



# COUNTRY EXPERIENCES ON PDMPS CONTINGENCY

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**SPAIN**

# Background

## Current situation

- Decentralized country
- CCAA:
  - Ministry of Health
  - Regional governments



Centros de Transfusión (CT): 20

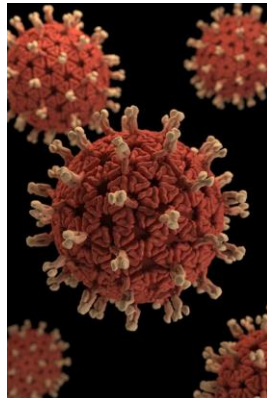


Suministro a hospitales:

**Servicios de Transfusión (488)**

# Background

- Blood supply (components and PDMPs) → especially **vulnerable** in **crisis** situations
- The **COVID-19 pandemic** highlighted the need for
  - effective contingency measures
  - alternative activity models for SoHO organisations (Blood Establishments)
  - to safeguard the safe supply of essential SoHO for clinical use
    - in routine
    - during catastrophic situations.



- Scientific Committee for Transfusion Safety (CCST)
- General Directorate of Public Health of the Ministry of Health

Strategic Plan for Self-Sufficiency in Plasma (PENAP)



**EBA-----PROYECTO SUPPLY**

# Plasma Plan (PENAP)

- aim:
  - **self-sufficiency** in plasma for the manufacture of PDMPs
- principles:
  - donation **based exclusively on Voluntary Non-Remunerated Donation (VNRD)**
  - plasma **obtention and its management will always be carried out within the framework of the public health system**
- Requirements:
  - Public intervention
  - Plasma: To be **in the general interest for our country and for Europe.**

**Blood components: 100% (30 years)**

**PDMPs: 34-70%**



# Plasma Plan (PENAP)

## Principles. VNRD

- VNRD → Possible and realistic → requires time → it's a long-term plan
- Rationale for VNRD:
  - 1.1. Better resistance to crises. The model with plasma supply in non-profit organizations has proven to be **more resilient** during the COVID-19 pandemic, and therefore the best way to guarantee the continuity of the supply of blood and components. Therefore, in a contingency plan like this one, it is the first element to consider.
  - 1.2. It has been proven that when investing in the appropriate programs within the public network, the required self-sufficiency **can be achieved**, and in a more economical way.
  - 1.3. As the best guarantee of **safety** for the donor and the recipient.
  - 1.4. It is essential to be able to guarantee access to treatment for all citizens (**guarantee equity**)
  - 1.5. For **ethical/legal reasons**. Article 3 of the Charter of Fundamental Rights of the European Union prohibits converting the human body and its parts, as such, into a source of economic benefit. The exploitation of the most disadvantaged people by for-profit companies must be avoided.
  - Furthermore, as experience has shown by some Member States, **paid donations in no way guarantee** the availability of products.

# PENAP

## Principles. VNRD

- VNRD → Possible and realistic → requires time → it's a long-term plan
- Rationale for VNRD:
  - **Better resistance to crises.**
  - **Better prices**
  - **Best guarantee of safety (donor and recipient)**
  - **Equity**
  - **Ethical/legal reasons**
  - **Availability of products.**



# PENAP

Principles. Public Health System

- Commitment of regional and national authorities.
- Consideration of plasma as a critical strategic product.
- **PDMP use → in the public sector → participation of public Blood Establishments network**
- **to allow equitable and sustainable access.**
- **Management and obtaining system:**
  - **Plasma obtained in BE → Toll manufacturing (“maquila”) → Companies return the obtained PDMPs → hospital pharmacies.**
  - **In this model, plasma always belongs to the public health system.**
- **Public programs + VNRD: more resistant**
- **Existing BE, based on the VNRD → progressively greater volume of plasma**
  - **without damaging or interfering with the operation of a public System**
  - **donor and recipient protection**
  - **supply of products in the long term**



# RESILIENCE AND GLOBAL COMPETITIVENESS



- **“Resilient EU2030” report**
  - **It highlights areas where supply problems could arise**
  - **Stressing that Europe should not try to produce everything it currently imports**
  - **Efforts should be directed at high-value sectors, as well as those that are “crucial for the survival”**
  - **It identifies strategic goods, services and raw materials in which the EU should increase its productive capacity between now and 2030.**

**“open strategic autonomy in Europe”**

**ROME, 23-24 APRIL 2024 “THE SUPPLY OF PLASMA-DERIVED MEDICINAL PRODUCTS IN THE**

**FUTURE OF EUROPE”**



# Granada Summit



- "we will reduce external dependence in other key areas in which the EU needs to establish sufficient capacity to guarantee its economic and social well-being, such as..., ***essential medicines and their raw materials...***".
- In this sense, human plasma as raw material is granted the status of critical material, recognizing the importance of the repeatedly referred to independence of Europe with respect to plasma.
- The Granada declaration **ratifies the high strategic value of plasma** in the general interest of public health.

# PENAP

- A) INCREASING THE DONOR BASE
- B) INCREASE PLASMA OBTENTION AS RAW MATERIAL
- C) CENTRALIZATION OF THE PLASMA FRACTIONATION AGREEMENT
- D) MONITORING THE USE OF IMMUNOGLOBULINS
- E) CAMPAIGNS



**PLASMA**  
*Tu generosidad*

Únete a la fábrica de la vida.  
Hazte donante de plasma.

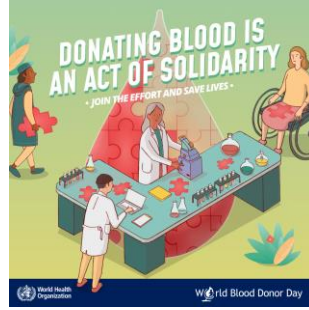
| Immunology  | Other  |
|---|--|
| Primary antibody deficiencies (A) <sup>104</sup>  | Kawasaki disease (A) <sup>105</sup>  |
| Specific antibody deficiency (GPP)  | Toxic epidermal necrolysis, Stevens-Johnson syndrome (no mortality benefit) <sup>106</sup> |
| Secondary antibody deficiency (including myeloma, CLL (RCT), drugs and other causes) (GPP) <sup>106</sup> | Immunobullous disease (A) <sup>107</sup>   |

in accordance with Cochrane reviews<sup>105</sup> A = level A or established evidence-based

# PENAP

Contemplated actions

- A) INCREASING THE DONOR BASE
- B) INCREASE PLASMA OBTENTION AS RAW MATERIAL



Algunos enfermos necesitan medicamentos que se obtienen del plasma.

donor

Plan base

ors



DVNR

≤12 /YEAR

In Spain,

- 1200000 WB: 1.8/donor-year +
- 200000 plasma: 4-5/year

## Needed Donors

PLASMA QUE LLEVAS DENTRO.

PLASMA DONANDO

- the overall strength of blood and PDMPs supply

Sp ca

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providing a higher plasma quality (immunoglobulin content)



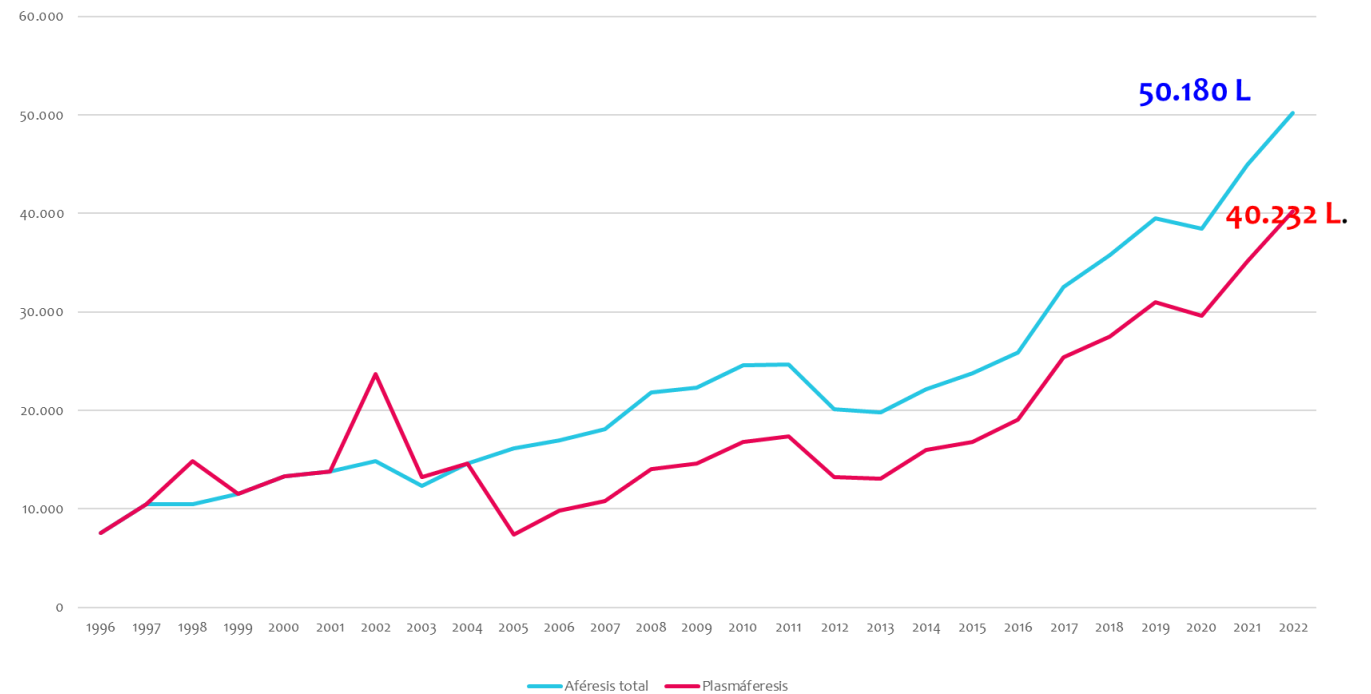
# PENAP

Contemplated actions. INCREASING PLASMA OBTENTION AS RAW MATERIAL

- recommendation to the regional health authorities:
  - priority objective of BE: sufficient PDMP from regional plasma.
- Plasmapheresis programs
- FACILITATING CITIZEN ACCESS TO PLASMA

Our current need: : **20 L/1000 inh/year**  
(now: 10/1000 inh/year)

APHERESIS PLASMA. 1996-2022





# PENAP

## Contemplated actions. FACILITATING CITIZEN ACCESS TO PLASMA DONATION

- Investment in mobile plasma units
- Study of new organizational formulas





# PENAP

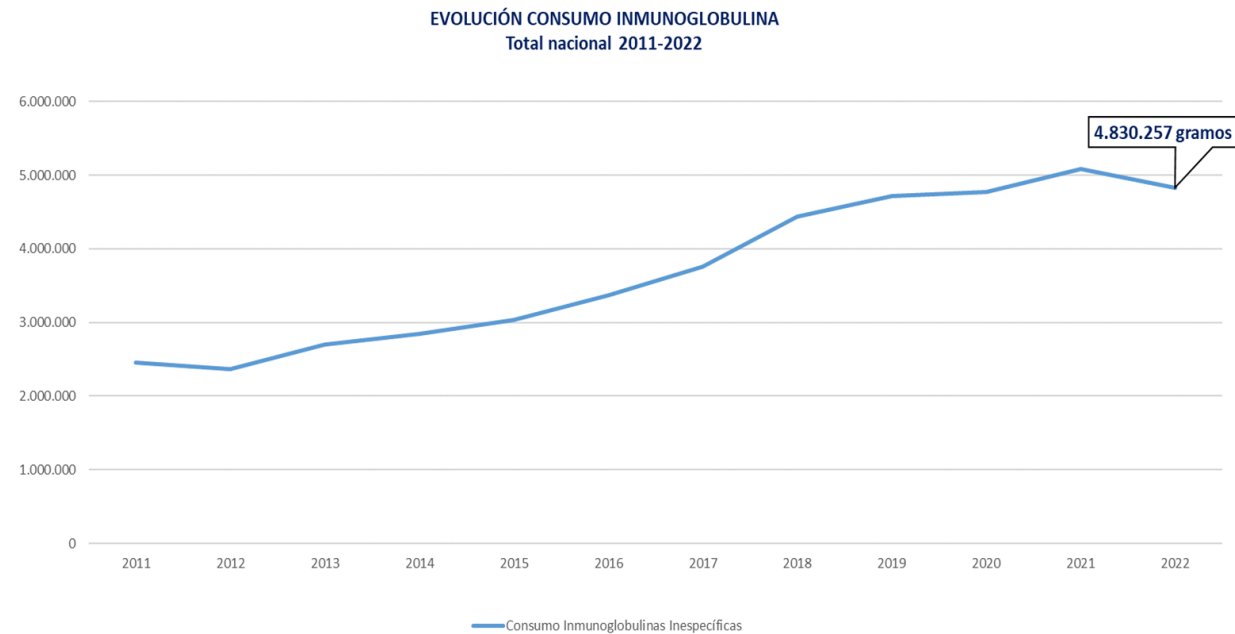
Contemplated actions. CENTRALIZATION OF THE PLASMA FRACTIONATION AGREEMENT

- Better plasma yields.
- A more stable and frequent supply of blood products.
- Better plasma quality.
- Possibility of expanding the product portfolio
- Reduced Plasma losses
- Better economic conditions (significant savings)
- Better use of the plasma donated by our citizens

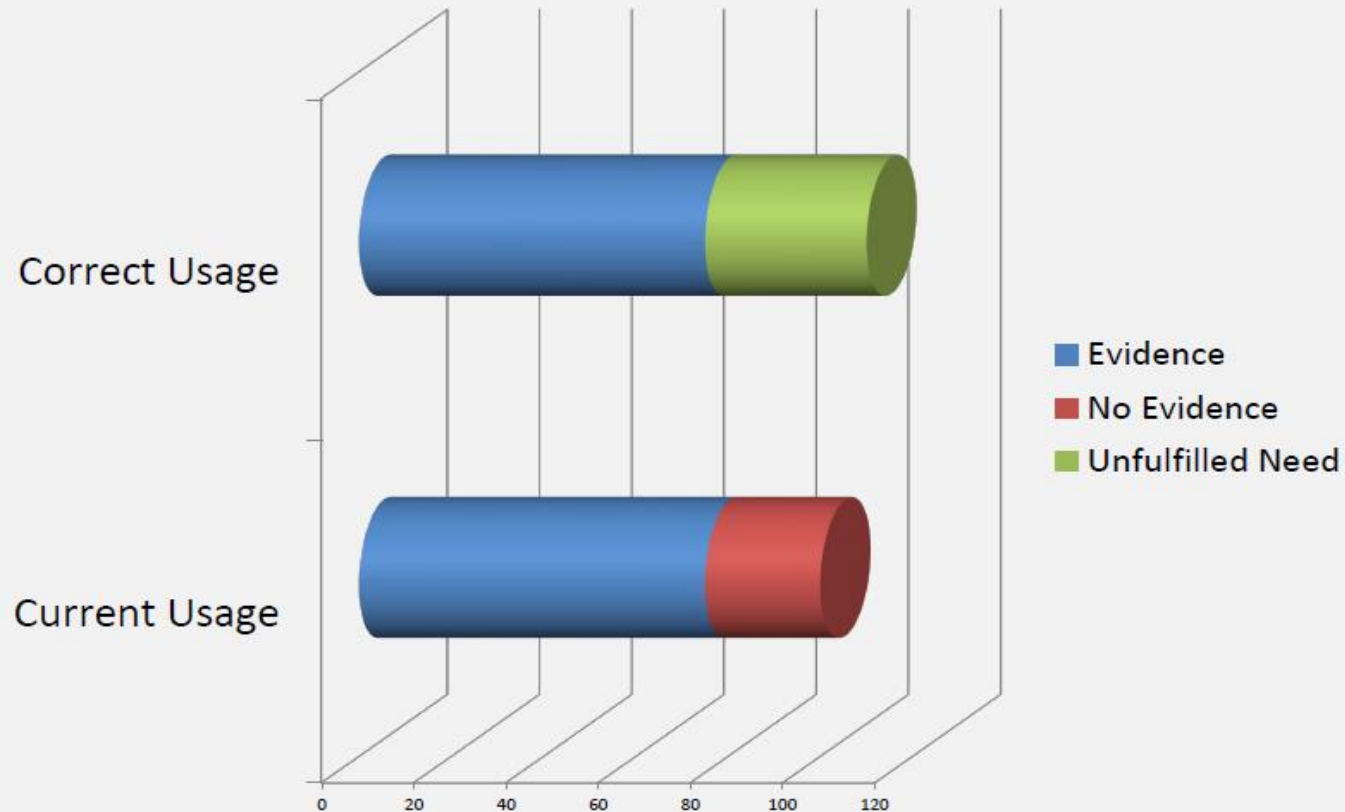
# PENAP

## Contemplated actions. MONITORING THE USE OF IMMUNOGLOBULINS

- control of the use of PDMPs (IG)
- Improving the quality of IG indications
- monitor the use of immunoglobulins

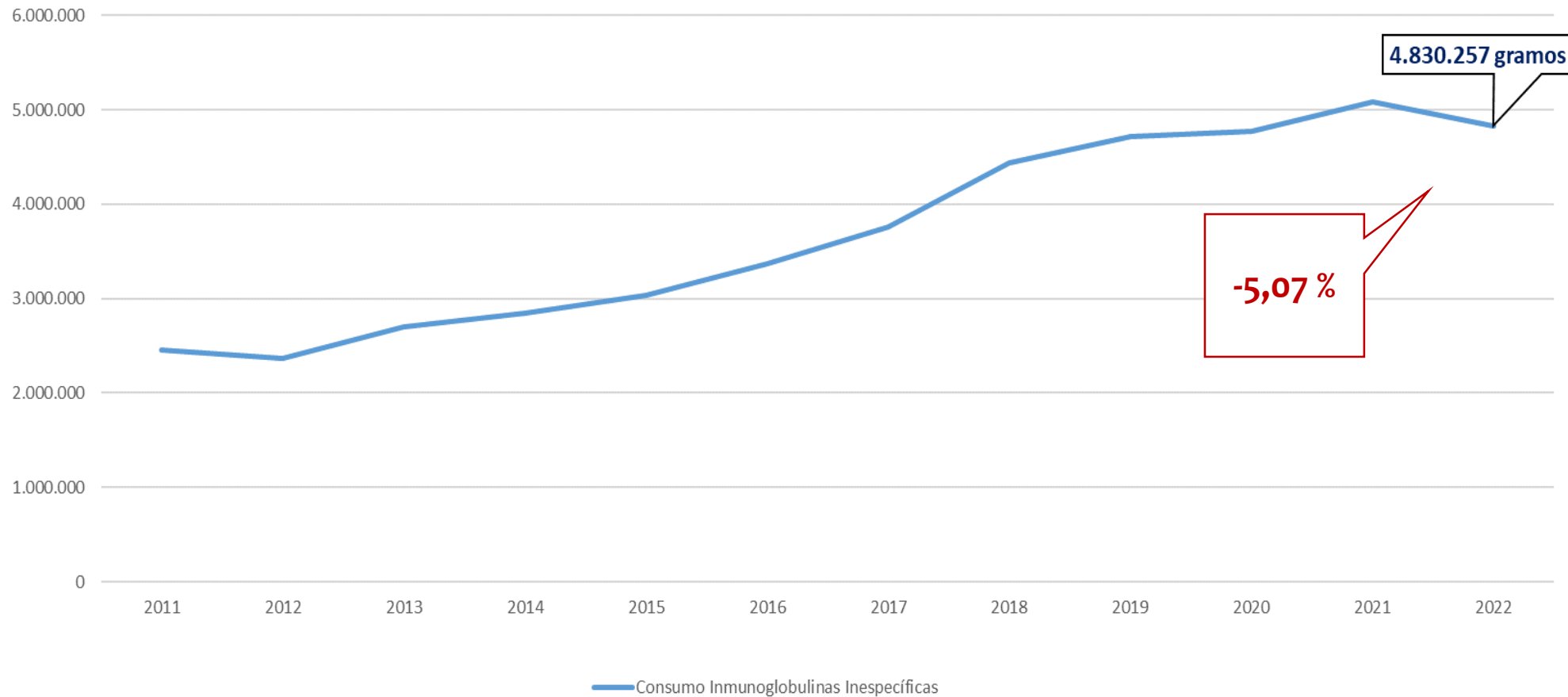


## The Other Gaps



# Consumo HD

EVOLUCIÓN CONSUMO INMUNOGLOBULINA  
Total nacional 2011-2022



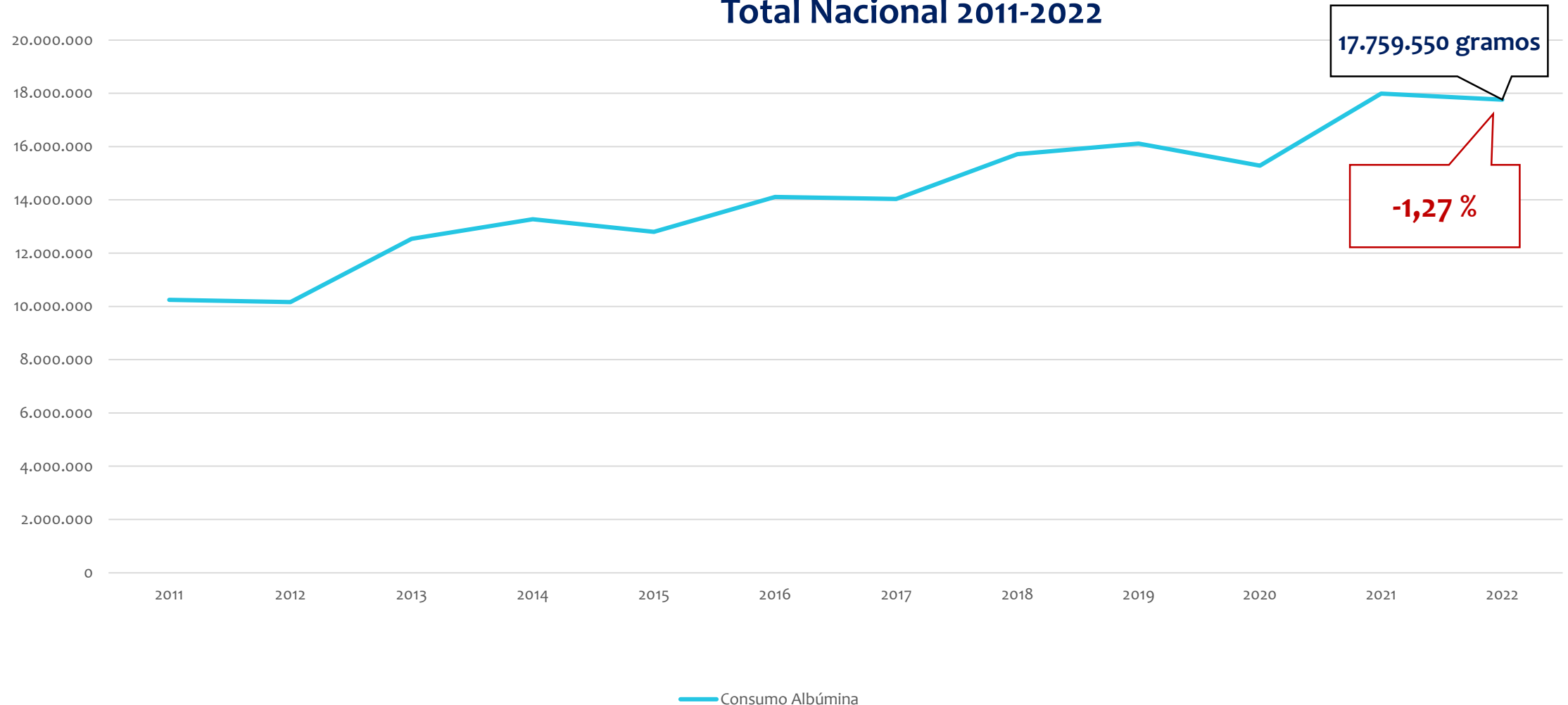
Fuente: Sistema de Información del Sistema Nacional para la Seguridad Transfusional (SI-SNST). Ministerio de Sanidad

ROME, 23-24 APRIL 2024 "THE SUPPLY OF PLASMA-DERIVED MEDICINAL PRODUCTS IN THE

FUTURE OF EUROPE"

# Consumo HD

## EVOLUCIÓN CONSUMO ALBÚMINA Total Nacional 2011-2022



Fuente: Sistema de Información del Sistema Nacional para la Seguridad Transfusional (SI-SNST). Ministerio de Sanidad

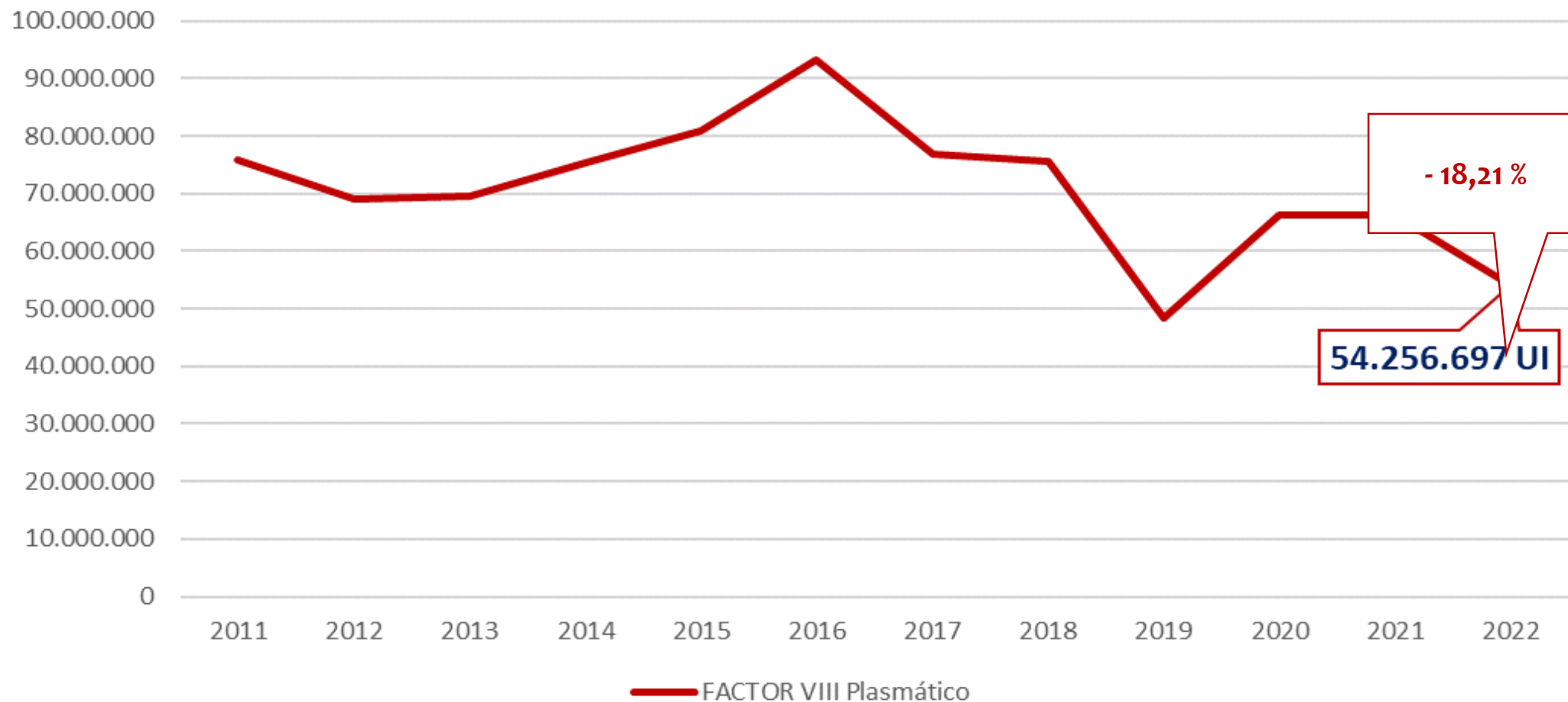
ROME, 23-24 APRIL 2024 "THE SUPPLY OF PLASMA-DERIVED MEDICINAL PRODUCTS IN THE

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# Consumo HD

EVOLUCIÓN CONSUMO FACTOR VIII PLASMÁTICO  
Total nacional 2011-2022



Fuente: Sistema de Información del Sistema Nacional para la Seguridad Transfusional (SI-SNST). Ministerio de Sanidad

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# PENAP

Contemplated actions. CAMPAIGNS

- Raise awareness among the general population and the donor population about the need to donate plasma, creating committed and supportive attitudes.
- Inform about treatments manufactured from plasma and
- Increase the number of plasma donors and achieve their loyalty



# Gracias

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CENTRO DE TRANSFUSIÓN  
DE LA COMUNIDAD  
VALENCIANA

