophylaxis versus Episodic Treatment to Prevent Joint Disease in Boys with Severe Haemophilia. N Engl J Med. 2007 Aug 9;357(6):535-44. Routes J et al: Health-related quality of life and health resource utilization in patients with primary immunodeficiency disease prior to and following 12 months of immunoglobulin G treatment. J Clin Immunol. 2016 Jul;36(5):450-61.
- 10 Gelfand EW: Differences between IVIG products: Impact on clinical outcome. Int Immunopharmacol. 2006 Apr;6(4):592-9. 29. Clarke AE et al: Immunoglobulin Therapy Standards of Practice: Clinical Guidelines and Implementation. IgNS, June 1 2018. Available online: http://cmezone.net/Activities/3461/pdf/CMEZone_Activity_3461.pdf. Key Economic and Value Considerations for Plasma-Derived Medicinal Products (PDMPs) in Europe, Tomasz Kluszczynski, Silvia Rohr, Rianne Ernst; Vintura, Plasma Protein Therapeutics Association (PPTA)
- 11 The UK has banned locally-sourced plasma, relying exclusively on imports since 1998. The NHS Blood and Transplant service collects 350,000 litres of plasma yearly as part of whole blood donations for hospitals. Some 100,000 is used for transfusion and the remaining 250,000 was discarded or not used to manufacture medicines. Following the decision to lift the ban in February 2021, the whole blood donations from donors will be used the plasma from whole blood donations to also make medicines for patient care.
- 12 <https://ec.europa.eu/transparency/regdoc/rep/1/2016/EN/1-2016-224-EN-F1-1.PDF>
- 13 Dr. Franz Weinauer, Medical Director Blood Donation Service of the Bavarian Red Cross (The Source Fall 2018)
- 14 EU Directive 2002/98/EC on quality and safety standards for collecting, testing, processing, storage and distribution of human blood and blood components.
- 15 <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52016SC0130>
- 16 Commission staff working document on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution, 2016. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0130&qid=1616462768503&from=EN>
- 17 Principle of prohibition of financial gain laid down in Article 21 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: the Convention on Human Rights and Biomedicine (ETS No. 164; the Oviedo Convention), as well as in its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (CETS No. 186). Council of Europe Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors. <https://www.coe.int/en/web/bioethics/guide-financial-gain>
- 18 Paragraph 17, Convention on Human Rights and Biomedicine (Oviedo Convention)
- 19 Human bodies: donation for medicine and research; Nuffield Council on Bioethics (2012). https://www.nuffieldbioethics.org/wp-content/uploads/HumanBodies_report_developments_web.pdf
- 20 Paragraph 20, Convention on Human Rights and Biomedicine (Oviedo Convention)
- 21 Paragraph 23, Convention on Human Rights and Biomedicine (Oviedo Convention)
- 22 paragraph 24, Convention on Human Rights and Biomedicine (Oviedo Convention)
- 23 Paragraph 25 Convention on Human Rights and Biomedicine (Oviedo Convention)
- 24 Article 12, Directive 2004/23/EC on the safety and quality of tissues and cells. EU Blood Directive (2002/98/EC)
- 25 CPMP (EMA) Position Statement: 'Non-remunerated and remunerated donors: Safety and Supply of PDMPs' (2002); SIPLA 1 study: Average IgG was found to be significantly lower in after end
- 26 Plasma Protein Therapeutics Association, Data collection Studies 2016; 2018.
- 27 https://www.bundesaeztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/MuE/Richtlinie_Haemotherapie_E_A_2019.pdf
- 28 Burkhardt et. al (2015): donor vigilance data shows that both whole blood and plasmapheresis donations are safe with low incidences of adverse events (LINK: <https://pubmed.ncbi.nlm.nih.gov/26074050/>)
- 29 <https://doi.org/10.1016/j.cpm.2013.08.001>
- 30 Executive Order - National Defense Resources Preparedness, 16 March 2012 Part II, Section 201 (a), specifically sub a and Part VIII, General Provisions, section 801, sub (i) October 2016 into practice for health resources to deal with a major crisis in the US.
- 31 On August 23, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19, pursuant to Section 564 of the Act.3. On November 30, 2020, the FDA reissued the August 23, 2020, Letter of Authorization to add a test acceptable to be used in the manufacture of COVID-19 convalescent plasma.
- 32 Convalescent Plasma EUA letter of Authorization, March 19, 2021: The 2021 Authorization specifies the use of 'high tier' COVID-19 convalescent plasma to treat hospitalized COVID-19 patients, early in the course of the disease, and those hospitalized with impaired humoral immunity. The decision is based on evidence from ongoing clinical and randomized control trials on COVID-19 convalescent plasma, and trial results from studies of other medical products to treat COVID-19. <https://www.fda.gov/media/141477/download>