

The demand for plasma-derived medicinal products in Italy

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

28/29
April 2022
Rome, Italy

Disclosure

I hereby declare that I have neither financial nor non-financial relationships related to any of the products or services described, reviewed, evaluated or compared in this presentation.

Agenda

- The Italian Blood System and PDMPs
- The demand for (some) PDMPs in Italy
- ...

The Italian Blood System and PDMPs

Law no. 219 October 21, 2005

Founding Principles

Art. 1 National Self-sufficiency

Self-sufficiency of blood and blood products, including PDMPs is a national supra-regional strategic goal, i.e. independent of the regionalised organization of health-care delivery

Art. 2
VNRB donation
PDMPs production is part of Transfusion medicine activities

Art. 5
Transfusion medicine activities (including the PDMPs production) are BHCLs

Art. 15
(PDMPs production)

4
Ministerial Decrees
April 12, 2012

Ministerial Decree
December 5, 2014

Art. 16
(import-export)

State-Regions Agreement
February 7, 2013

Ministerial Decree
December 2, 2016

Instruments

State-Regions Agreements
October 20, 2015
June 17, 2021

State-Regions Agreement
February 7, 2013

Lgs.D
261/2007

Art. 26

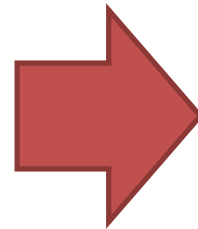
Ministerial Decree
December 2, 2016
Plasma and PDMPs
National Plan
2017 - 2021

National self-sufficiency of PDMPs

“[...] to provide patients, in a systematic and sustainable way, with the prompt and continuous availability of a defined set of PDMPs with the highest level of quality and safety and in compliance with the existing regulatory framework, which meets appropriate clinical needs through the national collection of plasma based on voluntary and not remunerated donations with the contribution of PDMPs shares acquired on the market.”

The annual National self-sufficiency program

Self-sufficiency of blood and blood products, **including plasma-derived medicinal products** (PDMPs) is a national *supra-regional* strategic goal, i.e. independent of the regionalized organization of health-care delivery.



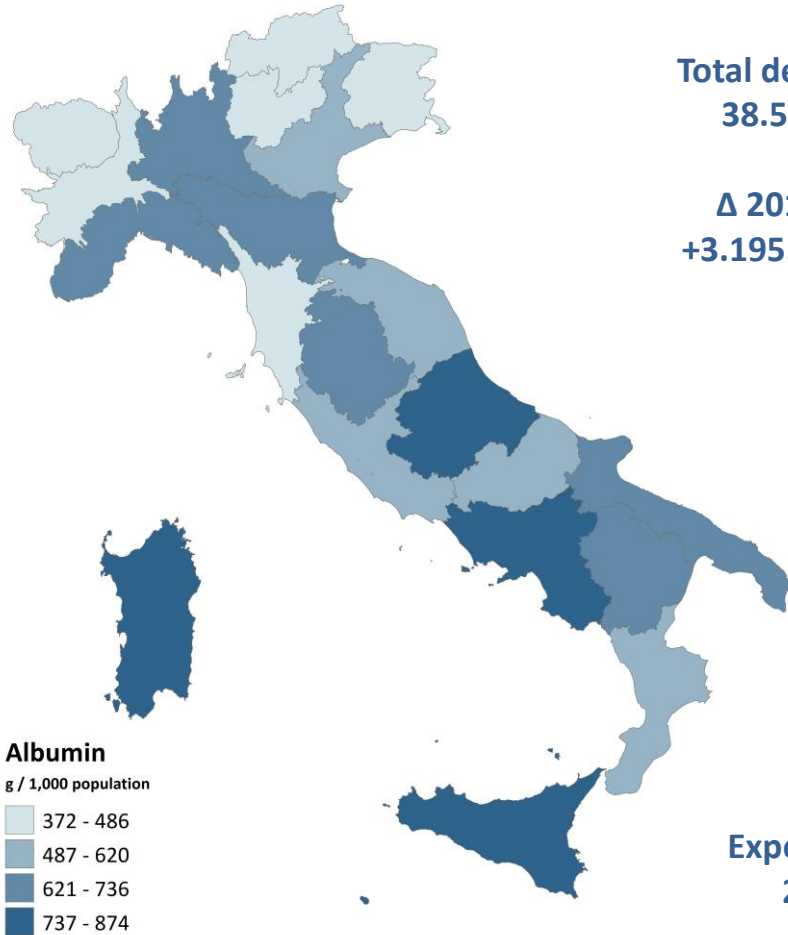
Every year, the Minister of Health, on the basis of the indications provided by the National Blood Center in accordance with Regions, annually defines the national self-sufficiency program, which identifies:

- the historical consumption,
- the real needs,
- the production levels required,
- the resources,
- the criteria for financing the system,
- the tariffs references for the compensation between the regions,
- the levels of import and export that may be needed.

Since 2008, several annual National self-sufficiency programs have been published and became Law

ALBUMIN

Total and regional demand 2017-2021

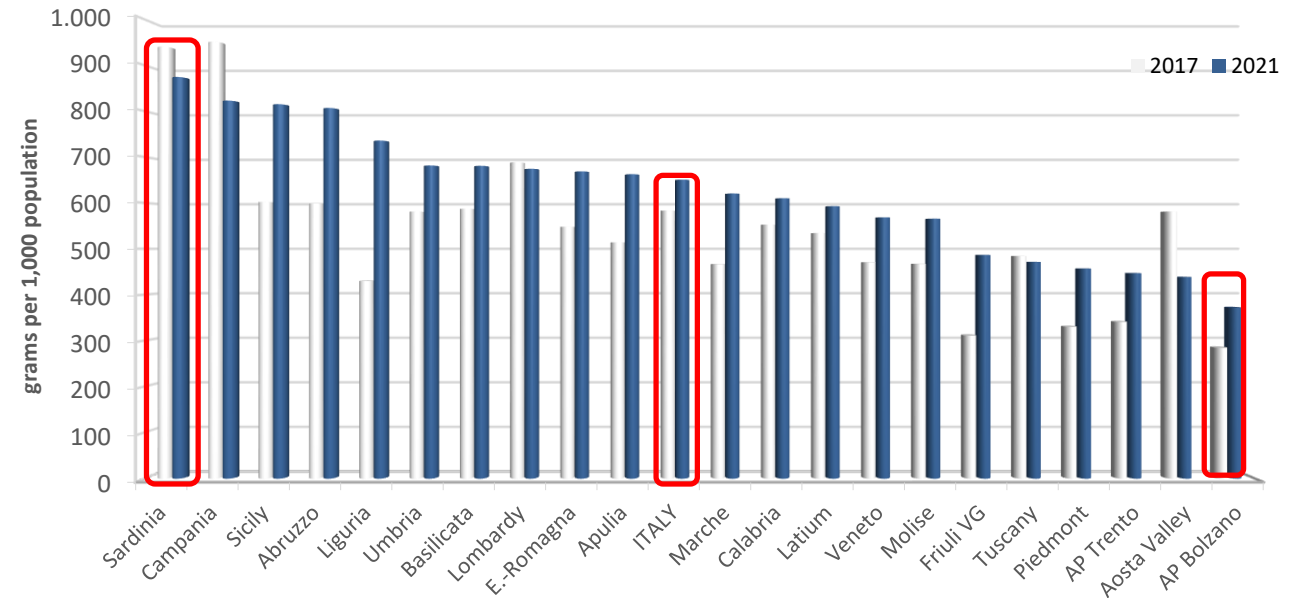
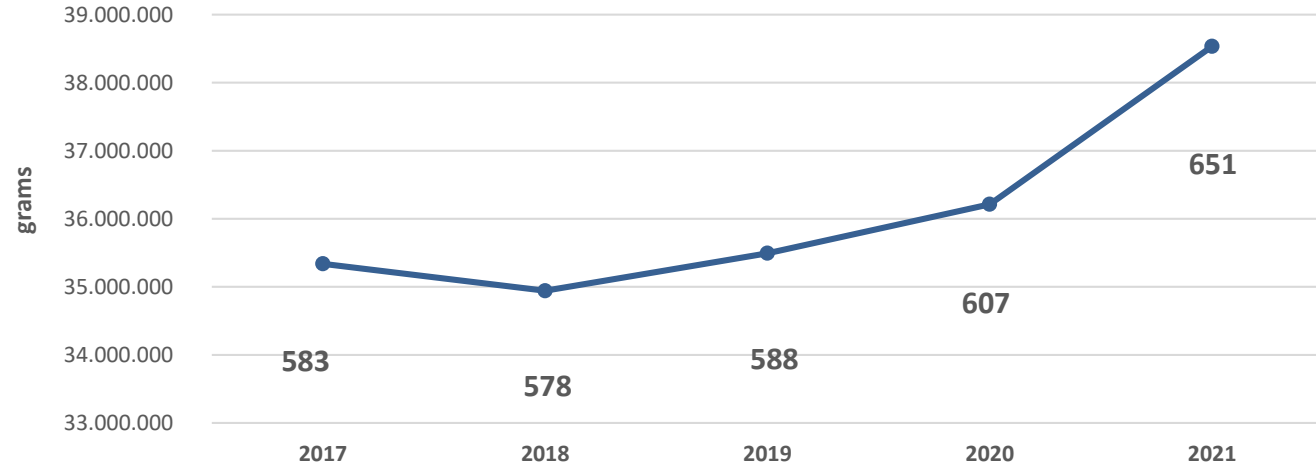


Total demand 2021
38.534.148 g

Δ 2017 – 2021
+3.195.255 g (+9%)

Total NHS
Expenditure 2021
25.2 mln €

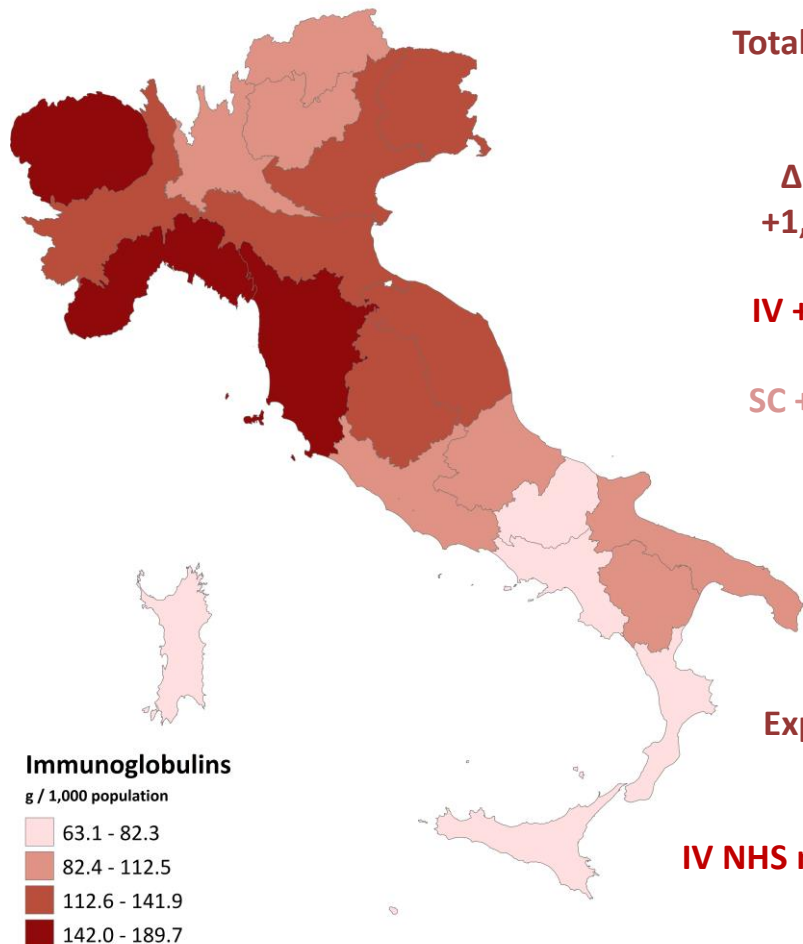
NHS mean price per gram
2.00 €



2021: preliminary data

IMMUNOGLOBULINS

Total and regional demand 2017-2021



Total demand* 2021
6,472 kg

Δ 2017 – 2021
+1,067 kg (+20%)

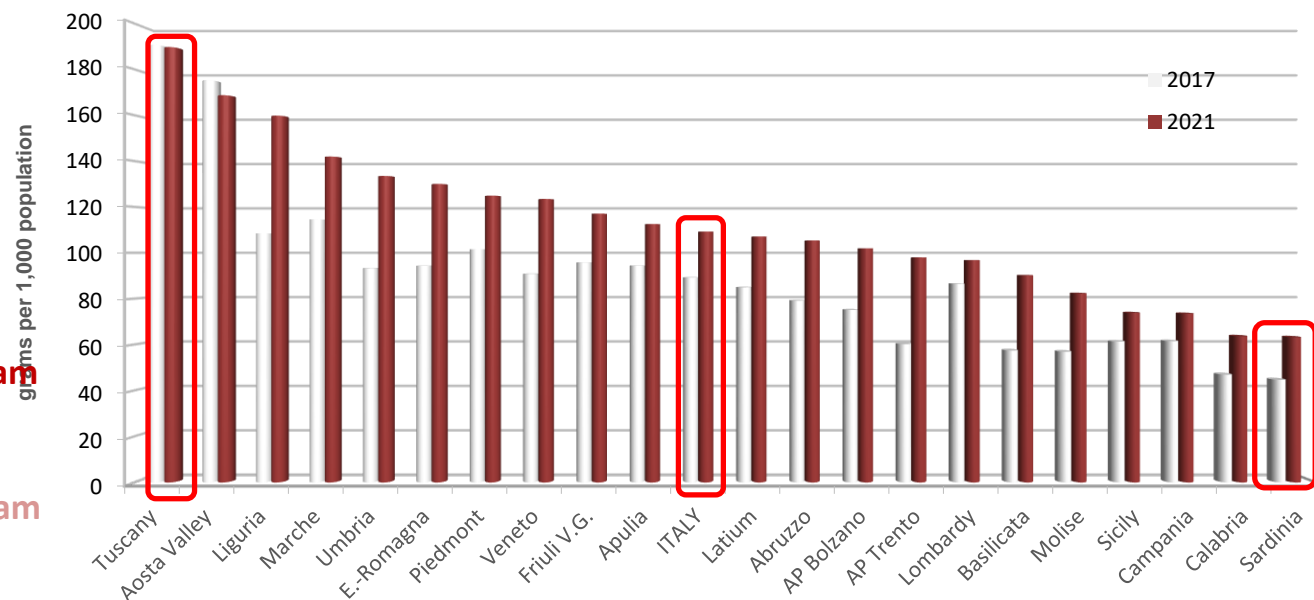
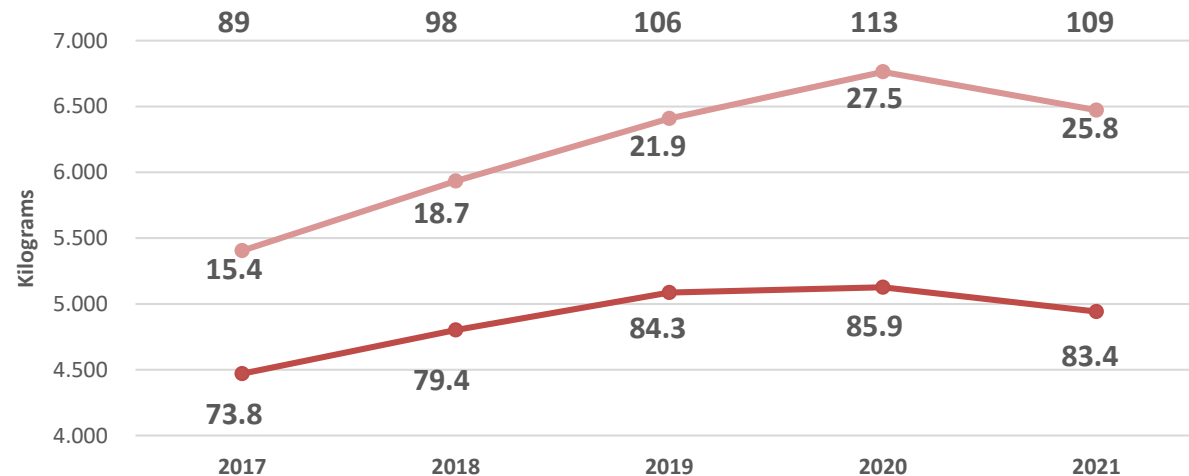
IV +471 kg (+11%)

SC +595 kg (+64%)

Total NHS
Expenditure 2021
117.6 mln €

IV NHS mean price per gram
46.6 €

SC NHS mean price per gram
53.2 €

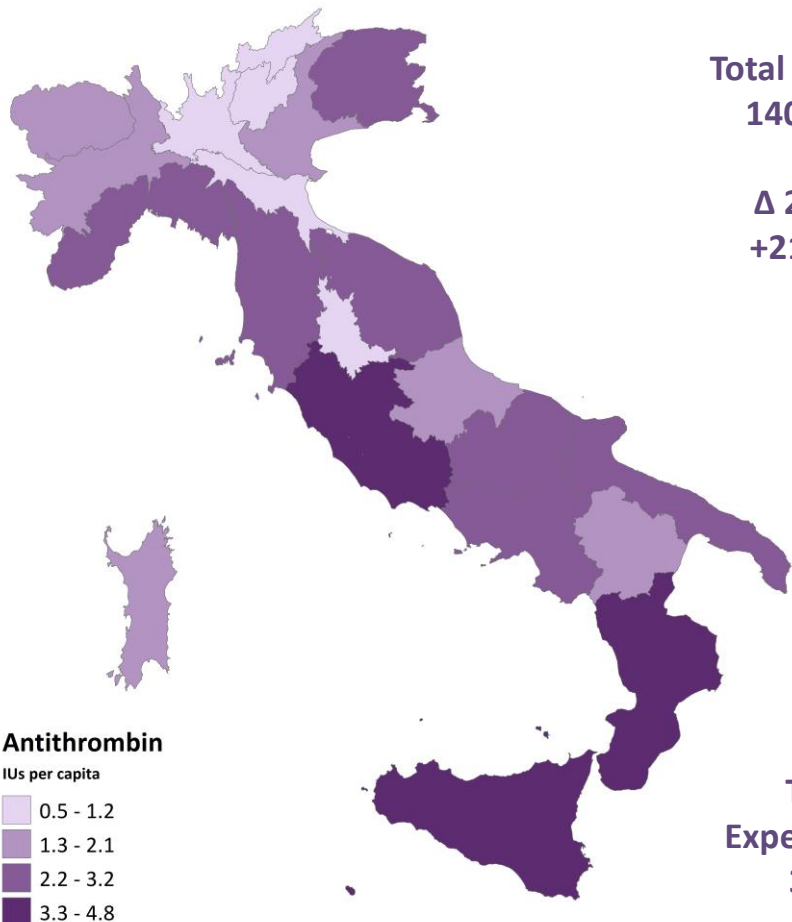


* values includes high IgM titre Ig

2021: preliminary data

Antithrombin

Total and regional demand 2017-2021

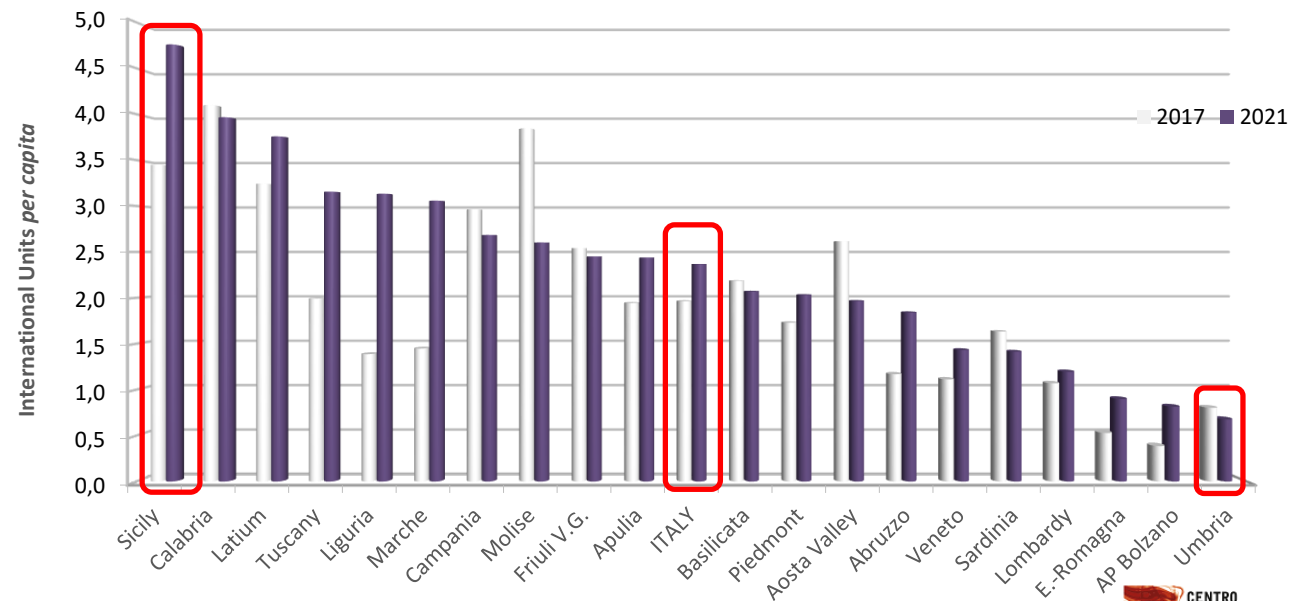
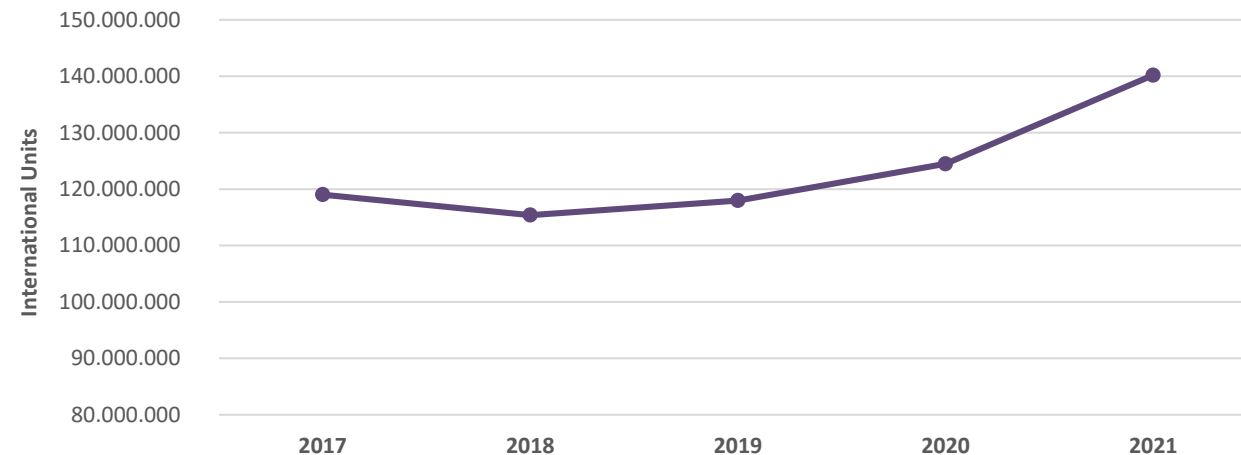


Total demand 2021:
140.192.500 IU

Δ 2017 – 2021
+21.173.000 IU
(+18%)

Total NHS
Expenditure 2021
3.6 mln €

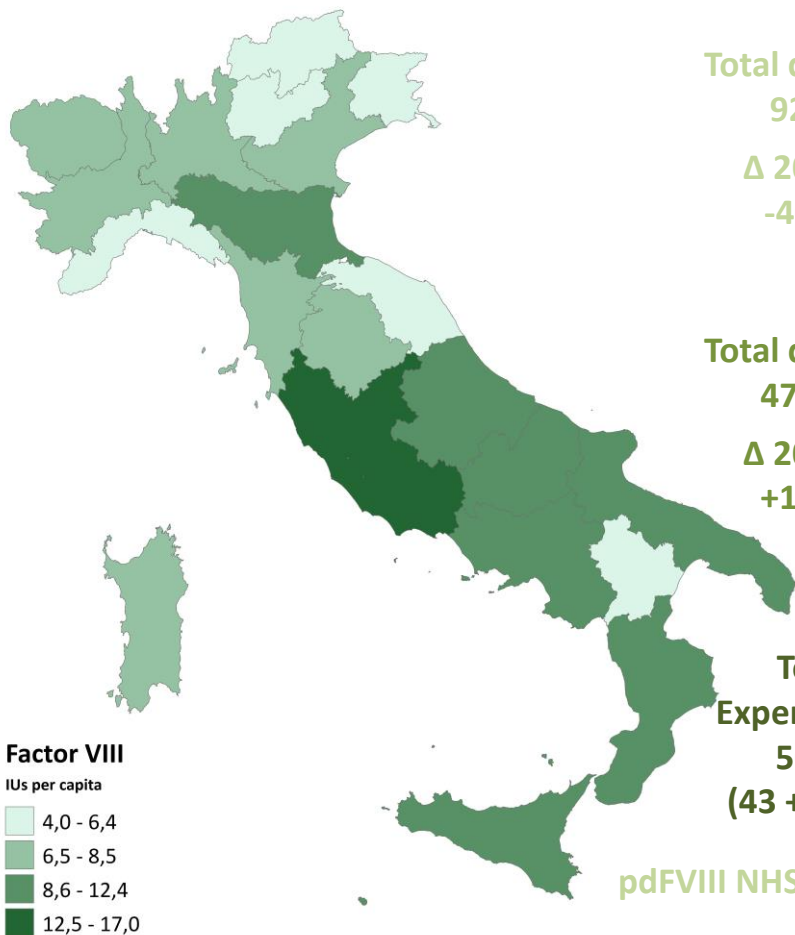
NHS mean price per IU
0.11 €



2021: preliminary data

Factor VIII

Total and regional demand 2017-2021



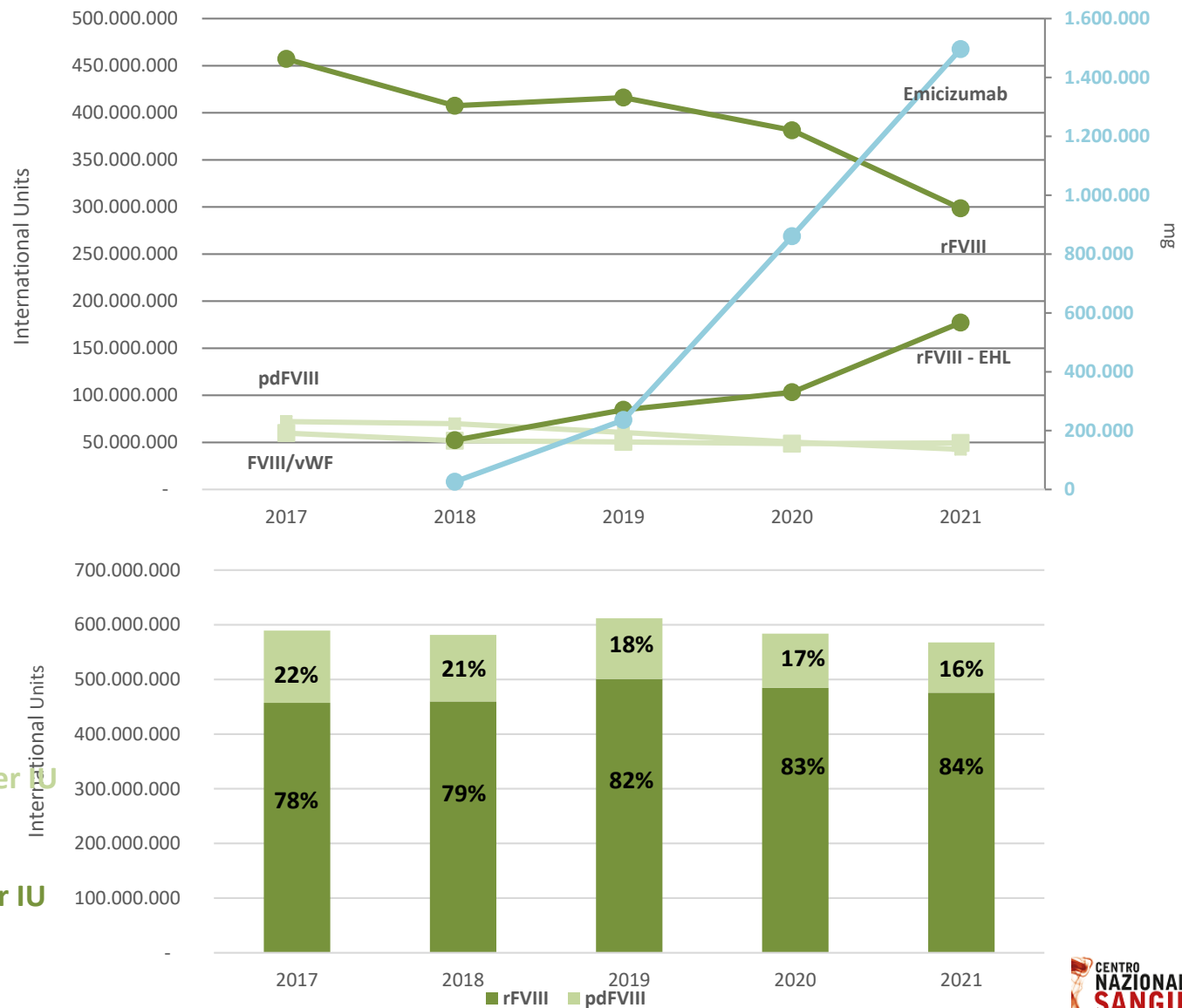
Total demand 2021
92 mln IUs
 Δ 2017 - 2021
-40 mln IUs
(-43%)

Total demand 2021
476 mln IUs
 Δ 2017 - 2021
+18 mln IUs
(+4%)

Total NHS Expenditure 2021
503 mln €
(43 + 460 mln €)

pdFVIII NHS mean price per IU
0.50 €

rFVIII NHS mean price per IU
0.66 €



2021: preliminary data

Prothrombin Complex Concentrates

Total demand 2017-2021

Total demand 2021
36 mln IUs

Δ 2017 – 2021
-1.2 mln IUs
(-3%)

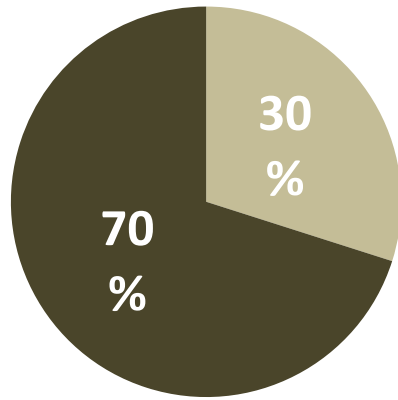
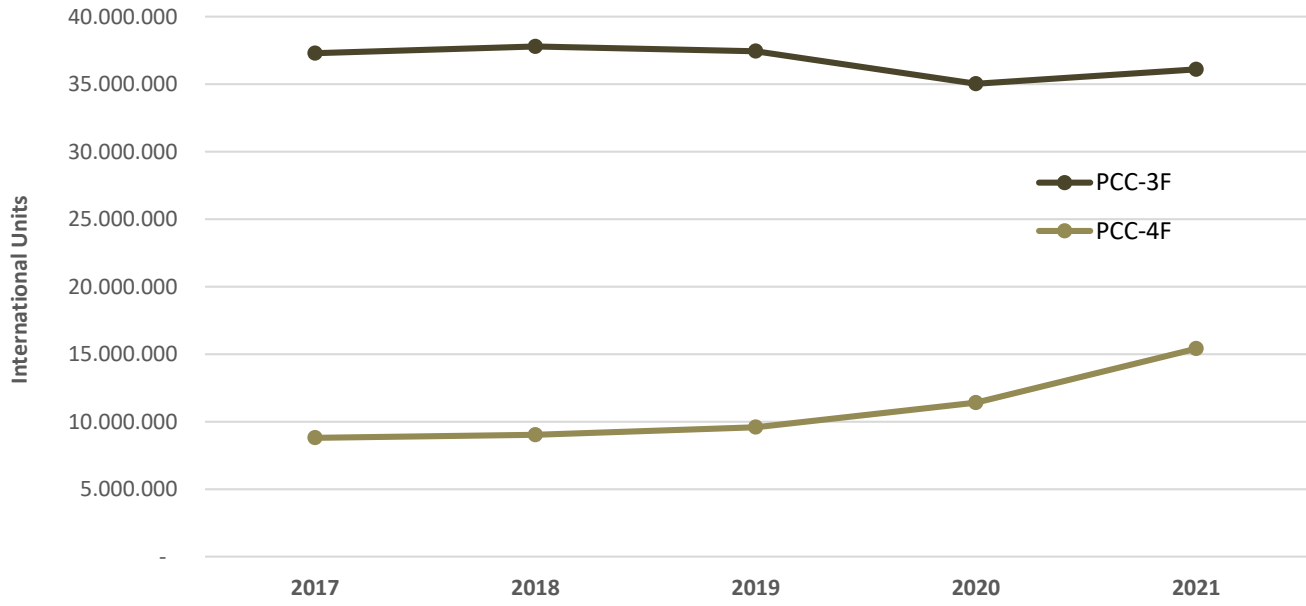
Total demand 2021
15 mln IUs

Δ 2017 – 2021
+6.6 mln IUs
(+75%)

Total NHS
Expenditure 2021
4 mln €

3F NHS mean price per IU
0.27 €

4F NHS mean price per IU
0.29 €

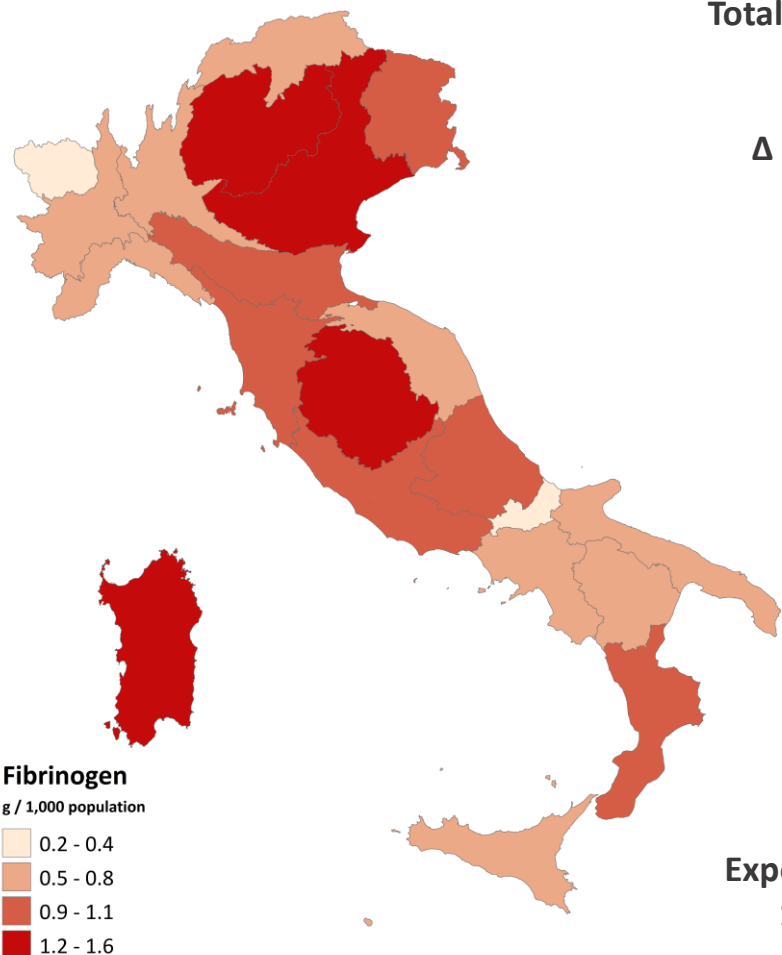


■ PCCs-4F ■ PCCs-3F

2021: preliminary data

FIBRINOGEN

Total and regional demand 2017-2021

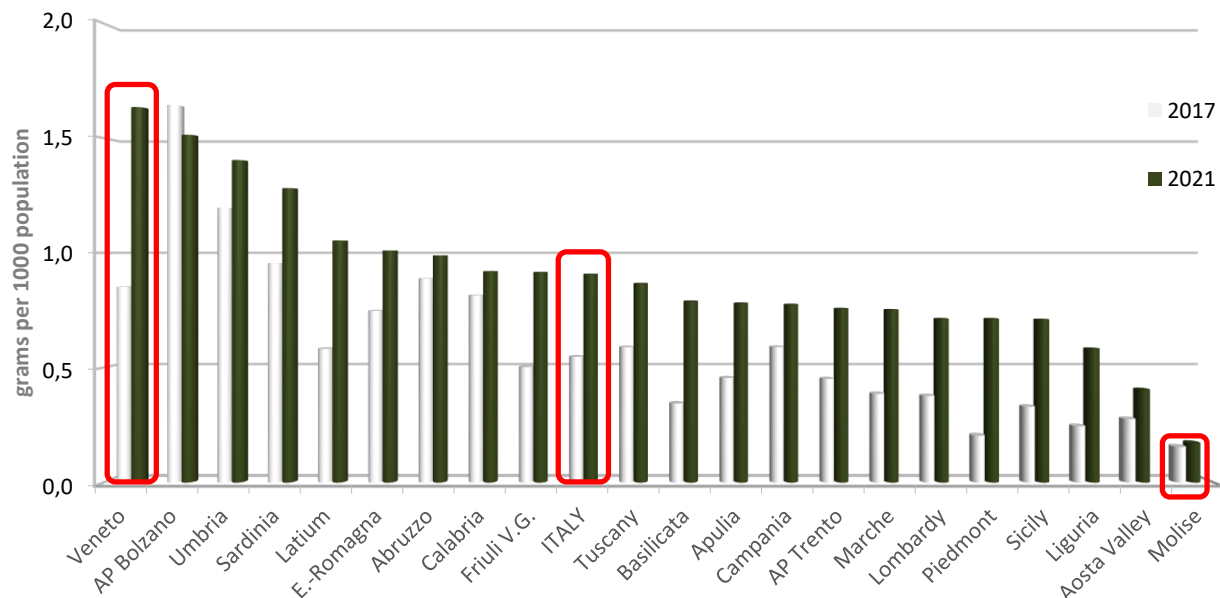
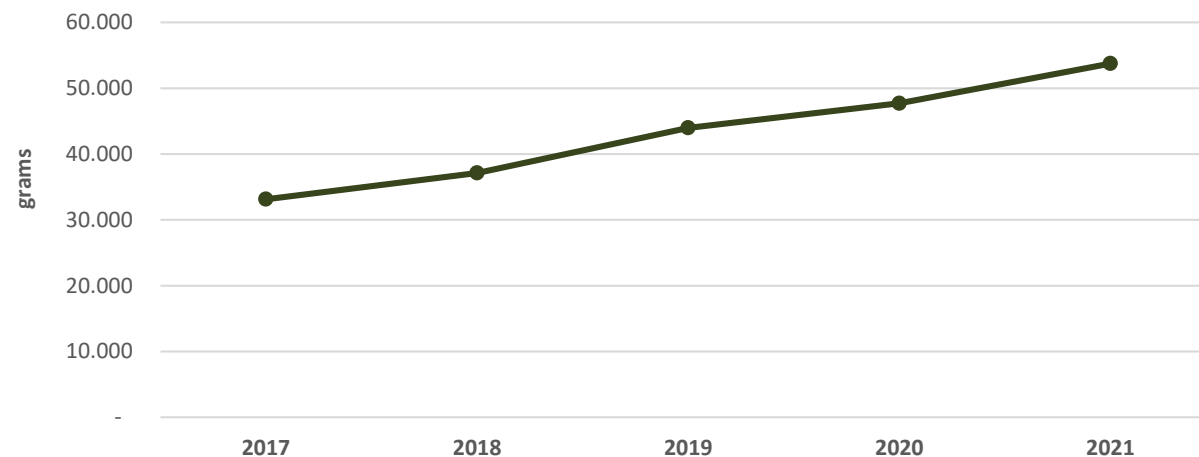


Total demand 2021:
53.8 kg

Δ 2017 - 2021
+ 20.615 g
(+62%)

Total NHS
Expenditure 2021
14.7 mln €

NHS mean price per g
~435 €



2021: preliminary data

Some conclusions...

In the last few years we observed:

- The increase of PDMPs demand and expenditure
- The increase of mean prices per unit
- More instruments/measures are needed to understand the appropriateness of clinical use

The analysis of the demand is essential for understanding (some) patient needs and set up appropriate actions for planning both the collection of plasma and the pharmaceutical provision of PDMPs

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<https://www.centronazionalesangue.it/rapporti-tecnici/>

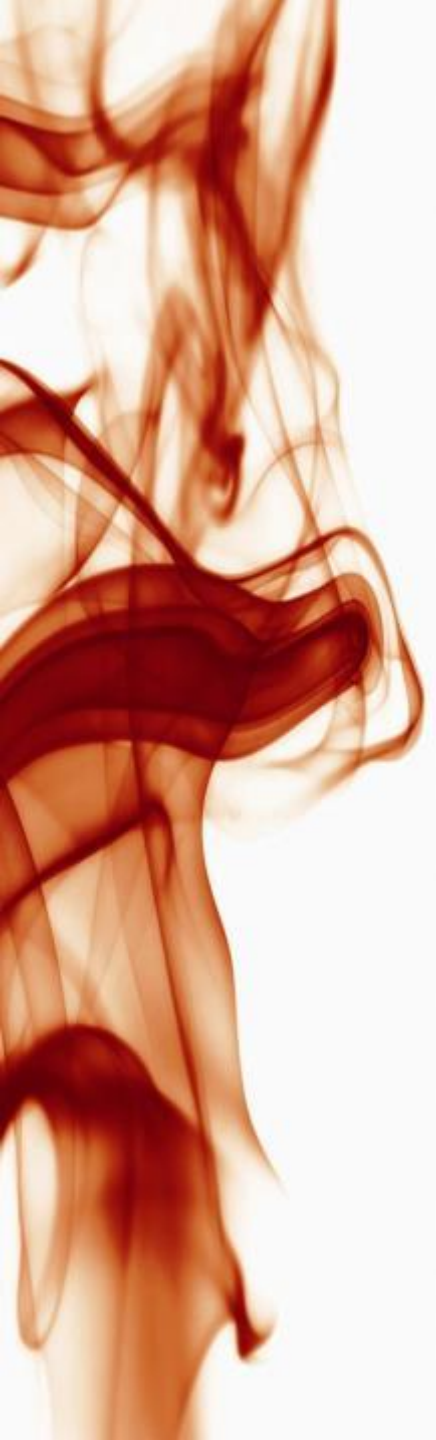
Stay tuned: 2021 ...coming soon !



Damascus Gate, Jerusalem - Summer 2018

Gabriele Calizzani

1971 - 2020



**CENTRO
NAZIONALE
SANGUE**

Istituto Superiore di Sanità



Grazie