The International Plasma and Fractionation Association

The supply of plasma-derived medicinal products in the future of Europe

28-29 April 2022 – Rome, Italy

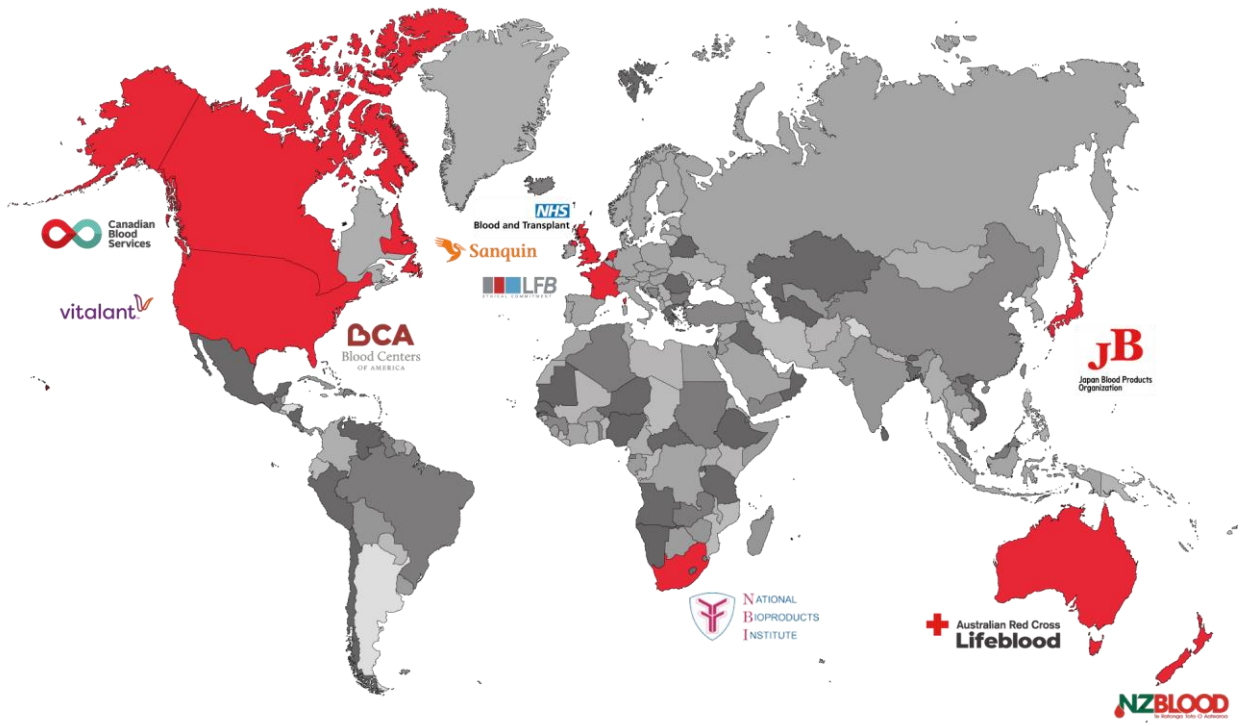
in collaboration with

Leni von Bonsdorff, Executive Director, IPFA

IPFA, our mission

IPFA supports and promotes the activities of not-for-profit organisations around the globe engaged in the collection and fractionation of plasma to enable robust, safe supply and patient access to plasma derived medicines.

Through education and collaboration with stakeholders, we advocate for public health values and donor health protection.



IPFA, our vision

IPFA's goal is for plasma to be acknowledged as a strategic resource within public health care systems, underpinned by a safe and reliable contribution from the not-for-profit sector.

IPFA will continue to show leadership in this field and bring expertise to reach this goal.

IPFA, our objectives

Public health impact

- To strengthen the role of the public blood establishments in collection of plasma
- Help countries and regions to gain high level of strategic independence for plasma and plasma-derived medicines
- Explain the value of plasma as part of the public health systems and its impact in balancing the expenditure of plasma-derived medicines
- Use science and education to increase knowledge and understanding of this specific field, and continue to arrange high-quality workshops on dedicated topics like screening and surveillance of blood-borne pathogens

Membership & stakeholder engagement

- Work closely with members and other stakeholders
- Communicate, cooperate and build strong networks in the field

IPFA, our objectives

Support for developing countries

- Actively support developing countries to improve their access to plasma- derived products using their own quality approved plasma
- Arrange education and training on our own and in collaboration with other stakeholders.

Regulatory Liaison & Legislative Advocacy

- Establish or maintain stable relationships/connections to relevant regulatory bodies and competent authorities
- Actively advocate and promote on legislative and regulatory measures to support our members´ goals and interests
- Collaborate with other stakeholders on items of mutual interest to increase impact

Who we work with

National competent authorities, Medicinal agencies & Governmental bodies

US Food and Drug Administration (FDA), European commission (EC), US Food and Drug Administration (FDA), UK MHRA, European Directorate for the Quality of Medicines (EDQM) of Council of Europe, ECDC, European Medicines Agency (EMA) , Paul-Ehrlich-Institut (PEI), World Health Organisation (WHO) and others

Scientific community and experts

Experts in blood-born pathogen safety, Experts in good manufacturing practicses (GMP) for manufacturing, Experts in plasma manufacturing technology

Individuals and other organisations with an interest in the field

international plasma and fractionation association

MEMBERS FROM THE NOT-FOR-PROFIT SECTOR

>> Fractionators <<

>> Blood establishments <<

(plasma collection)

Blood, donor and patient organizations and associations

European Blood Alliance (EBA), International Society of Blood transfusion (ISBT), International Federation of Blood Donor Organisations (FIODS), International Patients' Organisation of Primary Immunodeficiencies (IPOPI), Platform of Plasma Protein Users (PLUS), World Federation of Hemophilia (WFH), Arab Transfusion Medicine Forum (ATMF), African Society of Blood Transfusion (AfSBT), Alliance of Blood operators (ABO) and others

Companies and commercial associations

Plasma Products Therapeutic association PPTA, Companies in blood and plasma diagnostics, Companies in blood and plasma manufacturing technology

IPFA members 2022

Australian Red Cross Lifeblood

Australia

Blood Centers of America (BCA)

United States of America

Canadian Blood Services

Canada

Japan Blood Products Organization

Japan

LFB Biomédicaments

France

National Bioproducts Institute

South Africa

NHS Blood and Transplant (NHSBT)

United Kingdom

New Zealand Blood Service

New Zealand

Sanquin

The Netherlands

Vitalant

PLASMA SUPPLY AND PLASMA-DERIVED MEDICINAL PRODUCTS MANUFACTURING

Plasma collection during the pandemic among IPFA members

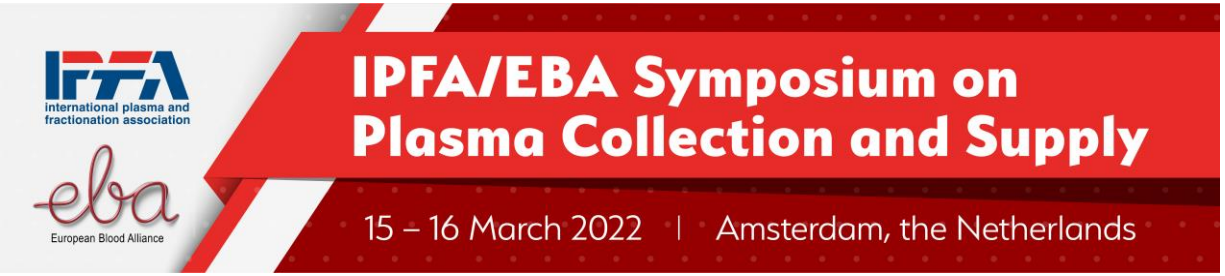
- No major decreases in overall plasma collection*
- Some have even been able to increase their collection, both for recovered and source plasma
- Others say that they have not been able to increase plasma collection as much as hoped for, even though the basic need for blood components has been secured and maintained.
- Donor access has in general been good, and the major challenge has been in securing the staff employment base during restrictions and due to vaccination mandates
- Challenges with the omicron wave

*compare with plasma collection -14% globally 2019->2020 of which
-18% North America
-9% Europe
-7% Asia and Pacific

IPFA

Focus Europe, what do we do?

- BTC directive revision
- Support for UK joining the plasma field after the ban on plasma lifted
- Participation in application for upcoming EU4health SUPPLY project to increase plasma collection of the public sector



IPFA/PEI 28th International Workshop on Surveillance and Screening of Blood-borne Pathogens

21 & 22 September 2022 | Porto, Portugal

European BTC directive revision

IPFA recommendations

1. **Plasma is a substance of human origin and belongs to the BTC legislative framework**
2. **Security of supply of human plasma for fractionation – strategic independence**
3. **Donor health and its protection, ethical considerations concerning donations**
4. Harmonisation and coherence is needed
5. Structure should allow quick adaptation. Technical requirements – need for regular updates

1. Plasma is a substance of human origin and belongs to the BTC legislative framework

1. **Plasma** is a **substance of human origin** and should as such be goverened by the provisions of all such substances, and therefore **remain governed within the revised directive**

   Plasma for fractionation needs a better definition and a specific status as raw material for industrial purposes. IPFA proposes: "plasma recovered from whole blood as well as plasma collected by apheresis (also named source plasma), and used as starting material for manufacturing of plasma derived medicinal products"

2. Security of supply of human plasma for fractionation – strategic independence

1. The EU blood directive should address the **security of supply of human plasma for fractionation**, and strive for a strategic independence of this raw material to mitigate risk related to dependency on supply from single countries and regions
2. The **contribution of the voluntary non-remunerated blood donation principle for plasma collection**, as carried out by the public sector like the blood establishments, should continue to form the sustainable cornerstone for the supply of plasma for fractionation
3. The **plasma collected by the public sector serves the interest of the public health in EU** by securing the plasma needed to produce the life-saving plasma derived medicinal products, and should therefore be supported

3. Donor health and its protection, ethical considerations concerning donations

1. The **health of the donor** always need to be protected. For both blood and plasma donors, so the main principles for ensuring this and the **heamovigilance/donor vigilance** should cover all donors and be better defined on EU level and developed.
2. The **definition regarding the voluntary non-remunerated blood donation (VNRBD)** should be defined better and in accordance with the Nuffield Scale on altruistic focused donations.
    - **Any incentives resulting in financial gain should be prohibited** because blood is not a commodity to be sold and donors should not become financially dependent
    - Donation promotion campaigns should be distinguished from advertising on financial gain

Thank you!

For more information about IPFA, please visit our website: www.ipfa.nl or send an email to info@ipfa.nl