


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

28-29 April 2022 – Rome, Italy



in collaboration with 



Plasma supply and PDMPs manufacturing Case Finland

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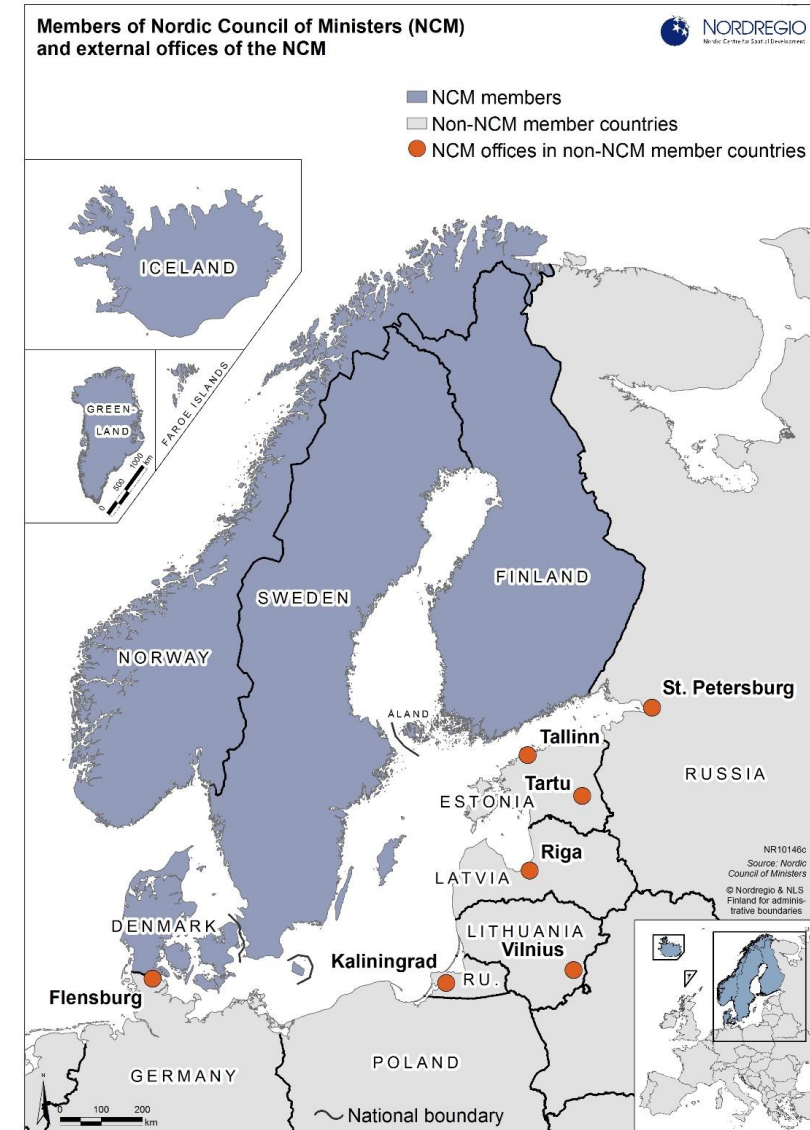
Finland facts

- Nordic country
- 5.5 M people
- Ranking happiest country in the world for last 5 years (to our continuous surprise...)

WORLD HAPPINESS REPORT (2022)

| RANK | COUNTRY |
|------|---|
| 1. |  Finland |
| 2. |  Denmark |
| 3. |  Iceland |
| 4. |  Switzerland |
| 5. |  Netherlands |

Source: United Nations Sustainable Development Solutions Network



Long history of fractionation

1947-48

Scientists Uroma and Vahvaselkä at Cohn's lab to learn technique

1951

Fractionation started small scale at the National Health Institute

1972

Fractionation increased and moved to Finnish Red Cross Blood Service based on Dutch CLB method

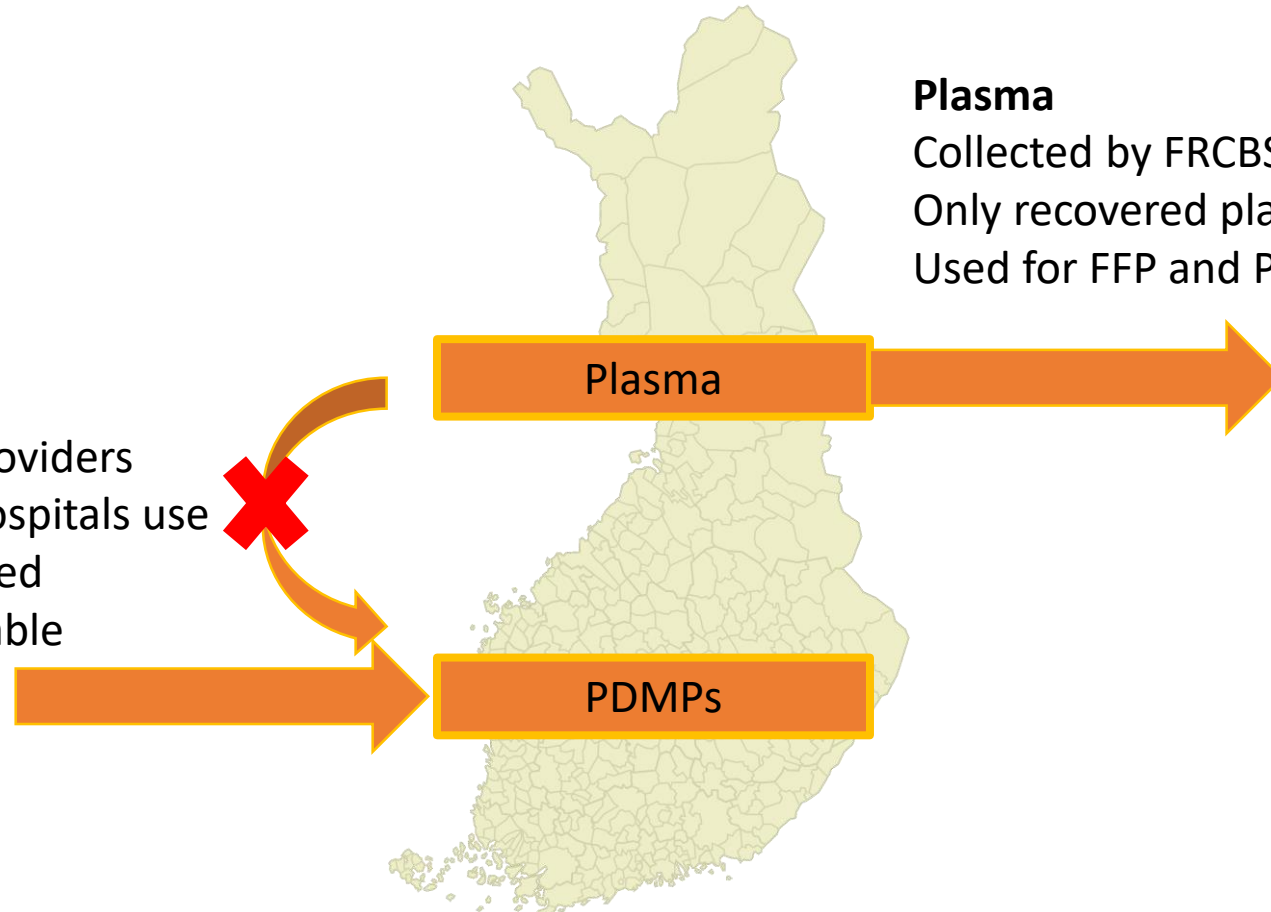
2004

FRC closed down the facility and PDMPs imported from Sanquin and others

Plasma and PDMPs today

PDMPs

Imported from commercial providers
Hospital districts tender for hospitals use
Home care products reimbursed
Normally, a broad range available



Plasma

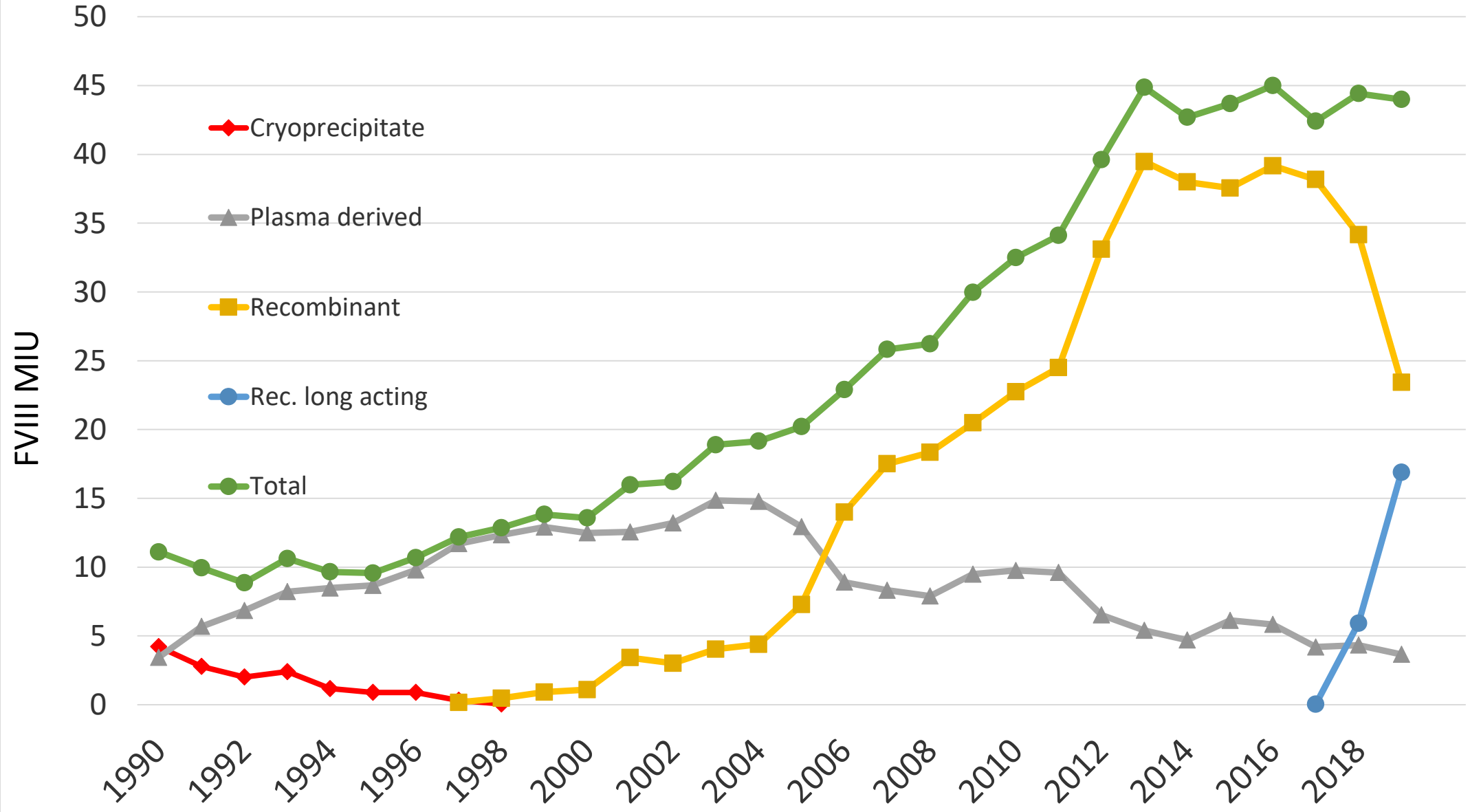
Collected by FRCBS (only)
Only recovered plasma
Used for FFP and PDPM production elsewhere

Plasma derived medicinal products in Finland

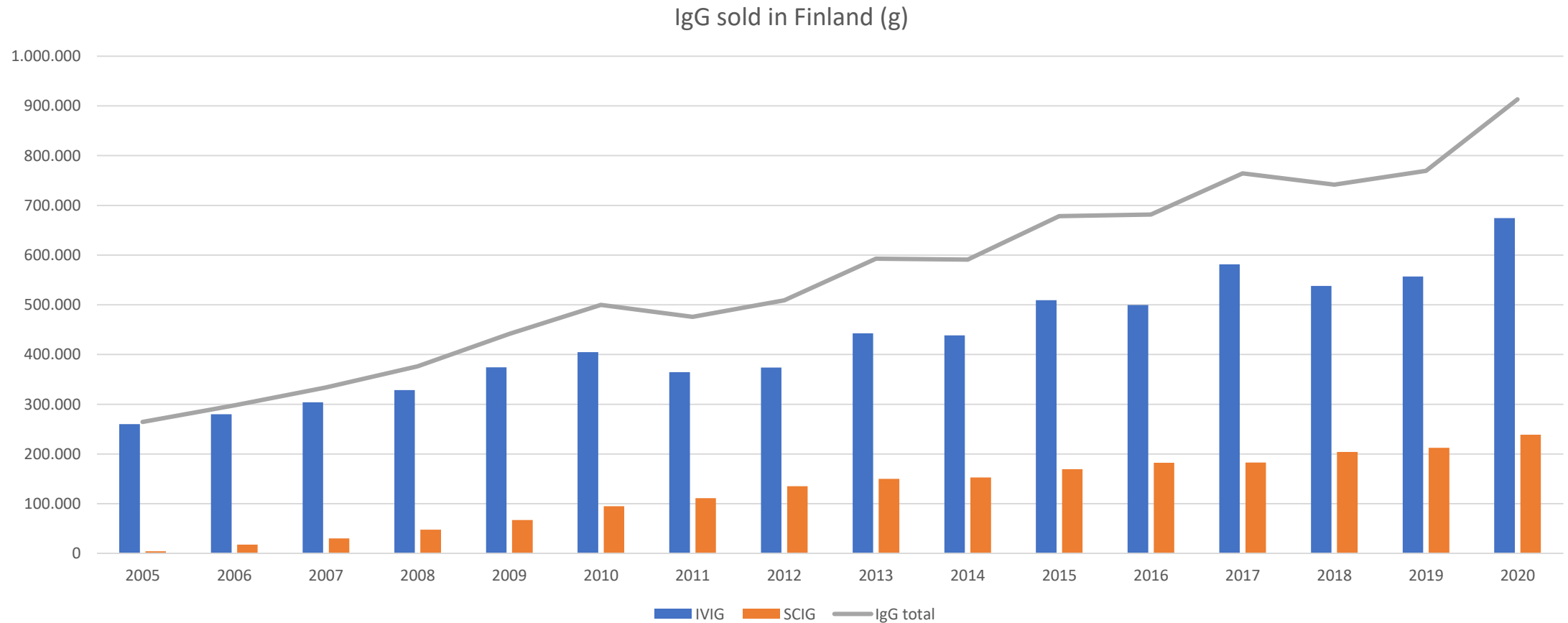
Long experience and use of:

- Albumin, increasingly since mid 2010's, now stabilising
- Coagulation factors:
 - pd-FVIII, pd-FIX not much anymore due to rec and other products
 - vWF, stable use
 - Fibrinogen, stable use
 - PCC for warfarin reversal, going down
- Rare diseases:
 - C1-inhibitor, going down due to new treatment options
 - Alpha-1-anitrypsin, very little and only hospital use
- IgG, increasing!
- Hyperimmunoglobulins from plasma (tetanus, varicella, HepB...), still used but sourcing can be challenging

FVIII Replacement therapy in Finland until 2019



IgG use in Finland



IgG usage 2020

- 913 kg IgG of which 675 kg IVIG and 239 scIg (26%)
- Per capita use: 166 g/1000 inh
 - Highish, compared with US and Canada 300 and Europe France >200 and Germany >100

All indications described in product SPC are treated, either in home care (scIgG mainly for for PID) or in hospital setting (with IVIG)

Noteworthy:

Selenius et al: Unexpectedly High Prevalence of Common Variable Immunodeficiency in Finland. Front Immunol. 2017 Sep 28;8:1190

“The prevalence of CVID in Finland appears the highest recorded, likely reflecting the genetic isolation and potential founder effects in the Finnish population.”



HUOLTOVARMUUSKESKUS
FÖRSÖRJNINGSBEREDSKAPSCENTRALEN
NATIONAL EMERGENCY SUPPLY AGENCY

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Security of supply of PDMPs

- Only legislated method is the mandatory stock-piling of medicines, includes PDMPs, as part of national emergency supply system
- Importer has to keep 6 months stock of IgG and 10 months of albumin
- Currently (2021 and 2022), no obligation for IgG due to supply constraints during pandemic (ministerial decision)
- Pros and cons with such a system
 - + always some supply
 - + importers are compensated
 - + use in crisis
 - no connection with plasma supply
 - barrier for import
 - use in crisis



The Big Read **Geopolitics** + Add to myFT

War with Russia? Finland has a plan for that

For decades, the country has harnessed every level of society to prepare for the possibility of conflict with its neighbour



Richard Milne in Helsinki MARCH 28 2022

564

Financial Times 28.3.2022

Situation with PDMP supply today

Today: PDMP supply is

- "Critical for several PDMPs. We work with one months stock of IgG" (comment from large hospital purchase area)
- prices are going up,
- fewer providers,
- less interest in tendering

Balance btw plasma collection/IgG usage:

- To cover for 900 kg IgG, 200-230.000 l of plasma is needed
- Collected recovered plasma today about 50.000 l
- => plasma collection has stayed at the same level as in 2005 whereas IgG use has tripled

Plasma strategy for Finland in discussion, but progress slow

Interest at FRCBC to collect plasma

But there has to be a true public health interest (and political will) to get it started!

Conclusions

- With a long history and know-how of plasma fractionation, Finland is now highly dependent on import on PDMPs and the national plasma supply is not linked to this import
- Products are available, but there are clear challenges in supply, especially of IgG
- The mandatory stockpiling of PDMPs, as part of the national emergency supply system is not sufficient to ensure a stable supply, and has no connection with the plasma supply
- There is an interest to find a better long-term solution for increased plasma collection but progress is slow and needs support and initiative from the government

Thank you!
Kiitos!
Tack!

