

Istituto Superiore di Sanità



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

**28-29** April 2022 – Rome, Italy



in collaboration with



with the patronage of



Ministero della Salute

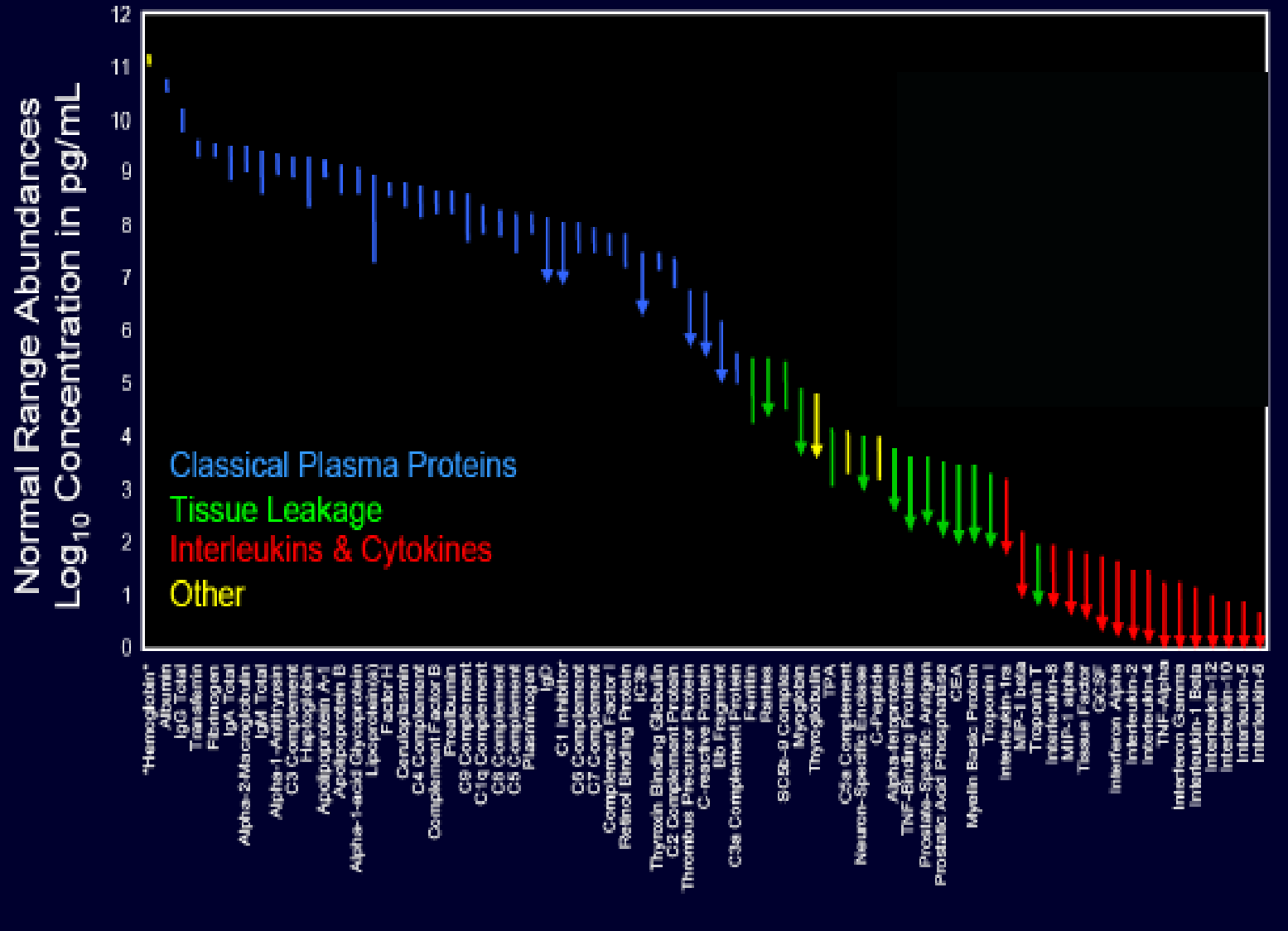


# Take home messages

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National Institute of Health, Rome

**28-29 April 2022**



- albumin	(47)	- fibrinogen	(7)
- immunoglobulin (G)	(40)	- thrombin	(3)
- IgM	(1)	- fibrin sealant	(9)
- factor VIII	(26)	- prothrombin complex	(15)
- factor IX	(16)	- activated prothrombin	
- factor VII	(2)	complex	(1)
- factor XI	(2)	- antithrombin	(14)
- factor XIII	(1)	- alpha-1 antitrypsin	(5)
- protein C	(2)	- C1-inhibitor	(2)
- activated protein C	(1)	- haptoglobin	(1)
- von Willebrand factor	(3)	- SD-plasma	(3)

# PLASMA IS «ESSENTIAL»...

- Very different patterns of use of products, with huge variations (relative percentage in the use of drivers – albumin and Ig) in Europe and in the rest of the world
- Questionable adherence to guidelines by prescribing physicians: need of tools (IT) to monitor the appropriate prescription of PDMPs
- Real life experience, to observe the effective use of products

# PLASMA IS «ESSENTIAL»...

- Usage: not only the level of lacking protein, but more the quality of life
  - On demand (bleeding control, mortality prevention)
  - prophylaxis (replacement therapy)
  - genetic cure
- Rare disorders – low frequency drugs are ethical urges
  - low frequency does not mean less importance
  - better understand the prevalence of disorders (underdiagnosis and misdiagnosis)
- Prioritization of distribution in case of shortage: it is a responsibility of regulatory agencies to define the priority but the involvement of clinicians and patients' organization is needed

# PLASMA IS «STRATEGIC»

- The system is complex and there is a “long journey from the vein of the donor to the vein of the recipient; we need to create strong links among all the actors
- Donor organizations, to understand how important is to increase the number of plasma donors and to recruit new donors (female....)
- Blood Establishment, to implement a good quality system and GPGs, to not waste plasma for fractionation
- Biopharmaceutical companies, to optimize the yield of driving products (increase yield in driving products....)
- Clinicians, to adhere to evidence-based use of products under guidelines formulated on the basis of well-designed, sufficiently powered and unbiased independent studies

# PLASMA IS “PRICELESS” BUT NOT “COSTLESS”

- We need to define the target for self-sufficiency and to consequentially adopt programs to achieve this result
- Models for ensuring collection and fractionation of national plasma differs among the Europeans countries (and also in the rest of the world)
- As a matter of fact, the contribution of the private sector is necessary to guarantee a regular supply of PDMPs to patients.
- *However.....*
- The plasma collected by the public sector is strategic for the countries and its contribution to self-sufficiency must be increased
- Countries must guarantee the financial sustainability of the program and BEs must care the cost of production

• **DIFFERENT MODELS, BUT ONE GOAL: SAFE AND SUFFICIENT PDMPs FOR**

# ...In the future of Europe

- EU: a revision of the BTC legislation (strengthening supply, monitoring emergency supply preparedness, removing causes of inequality in safety and quality across the EU)
- The importance of European bodies (CoE, EMA...) in ensuring Quality, safety and efficacy of medicinal products and providing recommendations to prevent or manage shortages of medicinal products
- The SUPPLY project will help increase the resilience and strengthen the unpaid plasma collection capacity in Europe
- The Governments must take the responsibility that there are rules in place to ensure that products from plasma collected in a country don't just follow the path of the price....

# PLASMA IS “HUMAN”

- **“Gratis accepistis, gratis date”**
- (You have taken freely, give freely. Matthew 10:8)
- **"Pecunia non olet"**
- (money doesn't stink, Vespasian)
  
- How to guarantee sufficient plasma for a safe and appropriate care of patients
- *Without...*
- “paving the way for the marketing of all tissues and cells” (R. Titmus, “The gift relationship”, 1970)





**Thanks to  
speakers,  
chair  
persons  
and  
attendants**



**Thanks  
to all the  
people at  
the CNS  
that  
made  
this  
meeting  
possible**

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