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international plasma fractionation association

The Plasma Chain

IPFA's perspective on plasma supply and the link between patient and donor

Dr. Paul Strengers,
Executive President,
International Plasma Fractionation Association

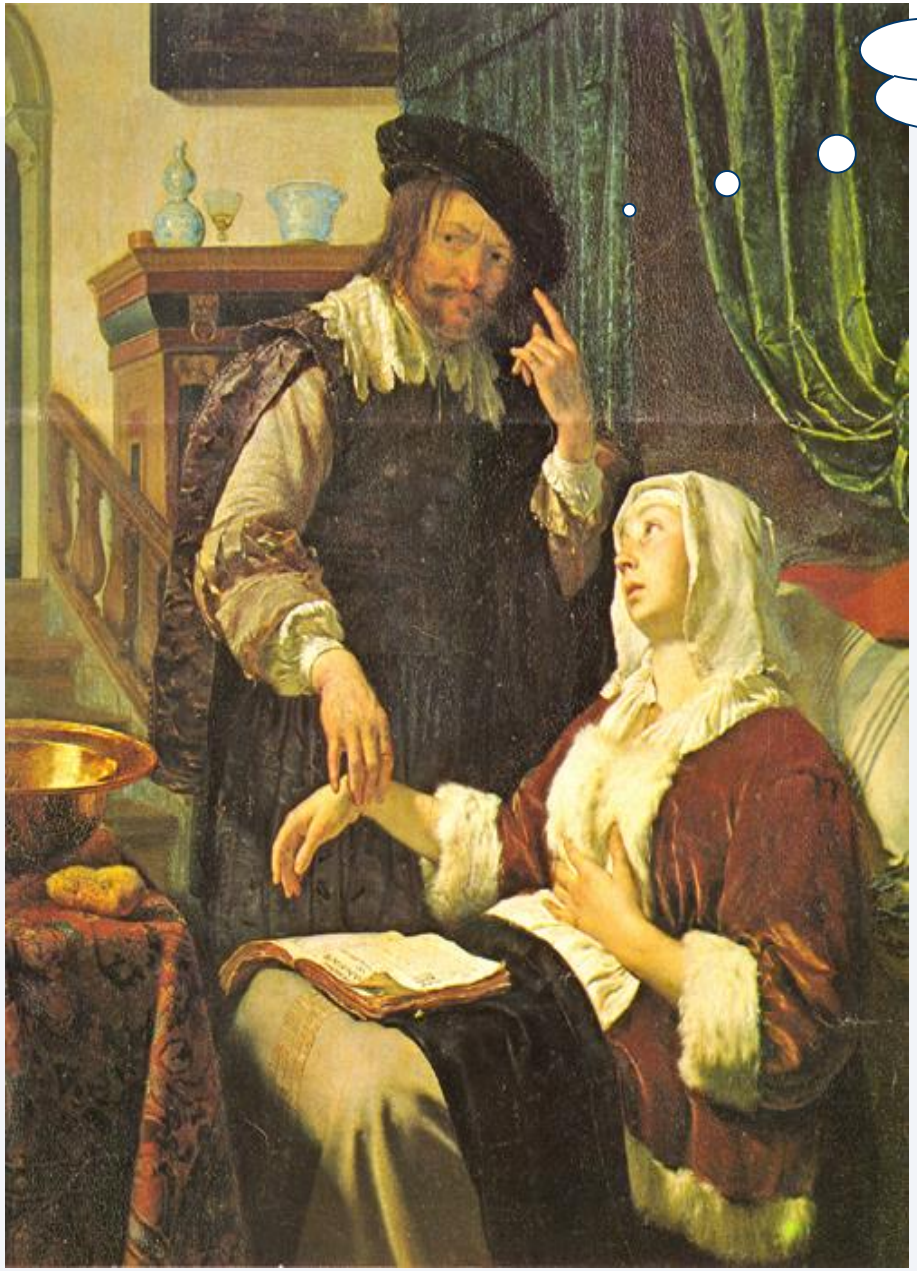
IPFA Workshop on Improving Access to Plasma and Plasma Products
Stellenbosch, South Africa
1 December 2015

Two pillars of IPFA

- Plasma and Quality of plasma
  - supply of plasma from whole blood donors and plasmapheresis donors
  - focus on the suppliers of plasma (blood transfusion organizations))
  - focus on high quality of plasma for fractionation
- Plasma fractionation and market developments
  - patients and hospitals: high need and demand for plasma products
  - expected developments in markets, worldwide

Different types of plasma

- Priority on recovered plasma from VNRBD
- Source plasma from VNRBD



Blood transfusion

- **Patients** think blood transfusion is special and beneficial, but have difficulty in accepting small risks they can't control.
- **Blood Donors** believe their contribution is a gift to the community that will be used appropriately and safely.
- **Clinicians** think blood is ordinary, take blood transfusion for granted, the benefit is assumed and the risks are regarded as minimal.
- **Governments** view blood as a commodity and transfusion medicine as an expensive support service which should be regulated and funded in a "McDonaldised" manner.

Blood transfusion medicine is a niche in clinical medicine

While :

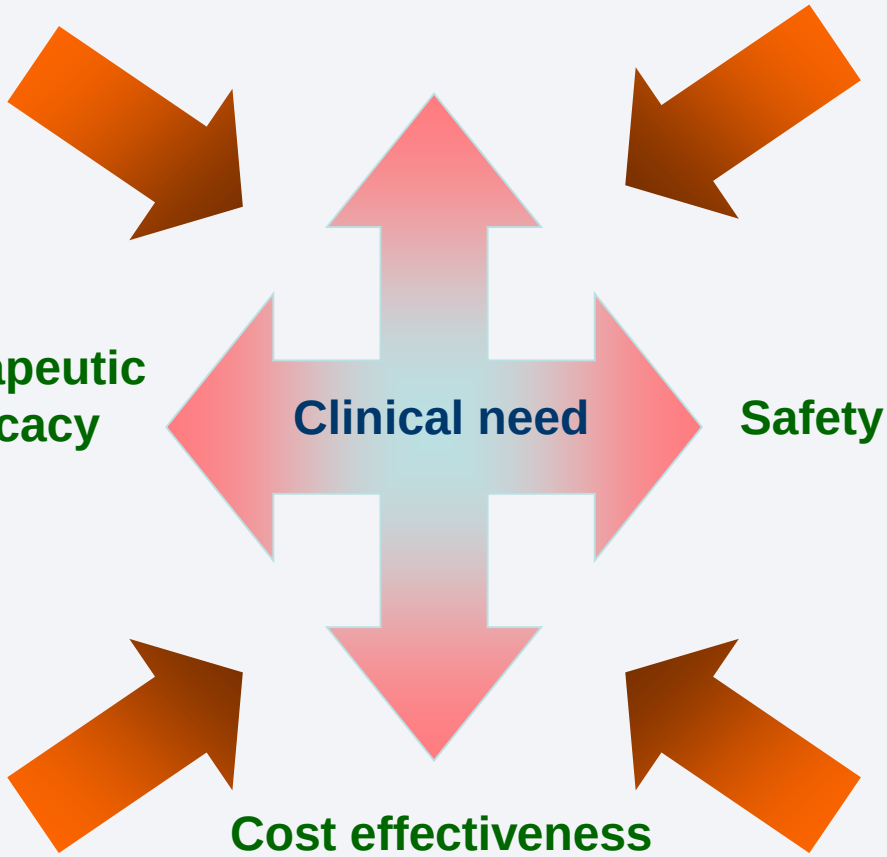
- **Blood is life saving**
- **Blood and plasma products are on WHO Model List of Essential Medicines**
- **Blood and plasma is essential and life saving for many patients with rare diseases**
- **Blood donors are ready to help**

Unfortunately:

- **The knowledge of clinicians regarding blood is relatively poor**
- **Transfusion medicine treatment is expensive**
- **Support from governments is relatively poor**

How can we change this situation?

Transfusion medicine



How can we change this situation?

How can we make blood and plasma attractive?

IPFA's position:

- Support the education of the health care professionals and regulators

- Put blood and plasma in a position which politicians and Ministries of Health understand !

1. Donors and patients are VIPs (voters at elections)

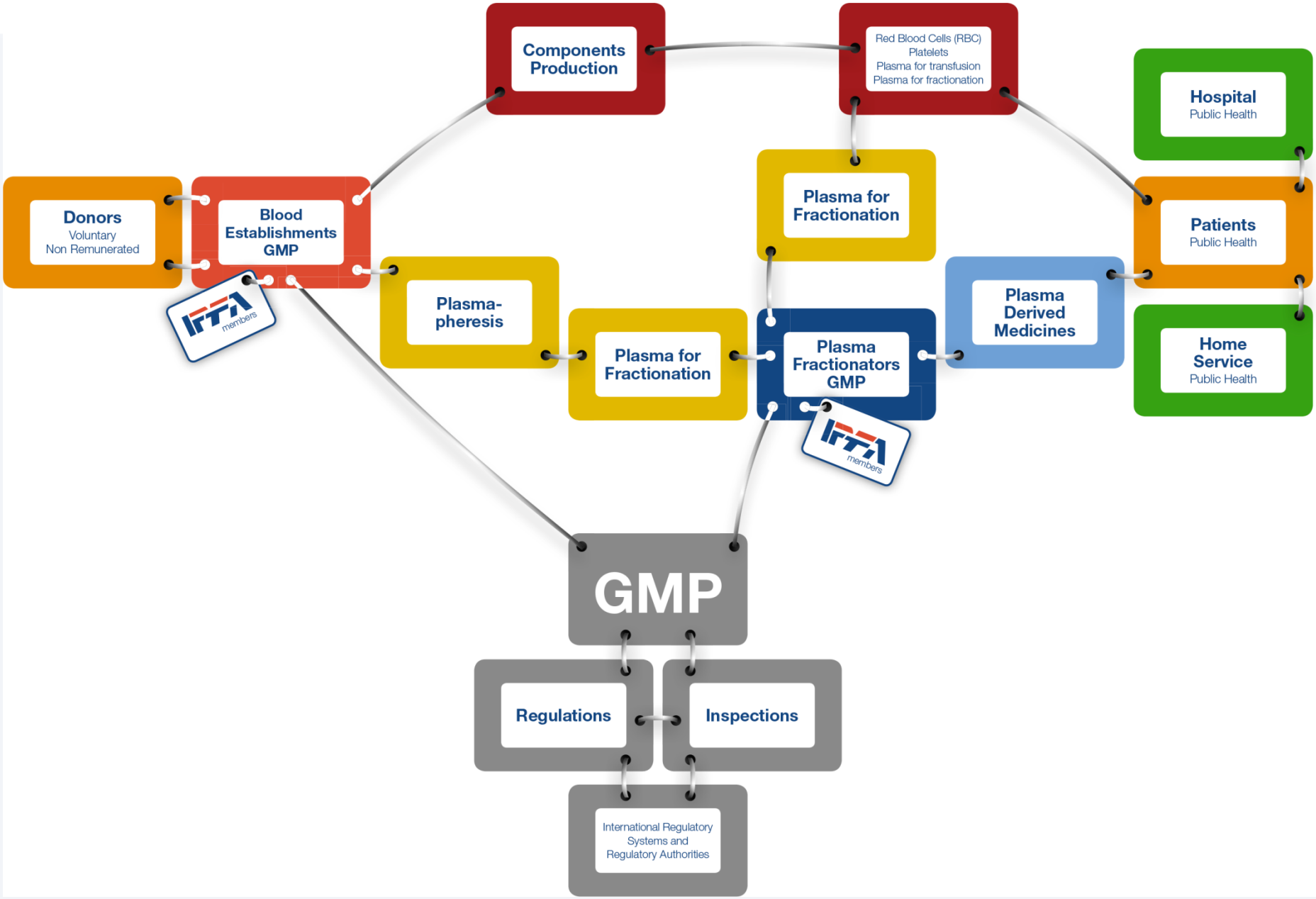
2. Put blood/plasma products at a place where regulators are familiar with i.e.:

- **Licensing and registration**
- **Audits and inspections**
- **Regulations and guidelines**
- **Economical traffic**

The Plasma Chain

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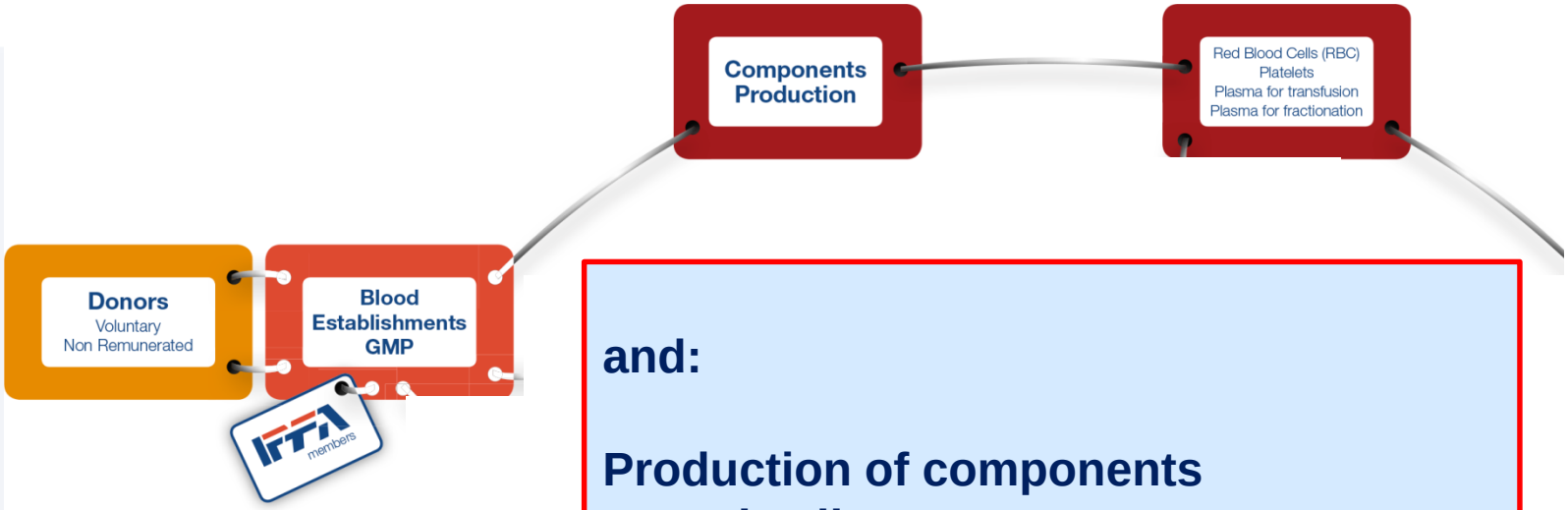




Most blood banks are active in :

- **Donor recruitment**
- **Donor selection.**
- **Blood collection**
- **Donation screening**
- **…**

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and:

Production of components

- **Red cell concentrates**
- **Platelet concentrates**
- **Plasma for transfusion (FFP)**
- **(Cellular therapy products)**
- **……**

To whom do they deliver the products to ?

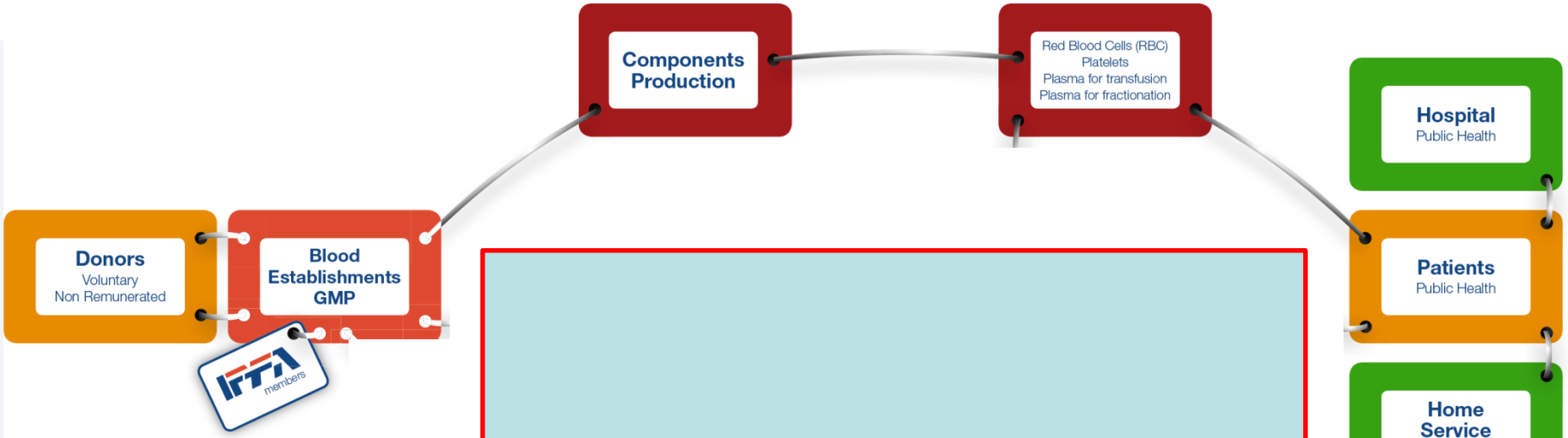
Patients ????????

In fact the products are provided to :

- **Physicians (diagnosis and treatment)**
- **Pharmacists (responsible for safety and efficacy)**
- **Clinical chemists / transfusion labs (compatibility testing)**
- **Hospital administrators (reimbursing)**
- **Nurses (administration)**



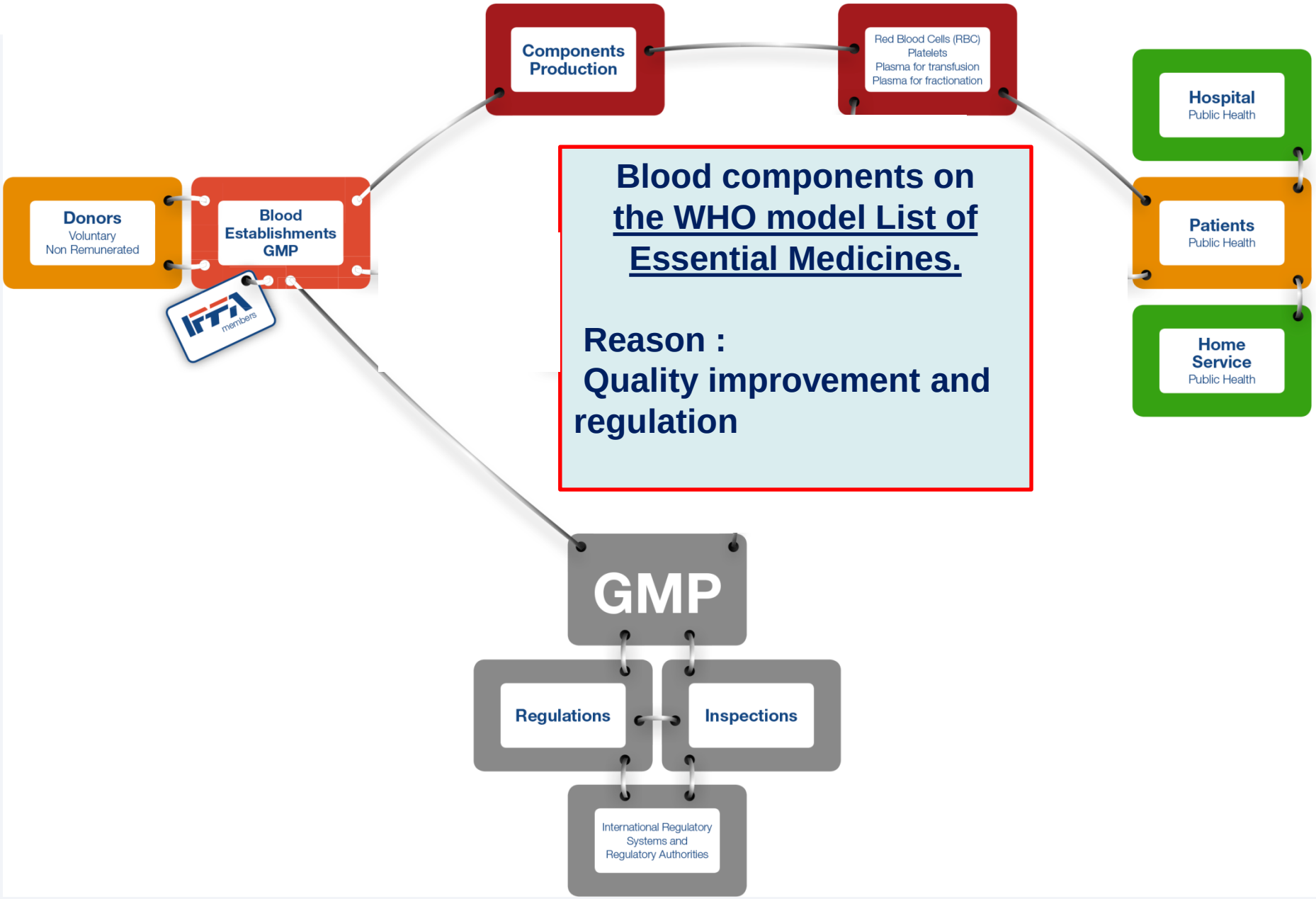
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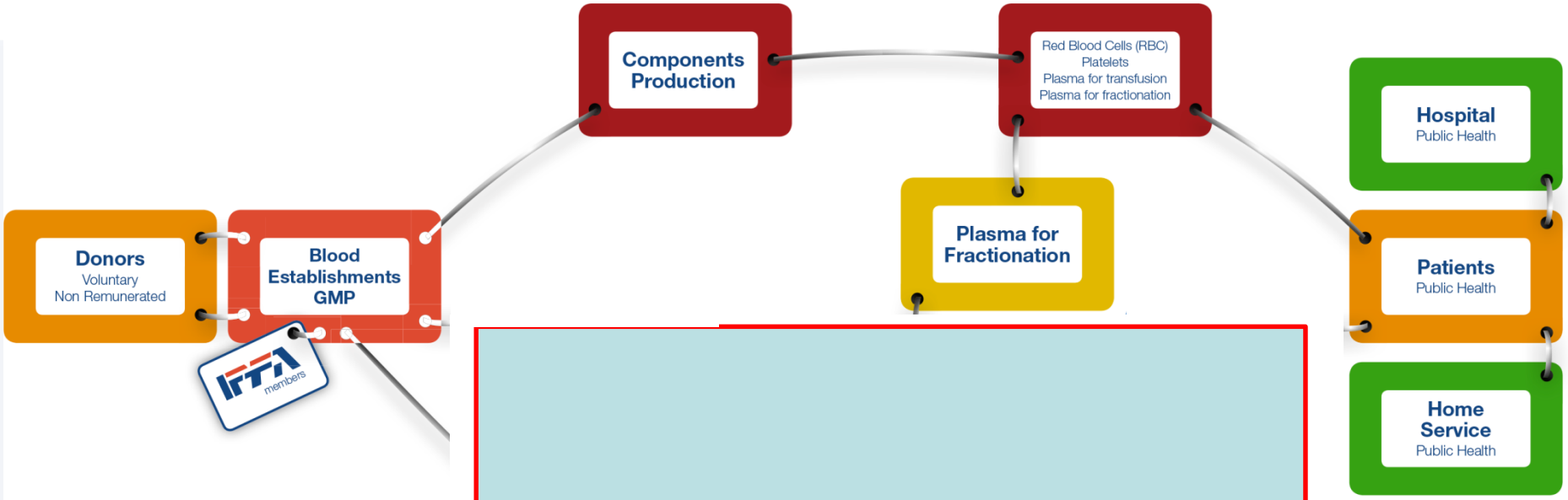
The classical blood transfusion chain :

vein-to-vein

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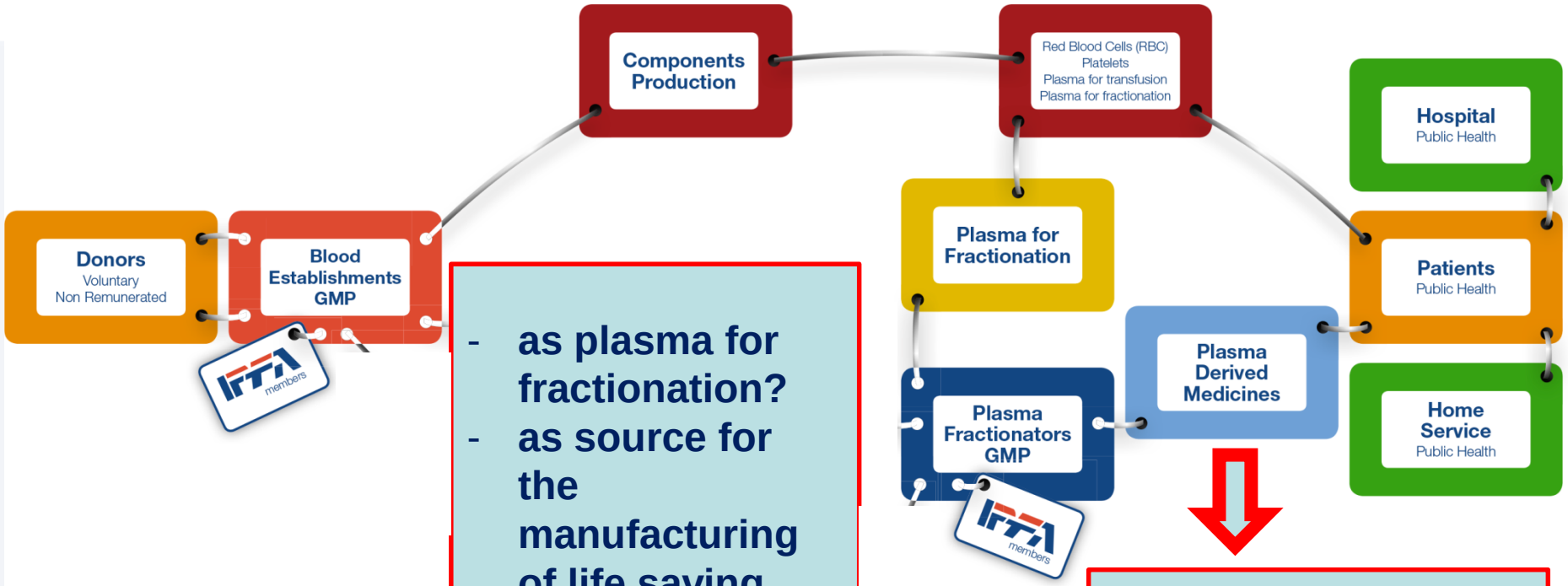
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Do you realize that the plasma for transfusion which is not used, could be used :

as source for
Plasma Derived Essential Medicines?

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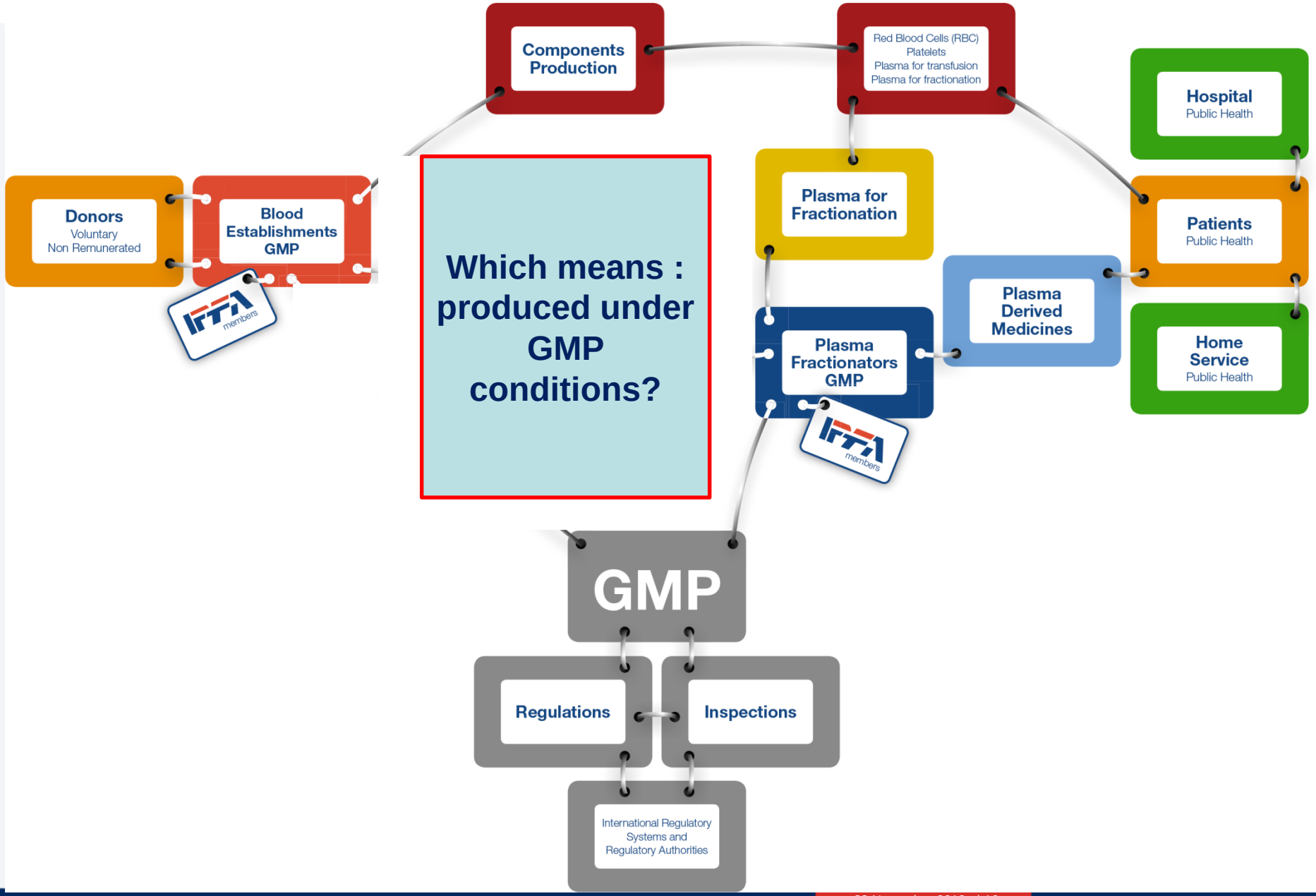


- as plasma for fractionation?
- as source for the manufacturing of life saving plasma derived essential medicines?

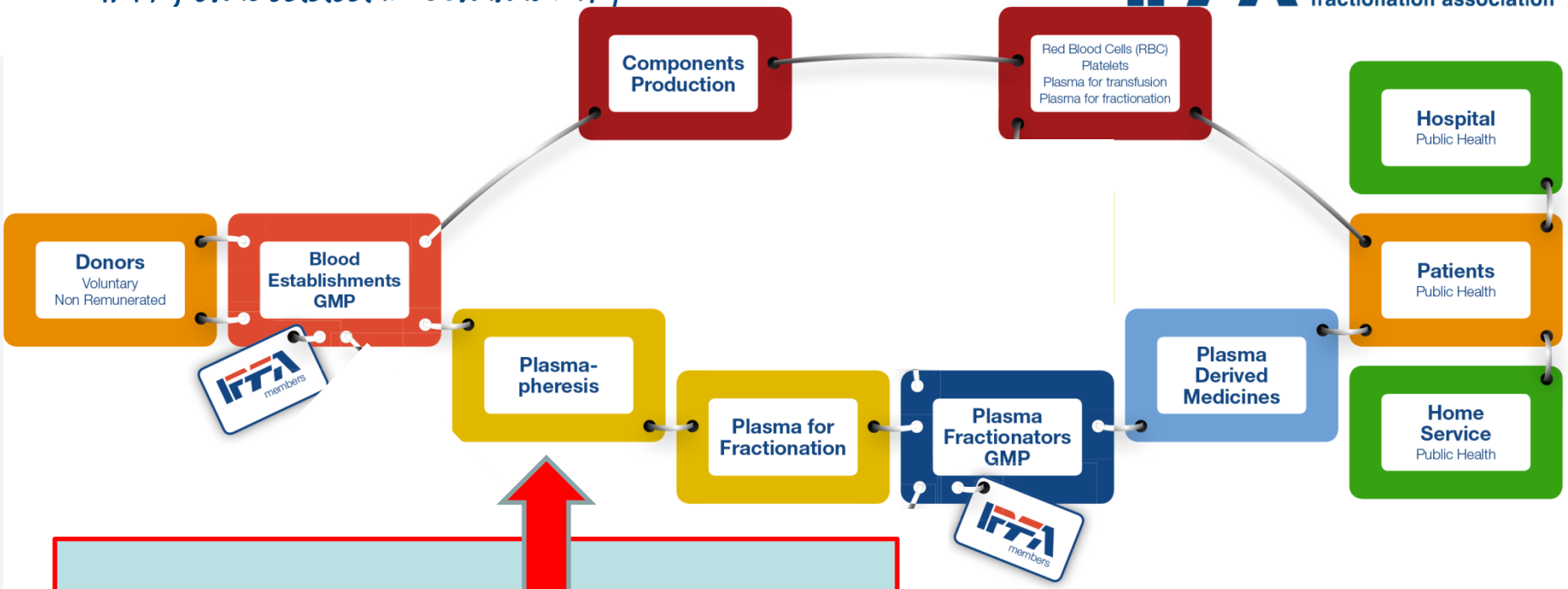
Essential Medicines:

Factor VIII,
Factor IX,
Immunoglobulines
Ant-D IgG
Anti-tetanus IgG
Anti-rabies IgG

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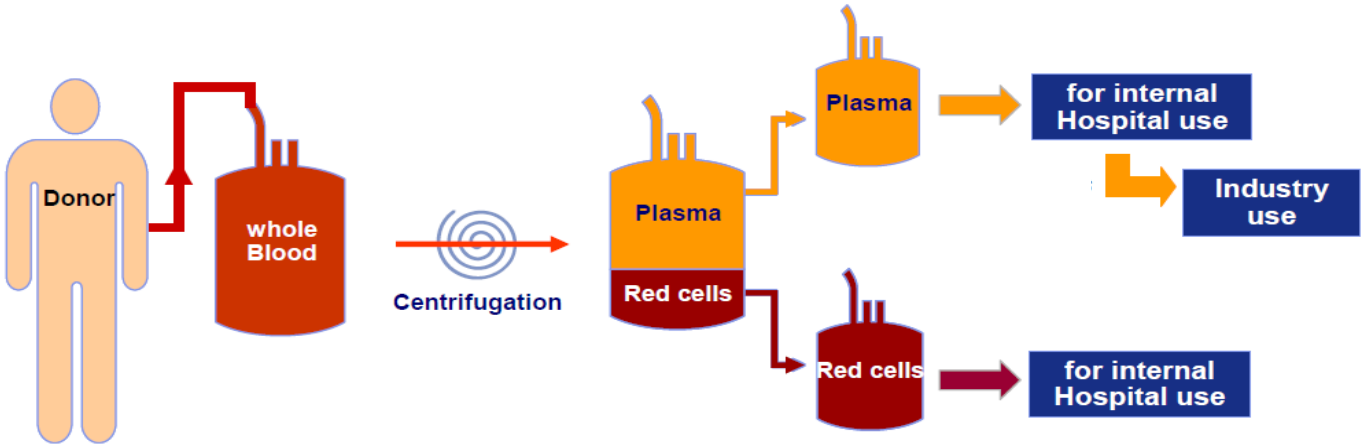
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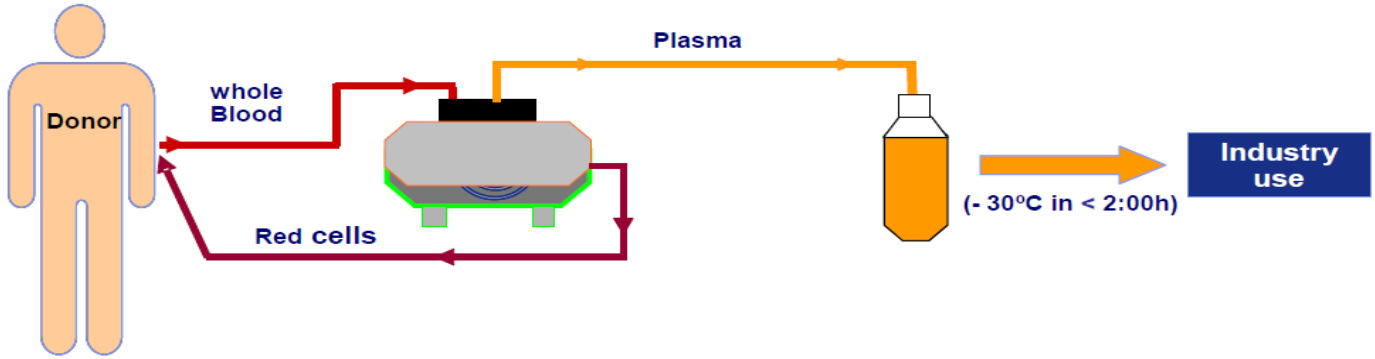


Another option for supplying plasma for fractionation is :

<u>source plasma</u>
obtained via plasma apheresis

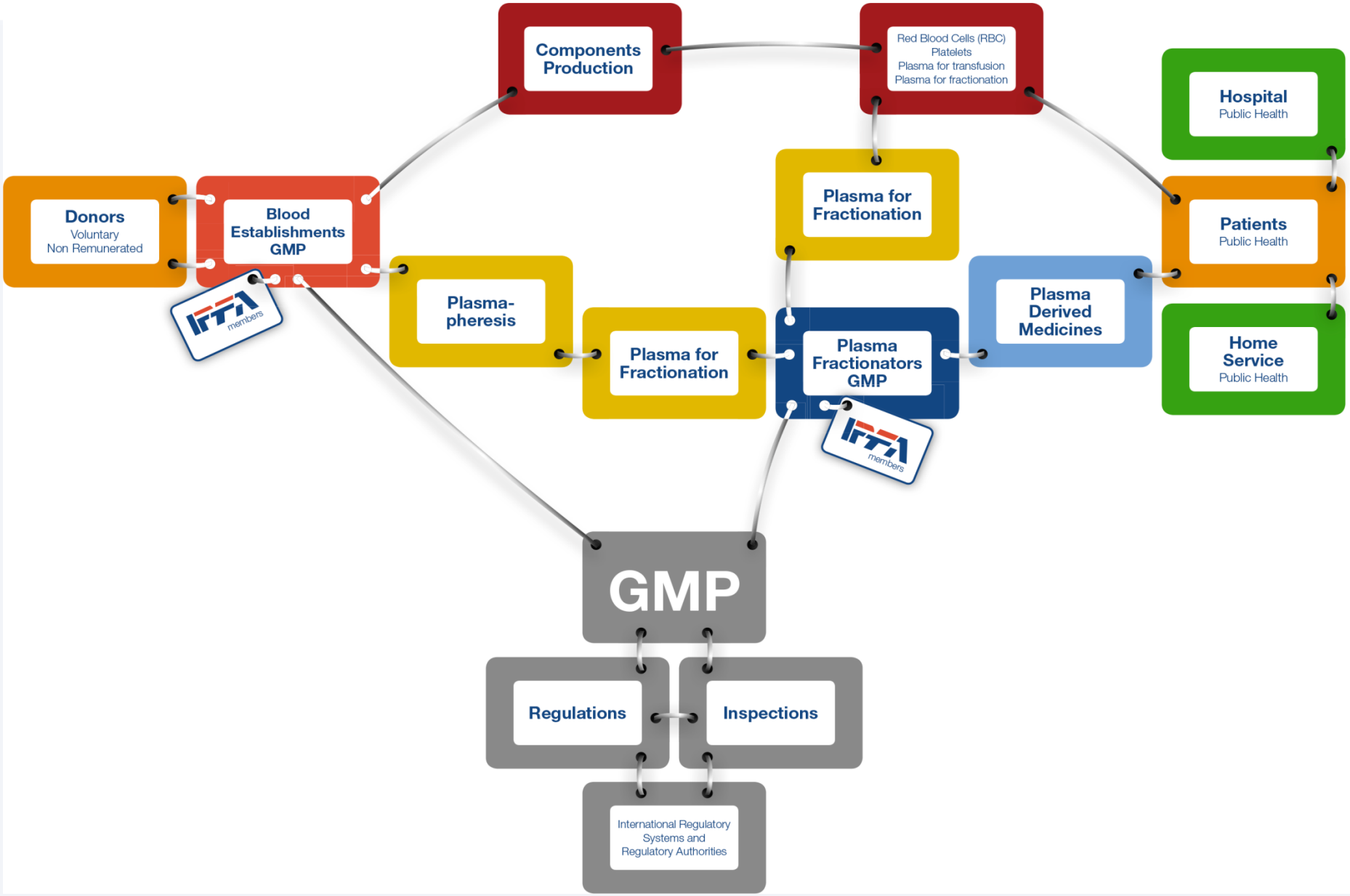
Plasma donation





Red cells are immediately re-injected into the donor

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How can we change this situation?

How can we make blood attractive?

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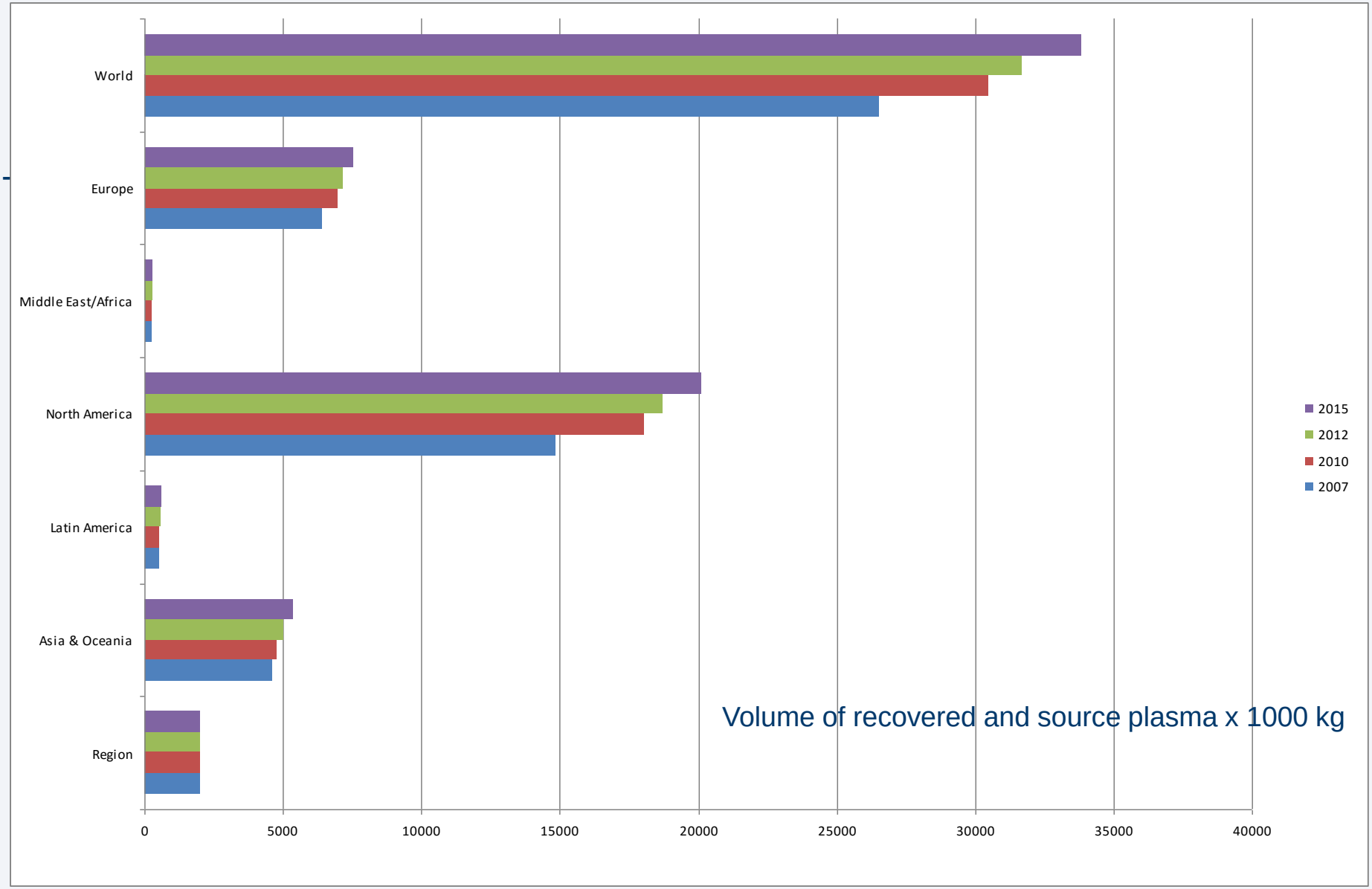
- **Licensing and registration**
- **Audits and inspections**
- **Regulations and guidelines**
- **Economical traffic**

Remember:

2. Put the products at a place that Ministries of Health understand i.e.:

- Licensing and registration:	**medicines**
- Audits and inspections:	**fractionation plant + source of plasma + blood bank where the plasma is coming from**
- Existing regulations and guidelines:	**medicines**
- Economical traffic:	**reimbursement of medicines**

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Make the plasma chain work

Summary:

- Focus on the health environment of the patients
- Try to understand what the physicians want for their patients
- Educate and train all persons and stakeholders involved
- Focus on quality management
- Involve the MoH and try to understand the processes at the MoH
- Follow these processes
- Comply with quality requirements

- Do realize : The better the quality of the plasma, the better the quality of the components.

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