

Rémunération / compensation du don de plasma en Europe

Remuneration / compensation of plasma donation in Europe

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Rémunération des donneurs de plasma humain



Le 8^e forum de biovigilance a pour thème la rémunération des donneurs de plasma humain.
L'événement est organisé par le Comité de biovigilance en collaboration avec le ministère de la Santé et des Services sociaux et Héma-Québec.



European Union - Blood directives



Directive 2002/98/EC – quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components

WHAT DOES THE DIRECTIVE DO?

- It lays down quality and safety standards for human blood and its components to ensure a high level of health protection.
- It covers blood collection and testing and its processing, storage and distribution when used in transfusions.

KEY POINTS

EU countries must ensure that:

- blood is collected and tested only by designated, authorized, accredited or licensed establishments with suitably qualified personnel
-
- the necessary measures are taken to **encourage voluntary and unpaid blood donations.**
-

WHEN DID THE DIRECTIVE APPLY?

It entered into force on 8 February 2003. EU countries had to incorporate it in their national law by 8 February 2005.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:c11565>

Voluntary and unpaid blood donations are a factor which can contribute to **high safety standards** for blood and blood components and therefore to **the protection of human health**. The efforts of the Council of Europe in this area should be supported and all necessary measures should be taken to **encourage voluntary and unpaid donations** through appropriate measures and initiatives and through ensuring that donors gain **greater public recognition**, thereby also **increasing self-sufficiency**. The definition of voluntary and unpaid donation of the Council of Europe should be taken into account.

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Logotype du Conseil de l'Europe.



Council of Europe / Conseil de l'Europe

Le **Conseil de l'Europe (CdE)** ; en anglais : *Council of Europe, CoE*) est une organisation intergouvernementale instituée le 5 mai 1949 par le [traité de Londres](#). Il constitue une [organisation internationale](#) qui rassemble environ 675 millions² de ressortissants de 46 États membres, par le biais des [normes](#) juridiques dans les domaines de la protection des [droits de l'homme](#), du renforcement de la [démocratie](#) et de la [prééminence du droit en Europe](#). Le Conseil de l'Europe est doté d'une [personnalité juridique](#) reconnue en [droit international public](#).

Conseil de l'Europe / Council of Europe: organisation intergouvernementale indépendant de l'Union Européenne

Institutions de l'Union Européenne (UE):

- **Conseil Européen / European Council:** institution de l'UE qui réunit les chefs d'Etats ou chefs de de gouvernement des 27 Etats membres pour définir les orientations et priorités stratégiques de l'UE
- **Conseil de l'Union Européenne / Council of the European Union:** institution qui réunit les ministres des Etats membres pour adopter les législations (conjointement avec le Parlement Européen, organisation bicamérale) et coordonner les politiques de l'UE
- **Parlement Européen / European Parliament:** représente les citoyens de l'UE
- **Commission Européenne: / European Commission:** organe exécutif de l'UE



Le don de sang, de plasma ou de composants cellulaires est considéré comme **volontaire et non rémunéré** lorsqu'il est fait par une personne **de son plein gré** et qu'il ne donne lieu à **aucun paiement** en espèce ou toute autre forme équivalente. Il en serait ainsi de l'octroi d'un congé compensatoire qui dépasserait le temps raisonnablement nécessaire pour le don et le déplacement. De modestes marques de reconnaissance, des rafraîchissements et le remboursement des frais liés au don sont compatibles avec le don volontaire et non rémunéré

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Council of Europe, Committee of Ministers, Recommendation No. R (95) 14 on the protection of health of donors and recipients in the area of blood transfusion, 1995

membres pour définir les orientations et priorités stratégiques de l'UE

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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

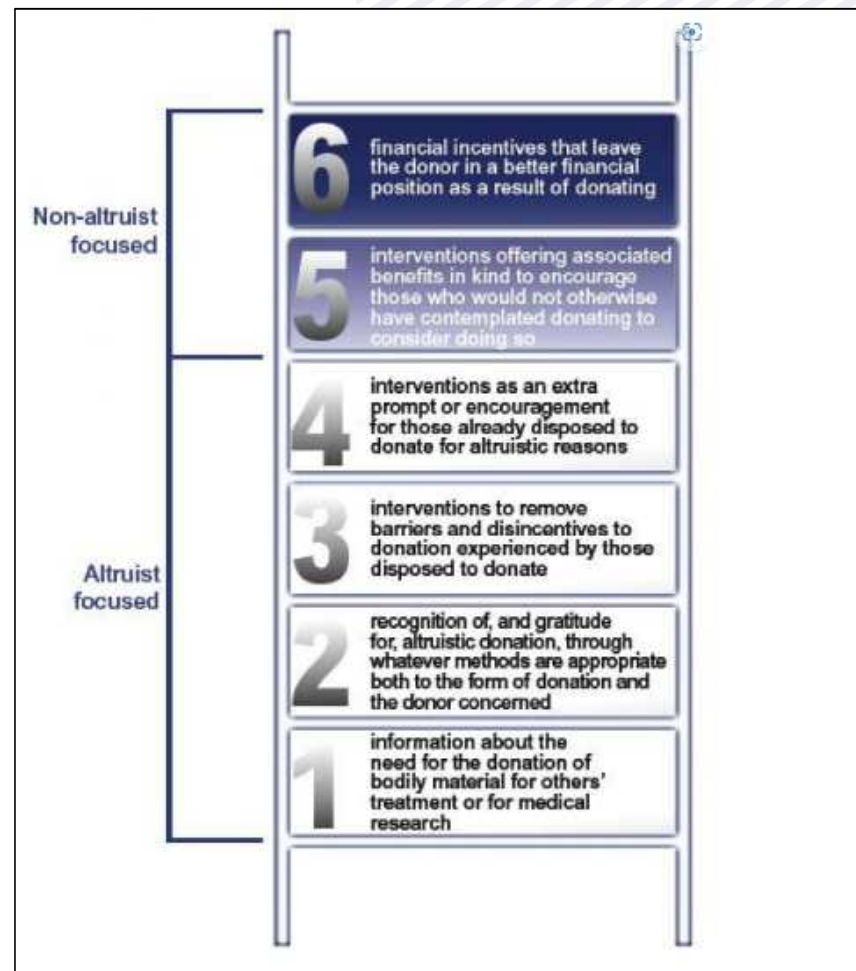


Principle of financial neutrality to define an altruist - focused donation
Principe de neutralité financière pour définir un don guidé par l'altruisme



The Nuffield Council on Bioethics is an independent body that examines and advises on ethical issues arising from developments in bioscience and health.

It was established by the Trustees of the Nuffield Foundation in 1991, and since 1994 it has been funded jointly by the Foundation, Wellcome and the Medical Research Council.





Brussels, 21.4.2016
SWD(2016) 130 final

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 of human blood and blood components and amending Directive 2001/83/EC

Accompanying the document

Report from the commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions

on the implementation of Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC setting standards of quality and safety for human blood and blood components



Brussels, 21.4.2016
SWD(2016) 130 final

2. IMPLEMENTATION OF THE PRINCIPLE OF VOLUNTARY AND UNPAID DONATION OF BLOOD AND BLOOD COMPONENTS

2.1. Legislative provisions, guidelines and policies concerning donation

2.1.1. Provisions and guidelines on VUD at national level and their application

The principle of VUD of blood and blood components is recognised in all Member States, albeit enforced to different degrees. The large majority of Member States (25) and Norway reported that VUD of human blood and blood components was mandatory in their country. Due to divergent interpretations of the term "mandatory", it has to be noted that in some of these 25 Member States, the national legal provisions rather "encourage" VUD. On the other hand, VUD may be the common practice or strongly recommended also in those Member States (Czech Republic, Lithuania, and United Kingdom) and Liechtenstein which reported that it was not legally mandated.

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Incentives for blood and plasma donors in Europe

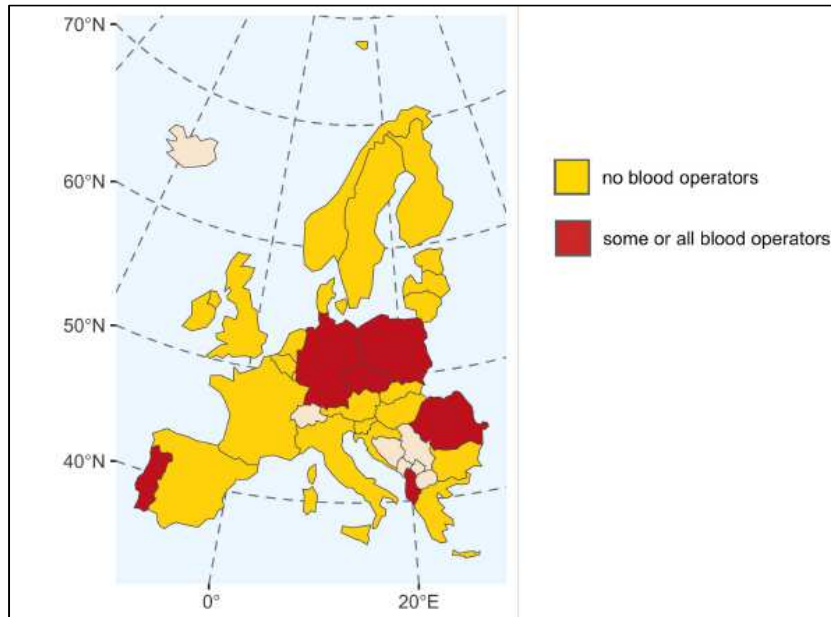
Blood Donor Incentives across 63 Countries

Caroline Graf

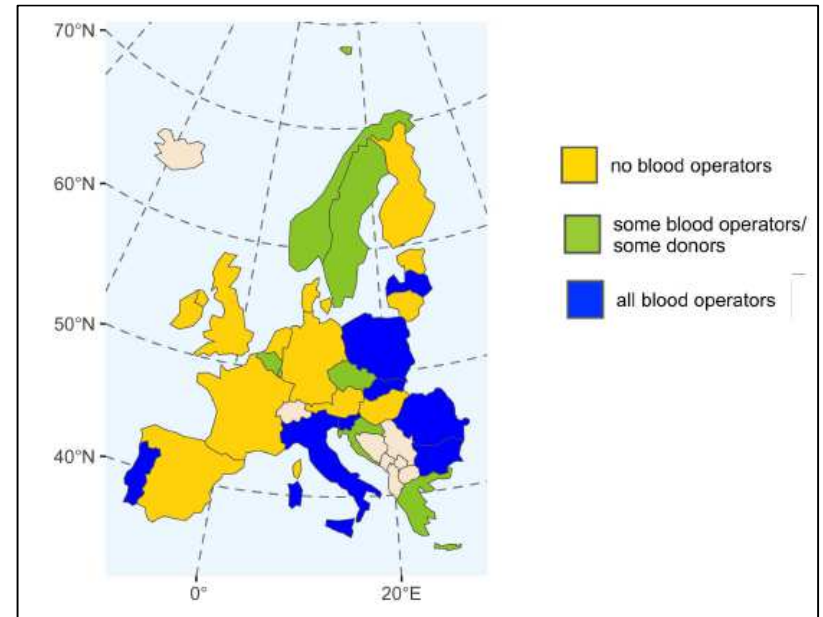
Krystal Oteng-Attakora, Eamonn Ferguson, Ralph Vassallo, Eva-Maria Merz and the Biomedical Excellence for Safer Transfusion Collaborative



Biomedical Excellence for Safer Transfusion



Financial incentive (> 10€)



Time off - work (full day) incentive



Incentives for blood donors in Europe

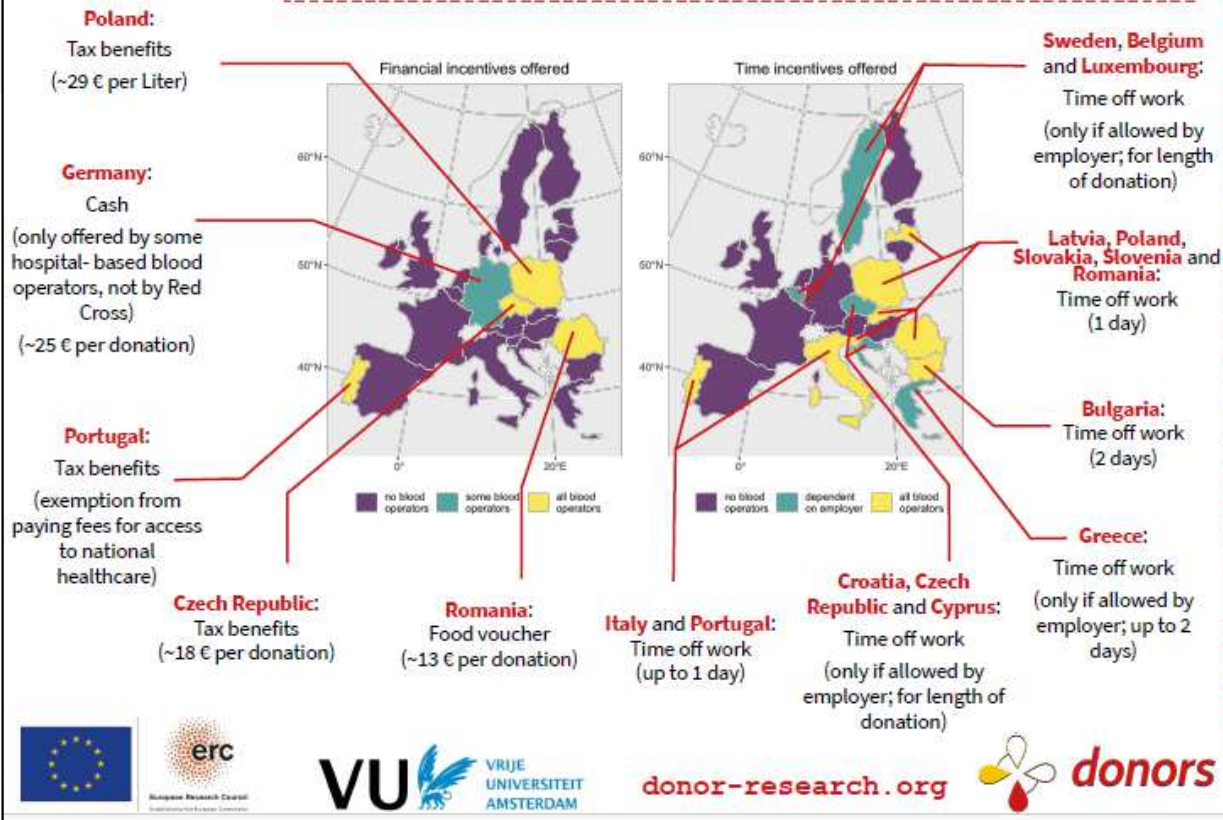
By Caroline Graf (Vrije Universiteit Amsterdam)

Blood donors in Europe are generally non-remunerated, but nonetheless donors often receive small rewards (such as a mug or T-shirt) to motivate them to donate.

Some countries also provide items of quite *high* value to their blood donors, including:

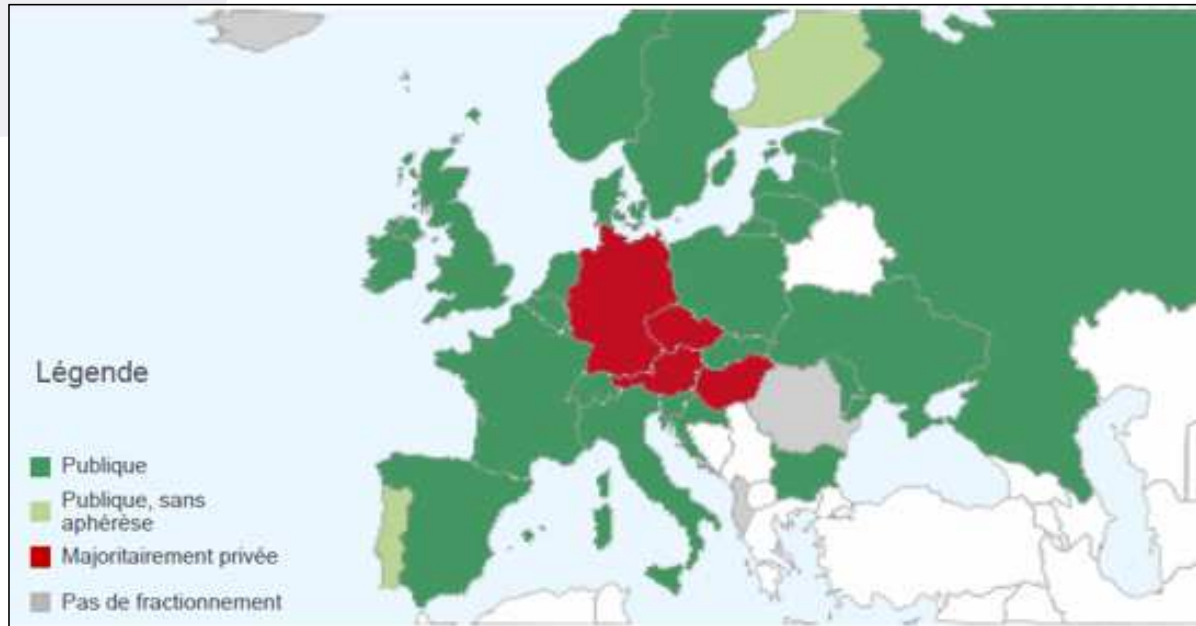
- *Financial* incentives, such as cash or tax benefits (>10 €)
- *Time* incentives, for example allowing donors to take the day off.

We were interested in incentive policies across Europe, and thus conducted a survey among experts to find out which *high-value incentives* are offered in various European countries.



Graf, C et al, *Journal of Economic Behavior & Organization*, 2022

Public and private plasma collection in Europe

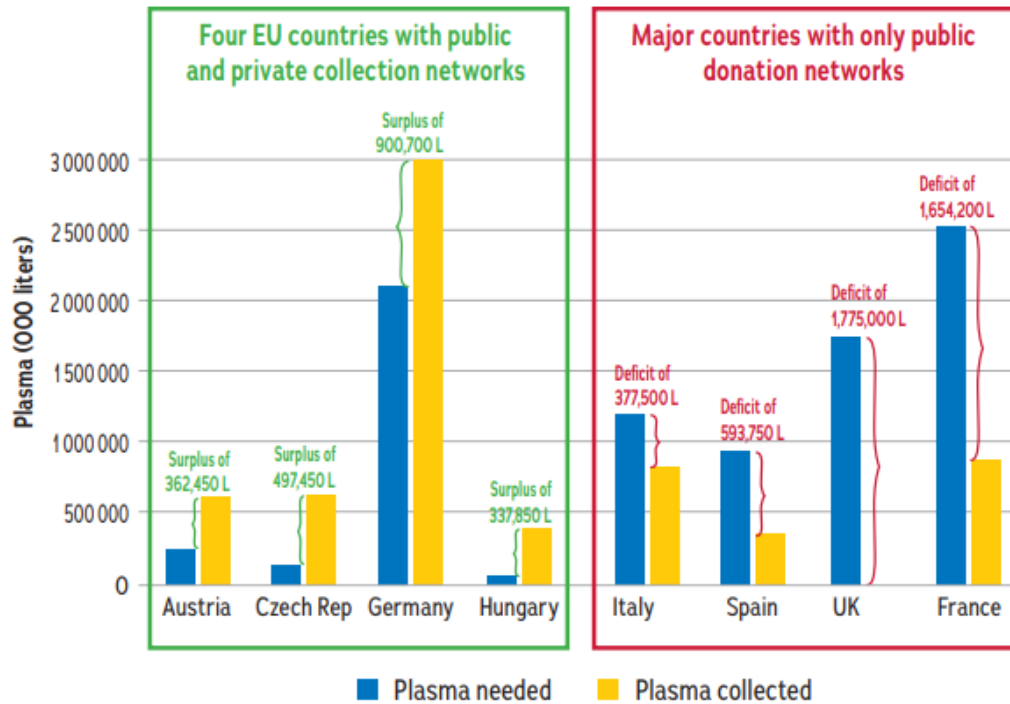


Germany, Austria, Hungary and Czech Republic:

- Financial compensation
- Mostly high frequency plasma donation
 - Germany: 60 donations / year
 - Austria: 50 donations / year
 - Hungary : 33 donations / year
 - Czech Republic: 24 donations / year

Elsewhere in Europe: 12 to 24 donations / year

Public and private plasma collection in Europe



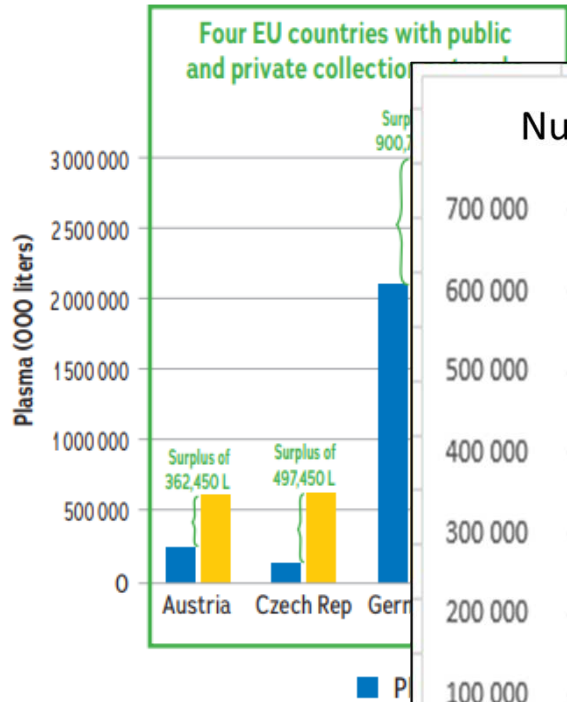
Source: PPTA, Market Research Bureau 2018)



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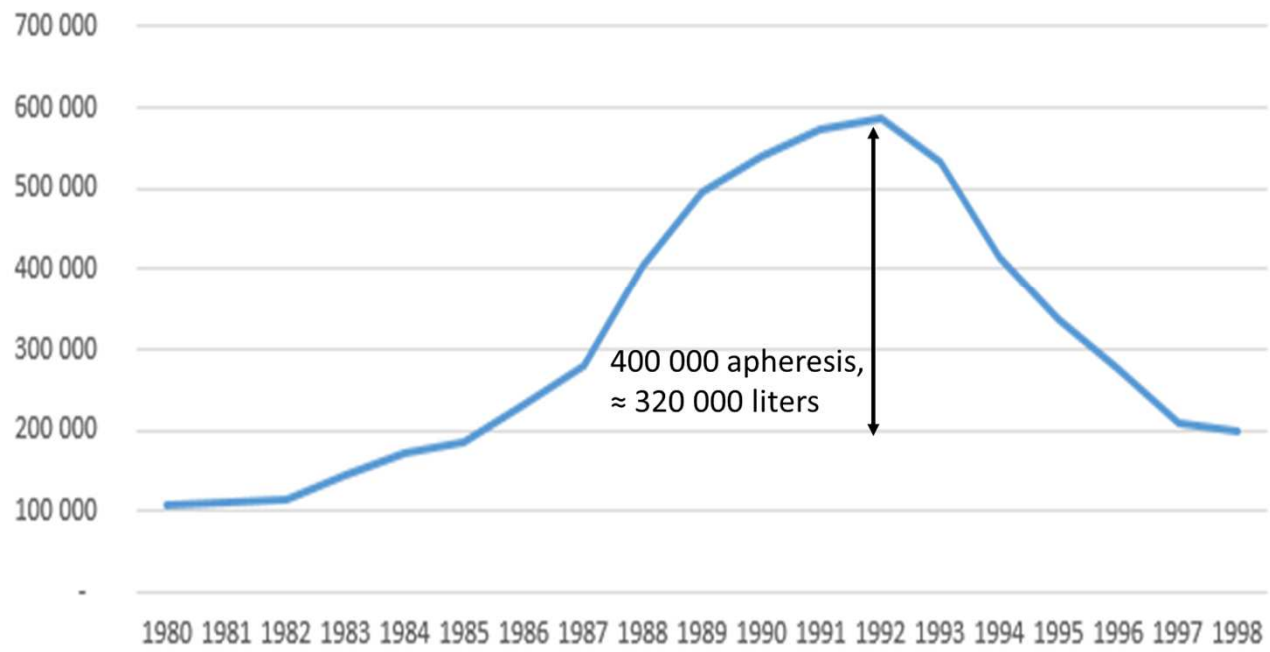
Public and private plasma collection in Europe



Source: PPTA,

Major countries with only public collection

Number of plasma apheresis in France between 1980 and 1998



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Private plasma collection in Germany

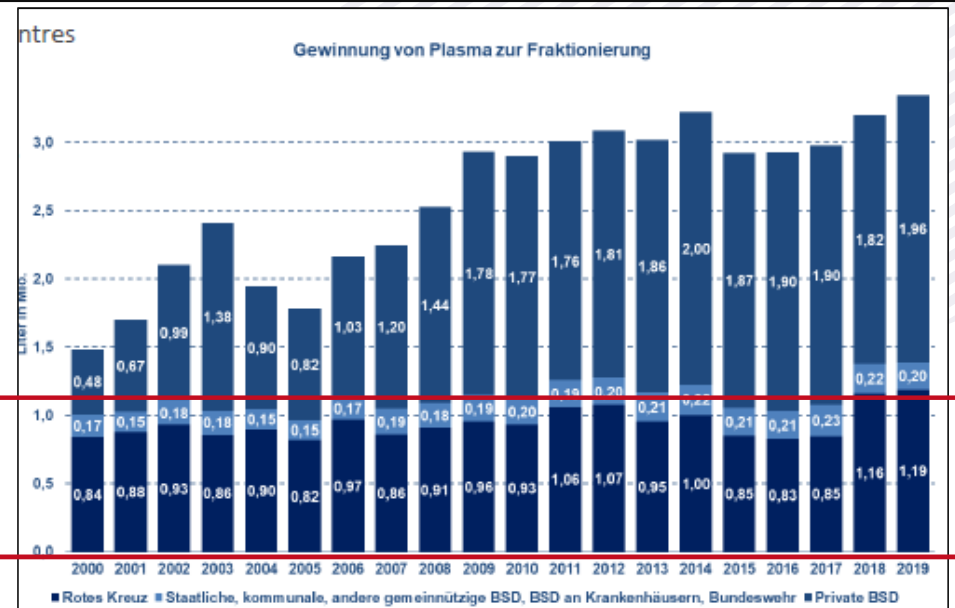
15 to 20 € per donation

Bonus : 20 euros / 5 dons (Octapharma)

Publicizing that plasma donation is compensated is forbidden

- Haema (now Grifols): over 40 collection centers
- Octapharma Plasma : 13 collections centers
- CSL Plasma Germany : 8 collections centers
- Biotest : 9 collections centers
- Plasma Vita : 3 collections centers

Mostly recovered plasma collected by the Red Cross



Private plasma collection in Austria

25€ to 30€ per donation

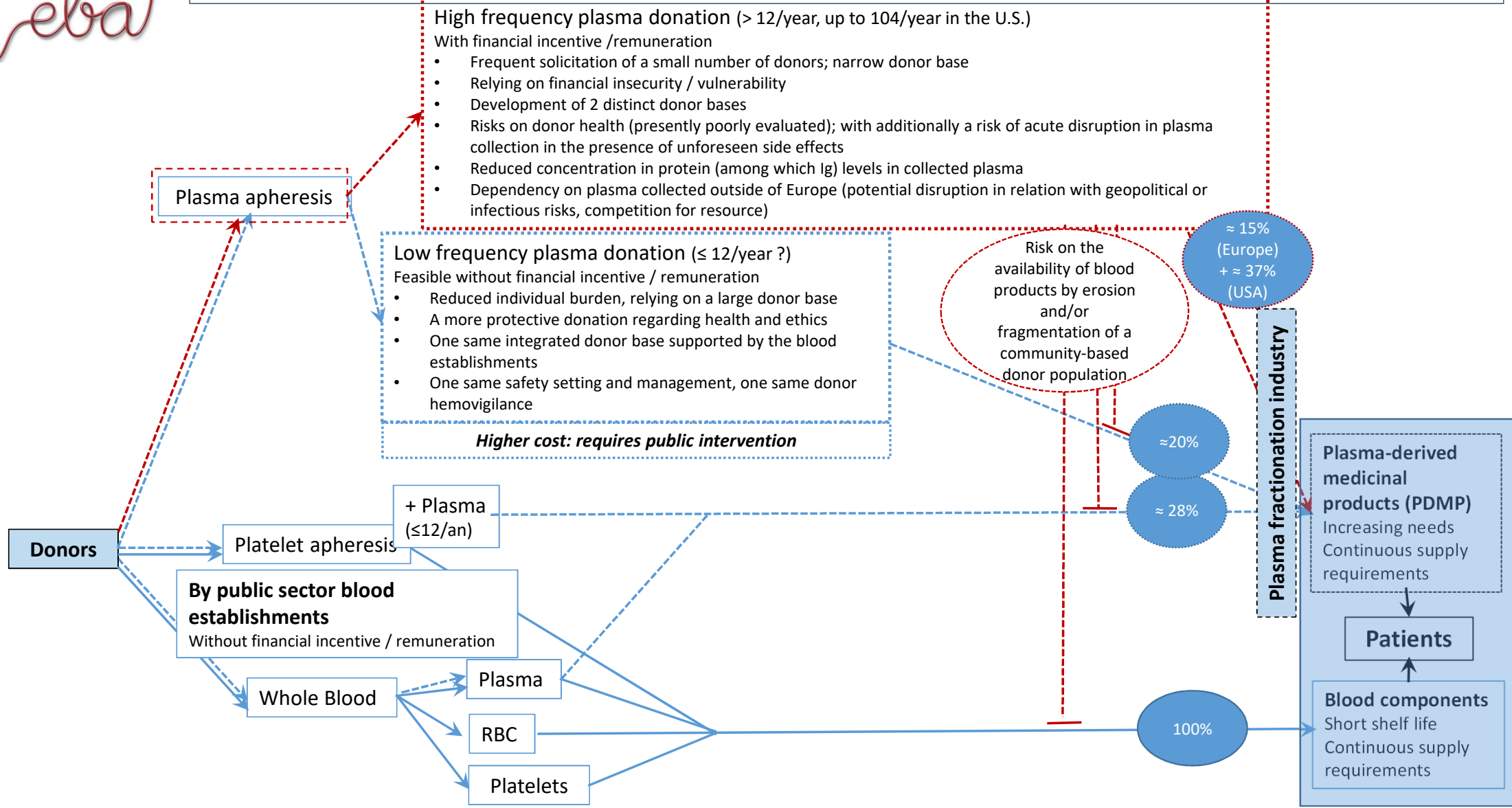
Bonuses after 5 and then every 10 donations of 15 €, 40€ for the 50th donation (Biolife)

Bonus if you bring a new donor after his/her third donation: 30€ (Biolife)

- Biolife: 12 collection centers
- Europlasma : 7 collection centers
- Plasmavita: 3 collection centers

eba

Providing blood components and plasma-derived medicinal products to meet the patients needs in Europe





Increasing non-remunerated plasma collection by European blood establishments

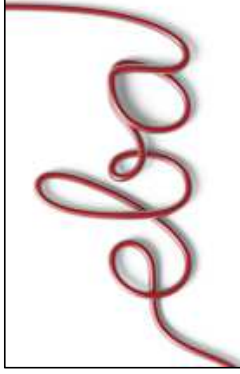
- To ensure European strategic independence regarding PDMPs
- To reduce plasma donor burden
- To safeguard plasma donor safety
- To prevent a “competition for donor”- related risk on the supply of labile blood products in Europe

- Collection of plasma, a substance of human origin:
 - a public service responsibility
 - a service of general interest

Strengthening unpaid plasma collection capacity in Europe will improve overall sustainability and resilience regarding PDMPs availability and meeting patients’ needs.

The European Blood Alliance is committed to achieving this important public health objective.

Tiberghien P. Increasing unpaid plasma collection by blood establishments to ensure availability of plasma-derived medicinal products and blood components in Europe. Transf Clin Biol, 2021
Tiberghien P, Frostin M, Thibert JB, Meyer W, Rodriguez B. Protecting blood donor health to meet the patient’s needs. Blood Transf 2022



EBA's commitment to increased plasma collection in Europe

- Benchmarking / promoting best practices
- Encouraging innovation (donor recruitment, collection technology, plasma center management)
- Communicating : social media, publications
- Interacting with DG Santé (EC), EDQM, Health authorities of Member States
- EBA position papers and publications
- EBA internal webinars on all aspects of plasma collection
- IFPA / EBA conferences on plasma collection and supply (1/2020 and 4/2022, Amsterdam)
- SUPPLY project, a collaborative approach with IPFA, EHA, FIODS, Universities

SUPPLY Project



The SUPPLY consortium represents the first united effort across the EU to develop good practices and recommendations to

- o Increase the volume and resilience of unpaid plasma collection in Europe
- o Ensure safe and adequate access for EU patients to essential PDMPs

and

Focus on the entire plasma-to-PDMP-to-patient supply chain

- SUPPLY project, a collaborative approach with IPFA, EHA, FIODS, Universities

SUPPLY Project



The SUPPLY consortium represents the first united effort across the EU to develop good practices and recommendations to

- o Increase the volume and
- o Ensure safe and adequate



IPFA/EBA Symposium on Plasma Collection and Supply

7 – 8 February 2024 | Leiden, the Netherlands



This report is part of the project "10102222SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Agency (H4DEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

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Moving from the Blood directives to a Substances of human origin (SOHO) regulation

The proposal by the European Commission



THE KEY MEASURES

STRENGTHENED LEVELS OF HEALTH PROTECTION



A wider scope to cover blood, tissues, and cells, together with other SoHO (like human breast milk or faecal microbiota)



High standards for safety and quality, implemented through **technical guidelines** developed mostly by expert bodies' based on up-to-date scientific evidence



Renewed commitment to the **principle of voluntary and unpaid donation**, protecting donors from exploitation and from risks to their own health without discouraging donations



Improved reporting and follow-up on adverse reactions

FACILITATION OF INNOVATION



Common EU-wide authorisation procedures for innovative SoHO preparations



Body providing advice on regulatory status of a substance or a product



HARMONISATION, SIMPLIFICATION & SUPPORT



Implementation of risk-based oversight, for more efficient use of resources (for authorising establishments and activities, carrying out of inspections...)



Application of **common technical guidelines** while safeguarding Member States' possibility to have more stringent rules



Collection of information on supply, quality and safety of SoHO for oversight, policy and research



EU support to Member States through training for authorities, joint activities and advisory mechanism

DIGITALISATION



Common IT Platform to facilitate data reporting and information sharing

Moving from the Blood directives to a Substances of human origin (SOHO) regulation

The proposal as voted by the European Parliament

On 12 September 2023, the **European Parliament** adopted the report on new rules governing the use substances of human origin (SoHO) intended for human application.

- Donation of those substances should always be **voluntary and unpaid, with donors able to receive compensation or reimbursement for quantifiable losses or expenses related to the donation process**
- **Compensation should not be used as a way to recruit donors or result in the exploitation of vulnerable people.**

“There is a concern that based on the text adopted by the European Parliament, countries like Germany, Austria, Hungary and the Czech Republic – which currently allow plasma donors to receive a fixed-rate allowance – would not be able to do so anymore as amendments proposed by the EU Parliament permit donor compensation only for ‘quantifiable’ losses”

Politico

SOHO regulation proposal voted the European Parlement
Focus on voluntary and unpaid donation

Text proposed by the Commission (18)

“....
Voluntary and unpaid SoHO donation is also a factor which **can contribute** to high safety standards for SoHOs and therefore to the protection of human health. It is also recognised, including by the Council of Europe Committee on Bioethics, that while financial gain should be avoided, it may also be **necessary** to ensure that donors are not financially disadvantaged by their donation. Thus, **compensation** to remove any such risk is acceptable but should **never constitute an incentive** that would cause a donor to be dishonest when giving their medical or behavioural history or to donate more frequently than is allowed, posing risks to their own health and to that of prospective recipients. Such compensation should, therefore, be set by national authorities, at a level appropriate in their Member State to reach such objectives

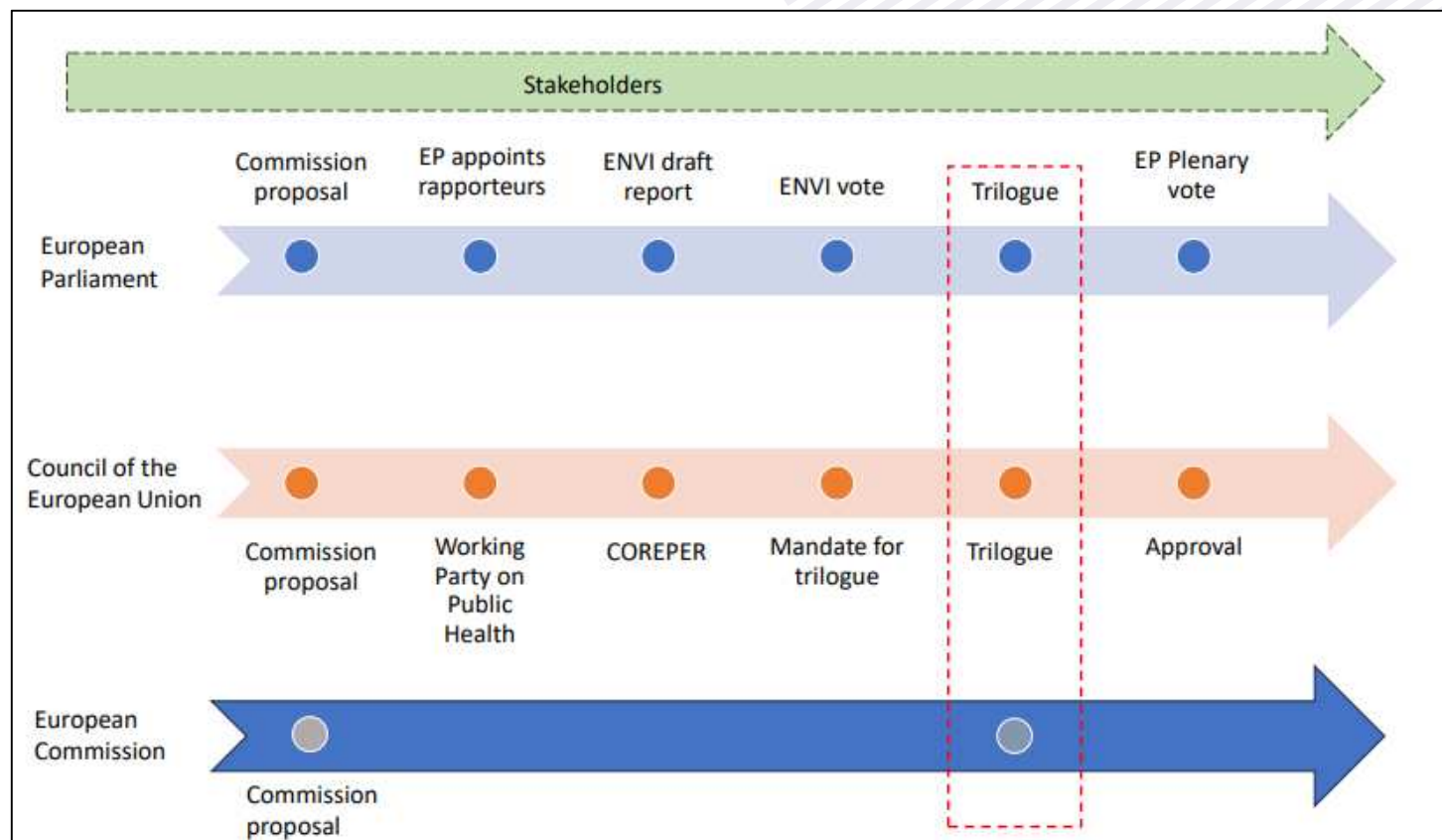
Text voted by the European Parlement (18) “...

“...
Voluntary and unpaid SoHO donation is also a factor which **contributes** to high safety standards for SoHOs and therefore to the protection of human health, **and increases public trust in donation systems**. It is also recognised, including by the Council of Europe Committee on Bioethics, that while financial gain should be avoided, it may also be **acceptable** to ensure that donors are not financially disadvantaged by their donation. Thus, **financially neutral** compensation to remove any such risk is acceptable but should never **produce a financial gain for the donor or constitute an incentive** that would cause a donor to be dishonest when giving their medical or behavioural history or to donate **in any way that could pose risks, in particular donating** more frequently than is allowed, to their own health and to that of prospective recipients. **Compensation and reimbursement should under no circumstances serve an incentive to recruit donors, should not expose vulnerable persons in society to exploitation and should not lead to competition among SoHO entities for the recruitment of donors**. Such compensation should, therefore, be **based on quantifiable criteria, for example. time given for the donation or proven expenses, and transparent criteria** set by national authorities, at a level **justified and** appropriate in their Member State to **respect the principle of financial neutrality. Recruitment campaigns and advertisements should not refer to any compensation, in order to avoid risks to the health of donors or to that of prospective donors**.

Moving from the Blood directives to a Substances of human origin (SOHO) regulation

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Voluntary non-remunerated blood and plasma donation

Position of the **European Blood Alliance (EBA)** and **International Federation of Blood Donor Organisations (IFBDO / FIODS)**

EBA and , representing public/not-for-profit blood establishments in Europe, and **IFBDA / FIODS**, the international organisation representing voluntary, anonymous, and non-remunerated blood donors, call on the **European Parliament, the Council of the European Union, and the European Commission** to adopt a final text of the SoHO regulation that reaffirms the **principle of voluntary non remunerated donation** and a **strict definition of the term “compensation”**.

Safe blood for patients

- Remunerated blood donors have a higher risk of blood-borne infectious diseases than voluntary non-remunerated donors (VNRD).
- Collecting blood for blood components from voluntary non-remunerated donors remains an important safety measure.
- By contrast, for plasma-derived medicinal products (PDMPs), the safety gain from collecting plasma from non-remunerated donors may be considered of less importance, given consecutive steps of pathogen reduction implemented during the production process.
- However, financial compensation for plasma donation raises other concerns regarding donor health and supply resilience.

Donor safety and wellbeing

- Compensation should never act as an inducement to donate
- A vague definition of what constitutes “compensation” risks undermining the principle of financial neutrality.
- Incentives that go beyond financial neutrality may encourage some donors to undergo blood or plasma donation in conditions or frequencies that may put their health at risk.

A resilient blood supply for Europe

- Payment for the donation of blood or plasma erodes community solidarity.
- A sufficient and sustainable supply of available and accessible blood components based on VNRD may be compromised through the presence of parallel systems of paid donation. <https://europeanbloodalliance.eu/resources/vnrd-eba-and-fiods-on-future-soho-regulation/>