

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

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A PERSPECTIVE FROM FRANCE

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THE FRENCH BLOOD SUPPLY

1952: The choice of Non For Profit

↪ A politic and society choice based on non remuneration of human parts

Law on the therapeutic use of human blood, its plasma and their derives- 21 July 1952

- Blood is **not a commodity** that can be sold, **no commercial transaction** on human parts
=> so **blood is not a medicine**
- **Donors cannot be paid, nor make financial profit**
- **Even PDMPs** «*products whose stability is assured*» (art. 3)

↪ One law but hundreds of local BEs

↪ Blood products: labile + stable

THE FRENCH BLOOD SUPPLY

90's: The choice of safety in a european context

➔ A safety choice:

Law on the safety of blood transfusion and medicinal products 4 January 1993

Law on the reinforcement of health monitoring and control of the safety of products intended for human use 1 July 1998

◆ A unique national organization with:

- 1 public operator for collection, processing, issuing: **EFS**
- 1 manufacturer of PDMPs: **LFB**

◆ Increasing safety of blood products/ donors

➔ Added to a European context

◆ Maintain ethical principles in the perspective of a common market

◆ Stabilized blood products became “medicinal products derived from human blood or human plasma” *Directive 89/381/CEE*



ACTORS OF A PUBLIC CHAIN



Ministry of Health and Solidarity
Ministry of the Economy and Finances
Directorate General of Health - Budget Directorate

- Act as guardians of EFS
- Push for legal and regulatory changes
- Set the prices of labile blood products (LBPs)



Healthcare Institutions

- Purchase LBPs from EFS
- Entrust laboratory tests to EFS
- Establish research projects



Blood Donors' Associations

Help promote blood donation



Patients' Associations

Help promote blood donation



French National Agency of Public Health

Analyses epidemiological data sent by EFS



French National Institute for Health and Medical Research

Made up of research units present in certain regional establishments




National Alliance for Health and Life Sciences

- Coordinates French research in health and life sciences
- EFS is an associate member of Aviesan

Education

Carried out by universities, Campus EFS (the EFS training organisation), and the National Blood Transfusion Institute (INTS)



French National Agency for Medicines and Health Products Safety (ANSM)

- Certifies and inspects EFS regional establishments
- Controls LBPs
- Oversees the haemovigilance network



ÉTABLISSEMENT FRANÇAIS DU SANG

From donor to patient



French Fractionation and Biotechnologies Laboratory (LFB)

Fractionates plasma collected by EFS to manufacture plasma-derived medicinal products

ACTORS OF A PUBLIC CHAIN



French National Agency for Medicines and Health Products Safety (ANSM)

- **Competent authority**
- Certifies, inspects, controls, oversees Vigilance
- Defines **list and characteristics of labiles BP**
- **PDMP: Marketing authorisation**

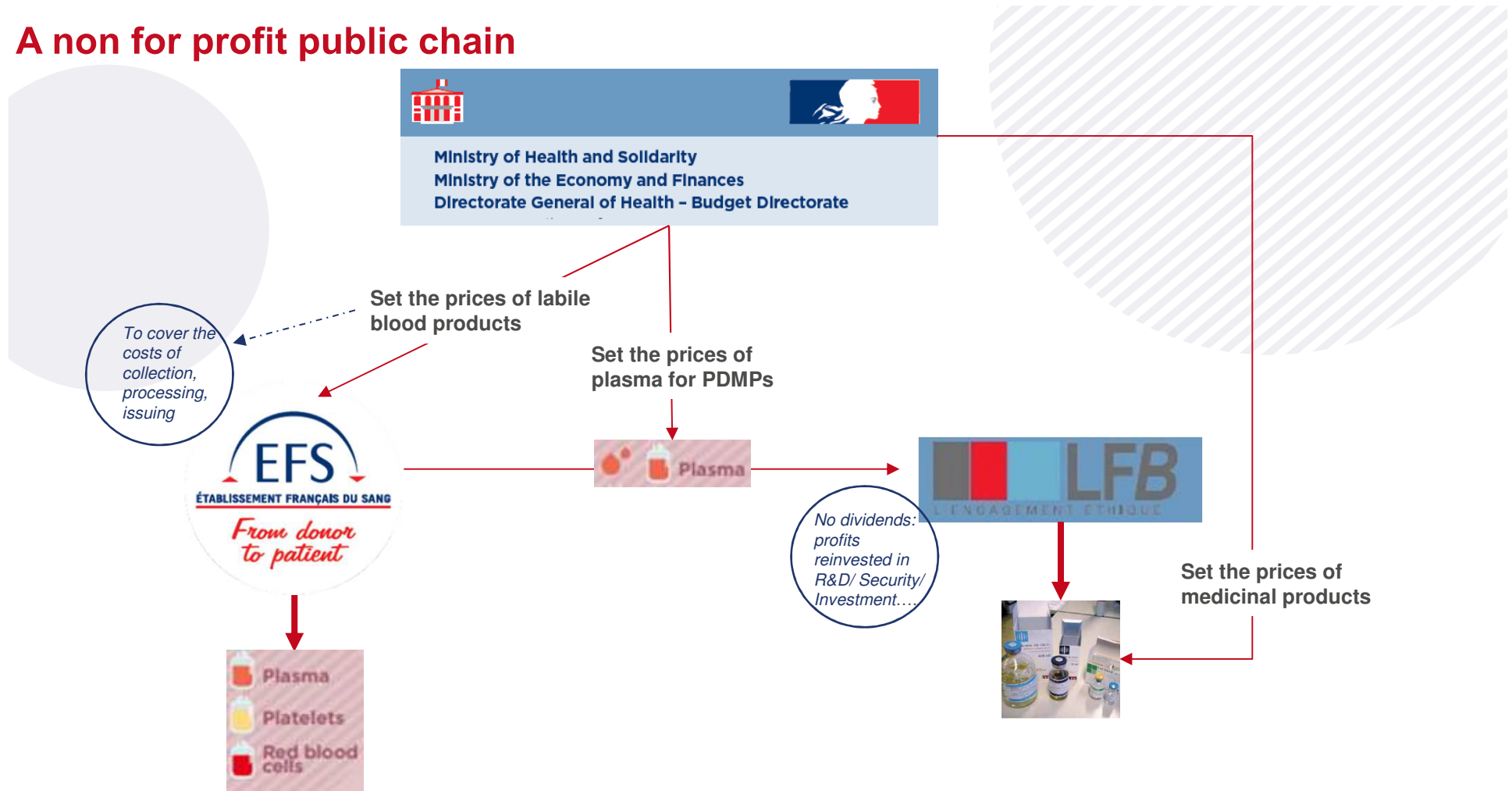


- **Unique civilian operator**
- **Collection/ processing and distribution-issuing:** RBC, PLT, Plasma
- **Public service mission:** ensuring self-sufficiency in blood products
- **Monopolistic**

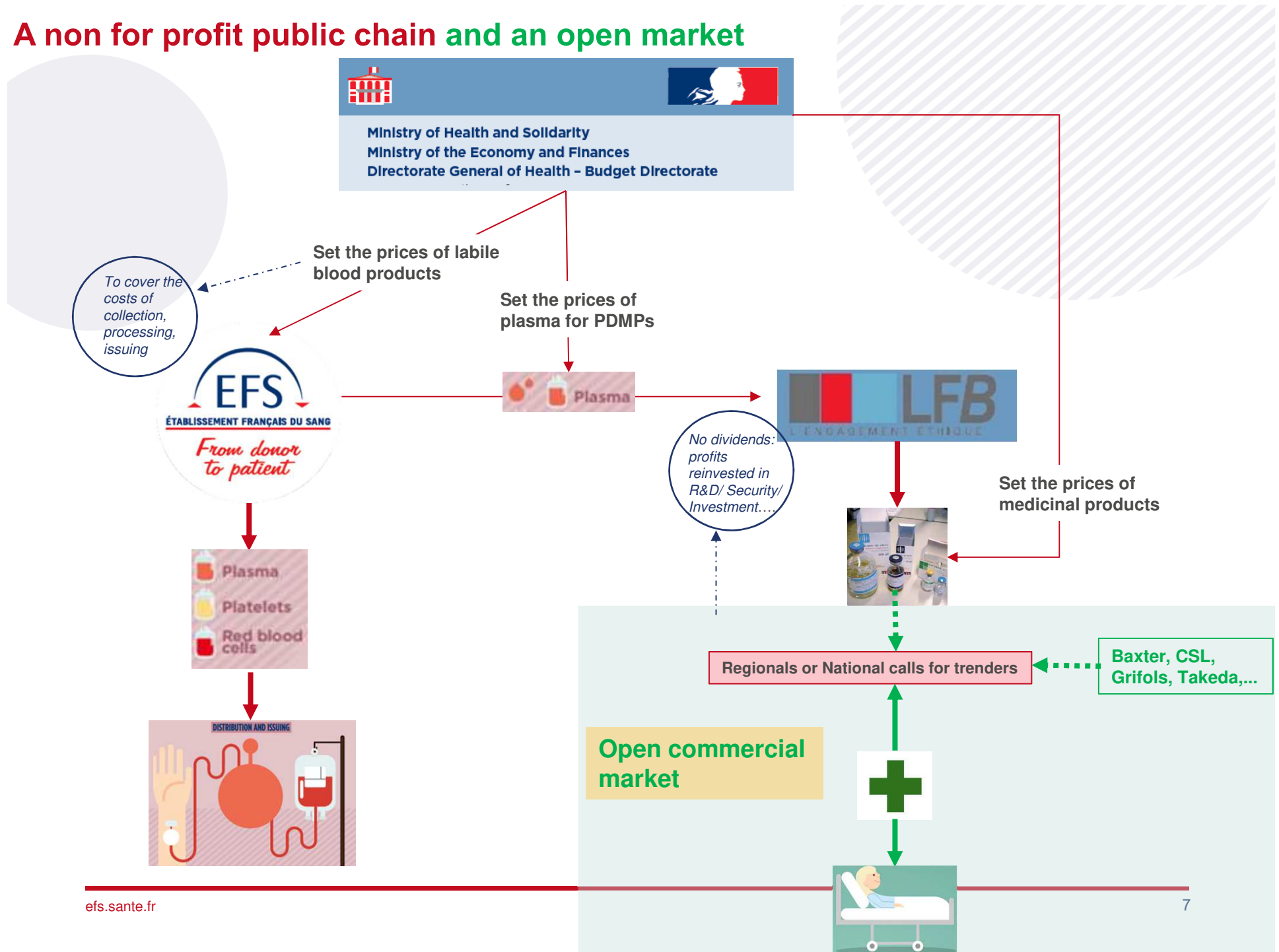


- **Unique pharmaceutical operator for fractionation** source or recovered plasma collected by EFS
- **Public health mission:** to meet national needs, in particular those related to the treatment of rare diseases
- **Non monopolistic** on French market (trends)

A non for profit public chain



A non for profit public chain and an open market



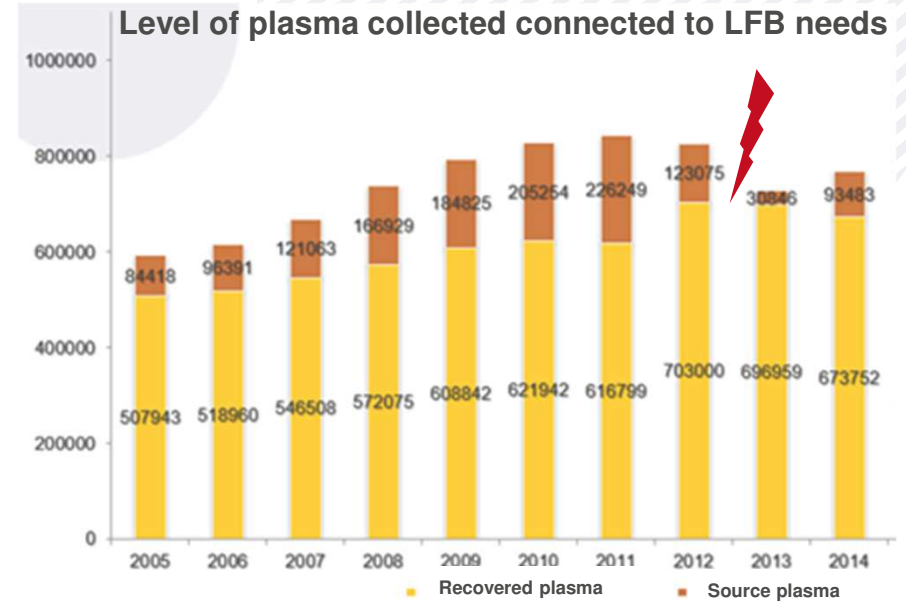
A LEGAL INTERDEPENDENCE

↪ EFS and LFB structurally linked

- EFS collect plasma for LFB
- LFB fractionate in priority plasma collected by EFS
- But the market is open

↪ Levels of plasma collection are therefore guided by

- Call for tenders win/lost by LFB
- LFB's capacities of fractionation
- And the capacity of EFS to collect enough plasma



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↪ LFB coverage of hospital needs (tenders):

- 75% of patients are treated with an LFB PDMP;
- Immunoglobulins market share (in volumes): 35%
- Public health mission in treatment related to rare diseases

↪ RBC demand is not growing in France

- Only source plasma can fulfil the increasing demand for PDMPs
- 900 000 plasma litres collected every years

Objective: increasing VNRD plasma collection to reduce international dependence and risks of shortages



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Immediate strategy

➔ Pluriannual conventions between operators :

- To adapt resources and mid-terms objectives
- EFS/ Health ministry
- LFB/EFS : to help development of the plasma collection offer, by offering greater visibility both to the EFS teams and donor's associations

➔ Toll manufacturing

- LFB's plasma stock mobilized to be fractionated by a European manufacturing partner
- To meet contractual obligations with the hospitals

➔ Ig prioritisation committee

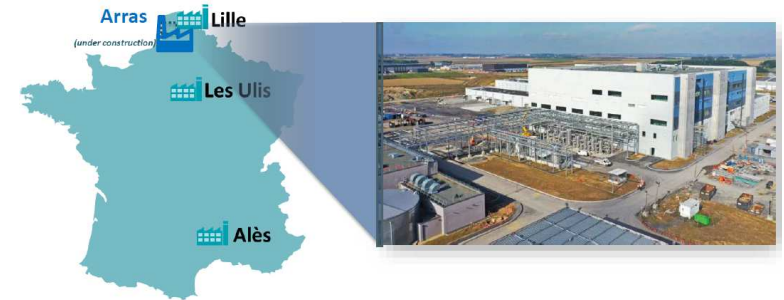
- Evaluation of priority levels in Ig indications

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Mid-term strategy: a national strategic plan

↪ LFB: New manufacture in Arras in 2024

- Will triple the production capacity



↪ EFS and Donors' associations

- “Plasma plan II” : to reach an objective of **1,4 million plasma litres collected in 2026**
- +300 000- 800 000 litres of source plasma /year
- Relying on **Fixed collection sites**: optimize existing ones or develop new ones
- **Increasing donor base**
- Imagine a **new strategy of communication** (social networks)



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Mid-term strategy: a national strategic plan

↪ Some issues

- Covid-19
- General shortage in medical/ nurse staff



Thank you

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