

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

Second edition

23-24
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Rome, Italy

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Ministero della Salute

Insights on PDMPs availability

Leni von Bonsdorff

IPFA, The Netherlands

Disclosure

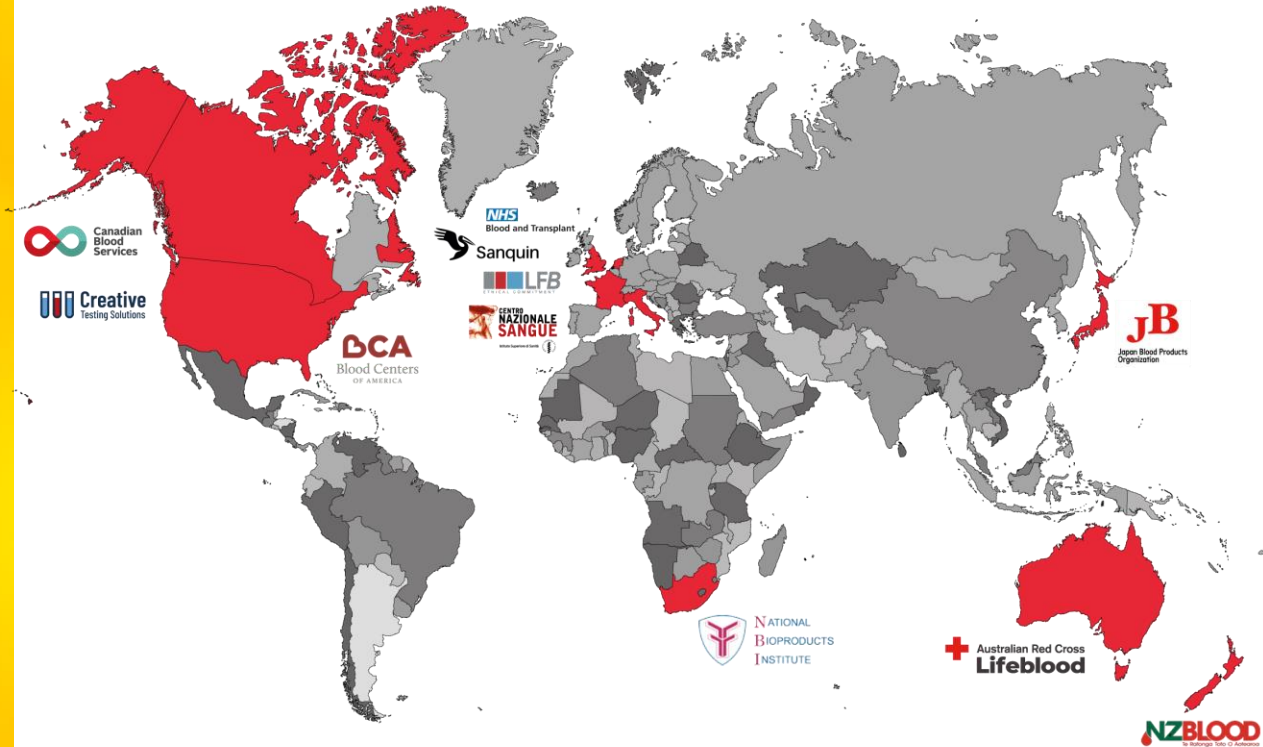
- Executive Director of IPFA



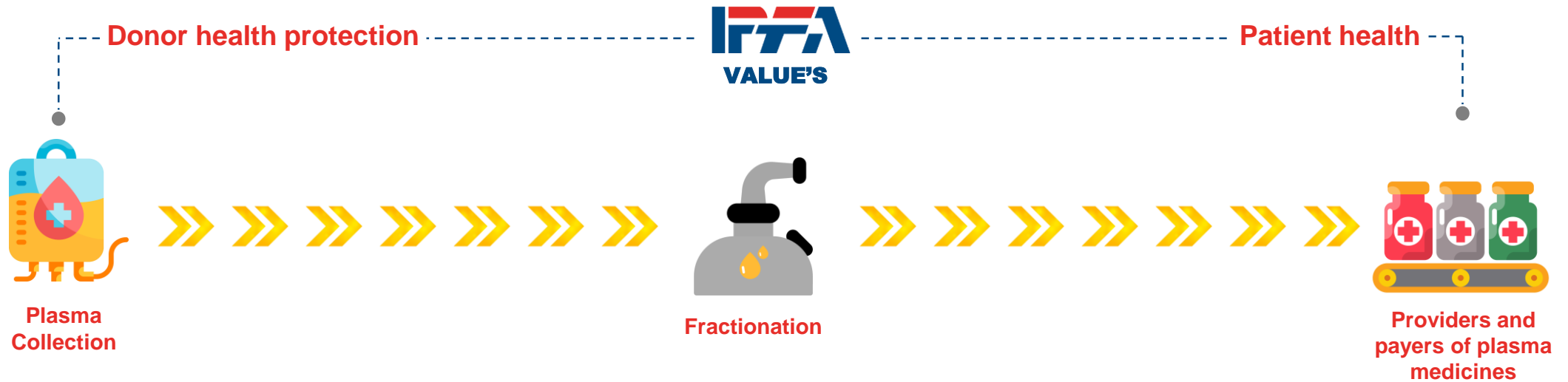
IPFA, our mission

IPFA supports and promotes the activities of not-for-profit organisations around the globe engaged in the fractionation, collection, and testing of plasma to enable robust, safe supply and patient access to plasma derived medicines.

Through education and collaboration with stakeholders, we advocate for public health values and donor health protection.



Our vision



IPFA's goal is for plasma to be acknowledged as a

- **strategic resource within public health care systems**, underpinned by a
- **safe and reliable contribution from the public sector** both in providing the plasma and arranging for access to plasma-derived medicinal products.

International, local, and regional events



Joint IPFA/ISBT workshop on Plasma fractionation and stepwise access to PDMPs Cape Town Nov 2023

Encuentro Internacional de Hemoderivados



Encuentro Internacional de Hemoderivados con personalidades latinoamericanas vinculadas al desarrollo, producción y usos de productos medicinales derivados del plasma, financiado por el Programa Adelante-2 de la Unión Europea, auspiciado técnicamente por la Organización Panamericana de la Salud (OPS) y convocados por Laboratorios AICA como anfitrión.

La cita tendrá lugar del 9 – 11 abril en la Habana, Cuba con la participación de representantes de México, Argentina, Brasil, Costa Rica, El Salvador, Colombia, Honduras, Guatemala y IPFA (Asociación Internacional de Fraccionadores de Plasma).



EVENTO

Entre la independencia estratégica y la seguridad farmacéutica:

Producción local de medicamentos derivados del plasma

MARTES 24 OCTUBRE 8:30 a.m - 16:30 p.m

LUGAR Cámara de comercio de Bogotá - Sede Salitre

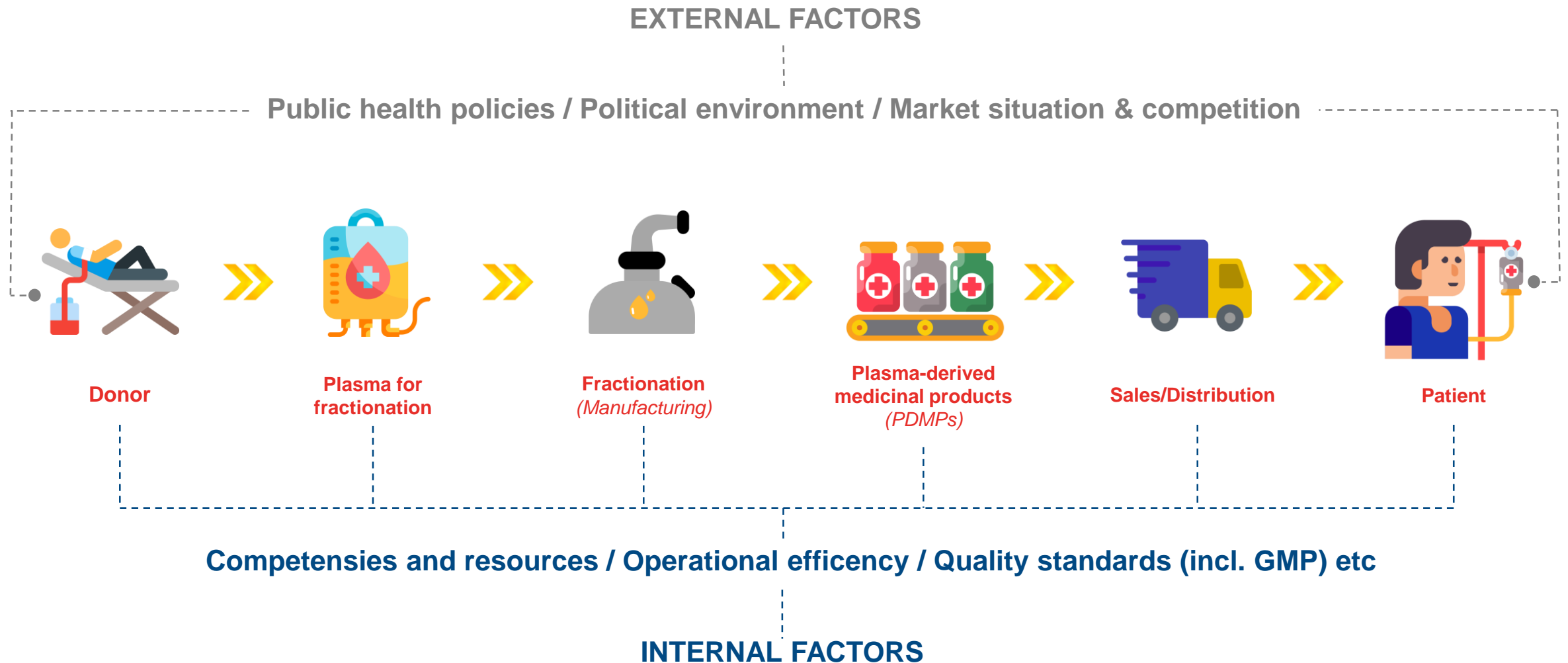
CENTRO DE PENSAMIENTO Medicamentos, Información y Poder

IPFA

UNIVERSIDAD NACIONAL DE COLOMBIA



The complex plasma value chain

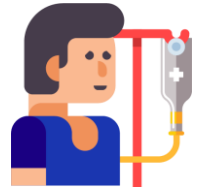


Arrangements for supply of plasma and access to PDMS





Original model





Domestic Plasma



Domestic Country



PDMP



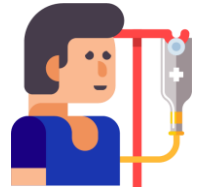
Patients within public health care



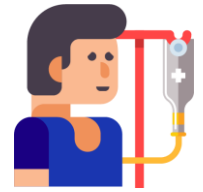
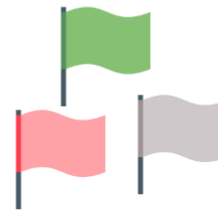
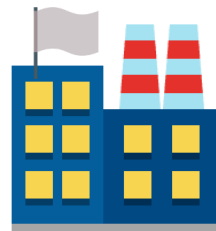
Other Countries



Original model



Sales of plasma / PDMPs from market

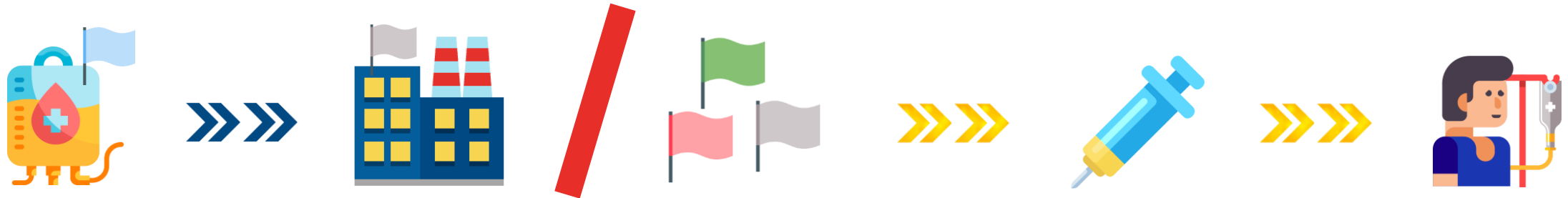




Original model



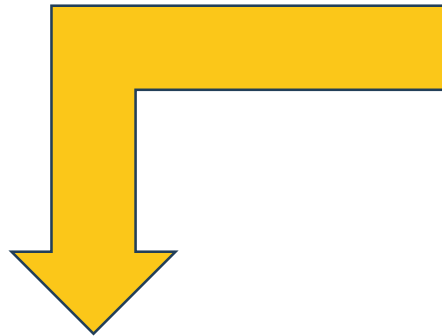
Sales of plasma / PDMPs from market



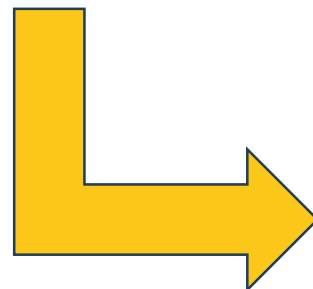
Mixed models, including access to PDMPs from domestic plasma



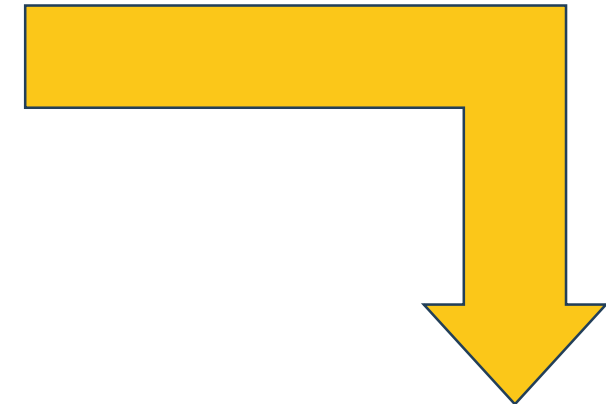
Examples of models in Europe



No European country
(USA)
(Cuba)



Belgium
Denmark
France
Italy
Netherlands
Portugal
Spain



Czech R
Finland
Sweden
...

Ref: SUPPLY project WP4.5 reoport, IPFA

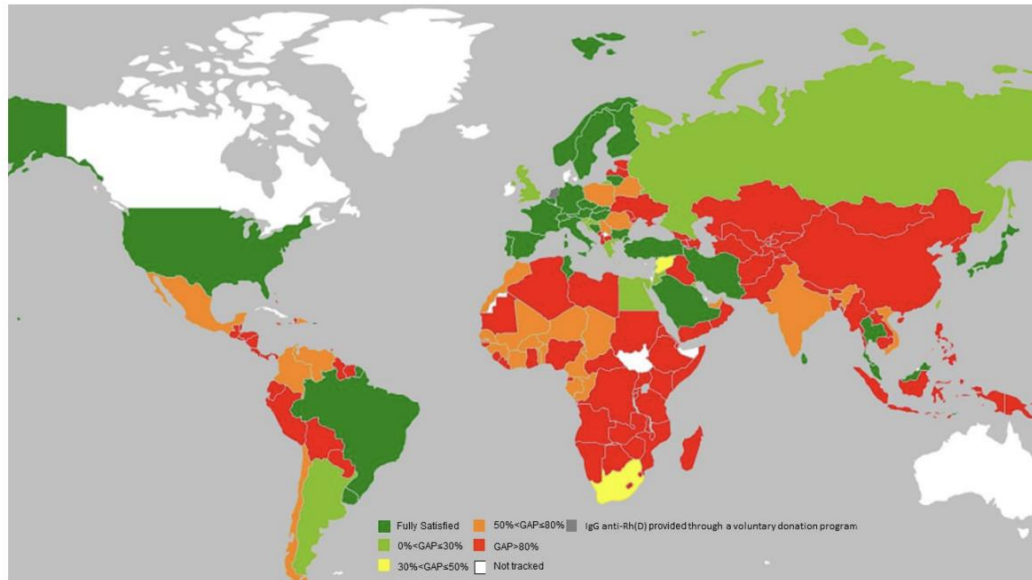


Can we have a common European Anti-D plasma programme?

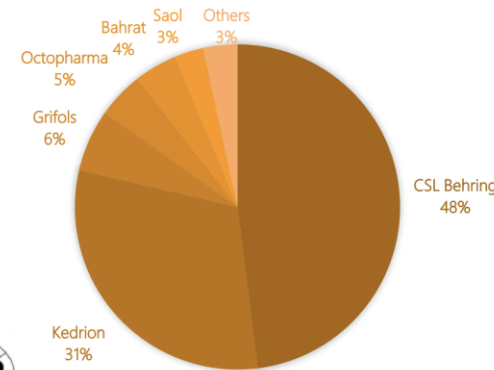
*C. Ellen van der Schoot, Sanquin Research, Amsterdam, NL
on behalf of the TS119 Anti D Working Group of CD-P-TS*

Presented at IPFA/EBA Symposium of plasma collection and supply, Leiden 2024

Gap between demand and supply: 50% of the women do not get anti-D



Total market of Rh immunoglobulin 4.4 x 10⁶ Units (2020)



All current anti-D IgG licensed in EU are national MA (no central MA)



Pegoraro V et al
PLoS ONE 2020;15: e0235807

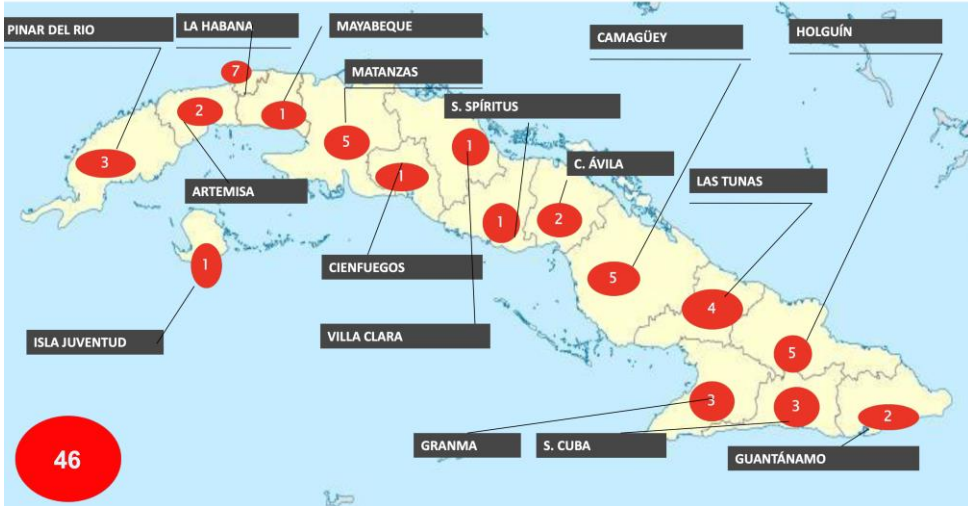
Summarizing remarks and conclusions

- Worldwide shortage of anti-D : more anti-D donors are needed
- Recruitment of donors naturally immunized by pregnancy might be considered
- Europe is completely dependent on US plasma
- European anti-D plasma collection is needed, but to become cost-effective harmonization of European Hyperimmune IgG requirements is needed in order to make pooling of plasma possible

- Programmes for plasma (recovered and plasmapheresis)
- Programmes for hyperimmune plasma
- Produce IVIG and hyperimmunoglobulins with same manufacturing process

A model for others, we should continue efforts for better hyperimmune programmes and manufacturing in Europe!

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CENTROS DE PLASMAFERESIS. DISTRIBUCIÓN NACIONAL



DONANTES ESPECIALES DE PLASMA HIPERINMUNE.

Provincias	Anti-D activos	Anti Hepatitis B activos	Anti Tetánico activos
Matanzas	1		
Cienfuegos			10
Sancti Spiritus	2		18
Villa Clara		9	20
Ciego de Ávila	8 (inmunización)		
Camagüey		19	
Las Tunas	8		
Granma	16	7	
Holguín	19		27
Sgto. de Cuba	8	23	
Guantánamo		26	17
TOTAL	54 (activos)	84	92

Ref: Porto Gonzales DE Programa nacional se sangre y plasmaferesis en Cuba estrategias para garantizarlo, at International meeting of hemoderivatives, Cuba 9-11 April 2024

IPFA/PEI 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens

15-16 May 2024 | Aarhus, Denmark



Registration and full programme on our website www.ipfa.nl





Thank you!

For more information about IPFA, please visit our website: www.ipfa.nl
or send an email to info@ipfa.nl

Thank you

