

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

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# Donors and patients regarding plasma supply

*Ethical implications*

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# Disclosure

- Employed by EFS
- EBA Board member

*What is said is the sole responsibility of the presenter and not of the institution that employs him*



# As a reminder about ethics...



A « *Limousine* »??



The breed of cow?

A type of car?

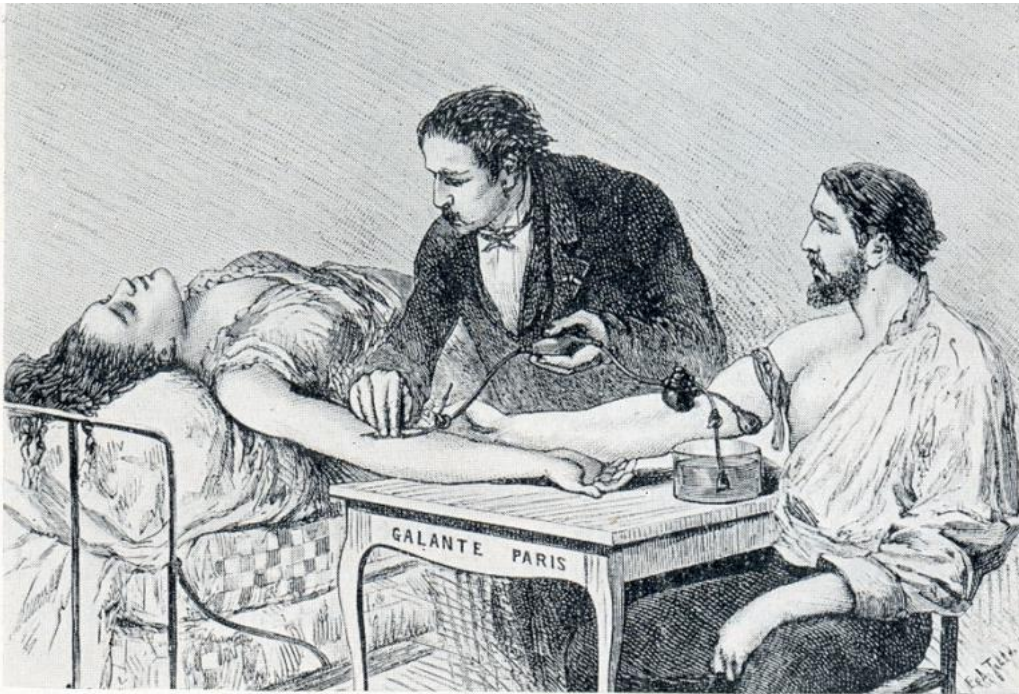
**Appearances can be deceiving**

**Universality of ethical dilemmas, plurality of the responses**





# What's the difference?



Early 20th century



Patient treated with IV IgG ULRIKA / GETTY IMAGES / ISTOCKPHOTO



Plasma donation

2024



# The process







From donors to patients: 7 to 12 months



Fédération Française  
du Don de Sang Bénévole  
Trimestriel  
2021  
Hors-série

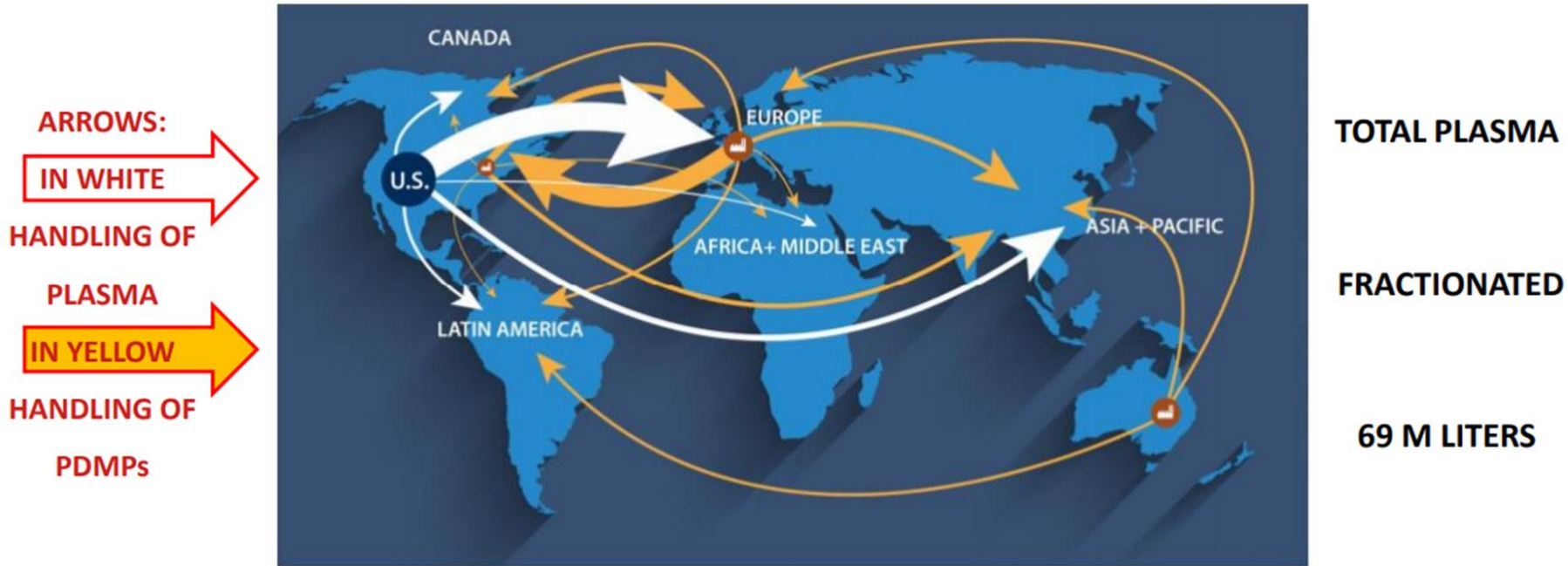


Protéines...

...Médicaments  
dérivés du plasma

# The status of medicinal product

## HANDLING OF PLASMA AND PDMPs IN THE WORLD 2019



Courtesy of: D. Medica on behalf of GAEF – Gruppo Aziende Emoderivati Farminindustria adapted from P.Robert «Dans un Marché Mondialisé, Quel Accès des Patients Français aux Médicaments Dérivés du Plasma »?, November 11, 2020





# But remains a human chain



16th october 1914: First arm to arm transfusion reported in France during the 1st WW



World Blood Donor Day



Give blood, give plasma, share life, share often.







# HEALTH PROTECTION

Protecting donors and patients  
through the prism of human fundamental rights



# Limits of the current approach

Donor protection and access to healthcare:  
two conflicting realities ?



- The issue of **self-sufficiency** is then shifted to that of **access to care**, and the dimension of donor protection then appears secondary.
- **Debate too often restricted** to the study of the **balance between supply and demand**, or even to the question of donor **remuneration**, even though the complexity of the subject calls for a **broader framework of analysis**

**The result is an inability to meet today's challenges, both in terms of supply and health protection**



# Health protection: what are we talking about?

- **Health protection:** *“Values and principles common to healthcare systems in the European Union... **universality, access to quality care, equity and solidarity**” (Council of the EU conclusions of June 22, 2006 on the values and principles common to healthcare systems in the EU).*
- **+ Prevention, continuity of care and the best possible health safety**
- **On a legal basis:** constitutional law of many **European countries** + a number of **international texts**

*(The EU Charter, the International Covenant on Economic, Social and Cultural Rights, the United Nations Resolution on Mental Health and Human Rights...)*



# Health protection : a human fundamental right



- **Human fundamental right:** abstract notion, set of rules that govern the behavior of Man in society, define and guaranteed in a state governed by rules and democracy, and sometimes at a geographical level
- **Human fundamental rights involved in the Blood chain:** respect for dignity, the right to personal integrity and autonomy, non-discrimination and the right to health protection
- **Not Universal but a strong legal basis to guarantee them:** sometimes constitutional and find in many international texts

*(Charter of Fundamental Rights of the EU, Oviedo Convention, the Universal Declaration of Human Rights, the United Nations Resolution on the Standard Minimum Rules for the Treatment of Prisoners...)*





# The benefits of Health protection as a global perspective

- **Patients:**

- Infectious risk mitigation
- Access to PDMPs

- **Donors :**

- Primarily seen as relevant to mitigate risk for the recipient of the blood components
- Now: need to improve Donor health protection

**And:**

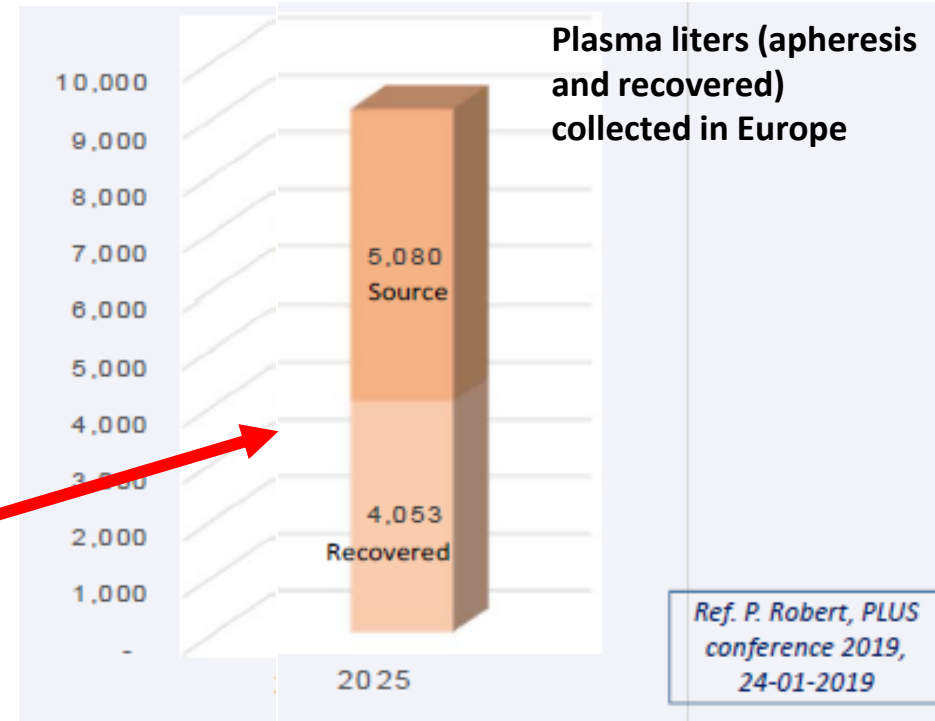


## Improving access to safe blood products through local production and technology transfer in blood establishments



### 3. Volumes of recovered plasma wasted in the world

The above estimates suggest that about 9.3 million litres of recovered plasma are wasted each year. It is a critical embarrassment to the world that such





# The benefits of Health protection as a global perspective

- Patients
- Donors

**And: Each parameter of this chain must be addressed too** and every initiatives supported:

- Evidenced-based use of PDMP's
- Good practices
- Manufacturing process
- Wastage
- National Health organisations and policy,
- Contingency plans, efficiency and resilience
- .....

 **SUPPLY**

Improving access to safe blood products  
through local production and technology  
transfer in blood establishments



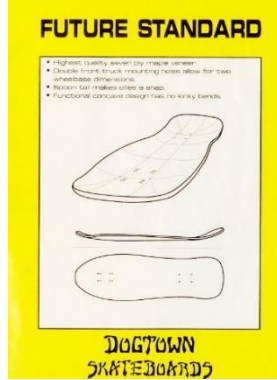
**COVID-19: Commission supports blood services to increase COVID-19 convalescent plasma collection**

Brussels, 11 January 2021



# Take home messages

An opportunity to define now the standards for tomorrow



- Health protection, as a human fundamental right, offers a **strong legal basis for action** and **internationally shared objectives**
- **Europe is a relevant and functional scale** to make **health protection a political ambition** as a whole, based on human fundamental rights and ethics
- **Protecting both patient and donor is possible, in a holistic approach to health protection**, where the search for a common Good could **allow certain market rules to be waived**
- **Only in theory?....**



# Take home messages

An opportunity to define now the standards for tomorrow

Only in theory?.....: probably not

***“Human rights are not for sale, at any price”*** U. von der Leyen, 15th September 2021

Internationally efforts are made to limit trade involving the exploitation of vulnerable populations



News  
European Parliament

## Corporate due diligence rules agreed to safeguard human rights and environment

Press Releases [JURI](#) 14-12-2023 - 09:08

Parliament and Council negotiators agreed on new rules obliging firms to integrate their human rights and environmental impact into their management systems.



U.S. Customs and  
Border Protection

23 Dec 2021

## Uyghur Forced Labor Prevention Act





Thank you

