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Istituto Superiore di Sanità



Italian regulation on plasma self-sufficiency programme

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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

- Founding principles and main figures
- Italy's self-sufficiency
- The Plasma and Plasma-Derived Medicinal Products National Plan 2016 - 2020

Healthcare governance in Italy

Federalist framework since 2001

Delivering healthcare (HC) is by law delegated to the 21 Regions

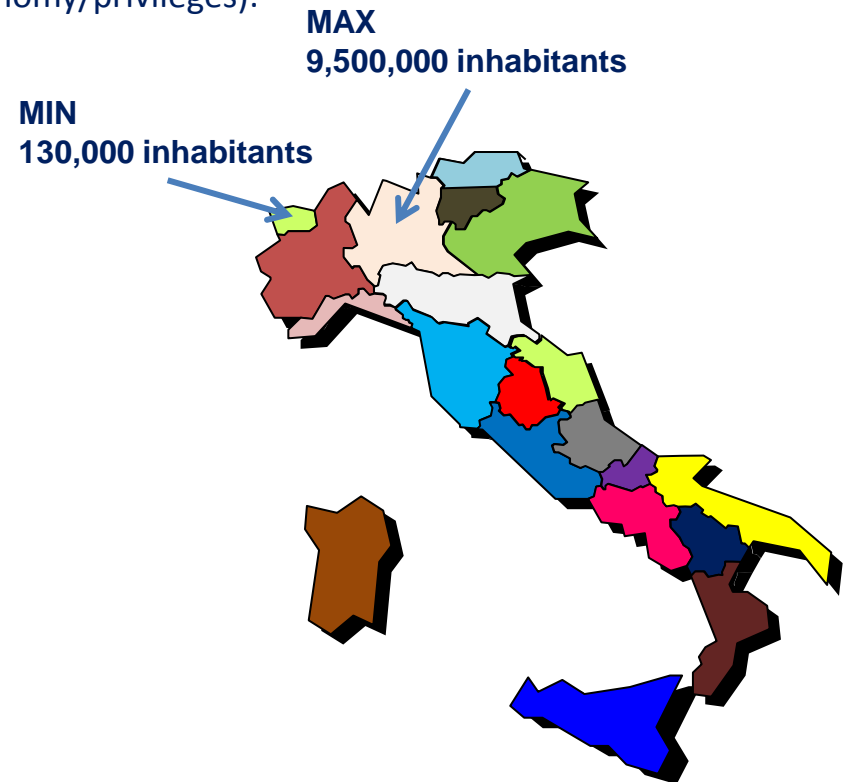
6 Autonomous Regions and Provinces (with additional autonomy/privileges):

- Aosta Valley
- Friuli-Venezia Giulia
- AP Trento
- AP Bolzano
- Sicily
- Sardinia

Ministry of Health

Responsible for:

- general healthcare legislation
- transposing EU provisions
- defining “basic healthcare levels” (BHCL)
- controlling BHCL application in the regions
- controlling regional budget balance
- general public health regulation



Any law / regulation must be preliminarily formally “shared” with Regions (State-Regions agreements)
Ministry of Economy strongly conditions the HC national budget (**114.5 billion € in 2019**; \approx 6.4% of GNP)

Italy's Blood System: founding principles



Italy's Blood System: strategic goals

Law 219 of 21st October 2005

- **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 regionalised organization of health-care delivery.
- **Promotion and continuous development** of voluntary non-remunerated (VNR), regular blood donation, and VNR donor retention.
- High **quality and safety** of blood components, transfusion medicine activities and PDMPs.
- **Compliance with European regulatory provisions** on blood and blood products (Italy has transposed and fully applies all the pertinent EU directives).
- Appropriate management and clinical utilisation of blood resources [including PDMPs and *patient blood management* (PBM) programmes)].
- Continuous **development of transfusion medicine**, aligned with scientific progress.
- Blood system's accountability, effectiveness and sustainability.



Blood components collected in 2017

3,006,726 donations
49.6 per 1,000 pop

2,579,438 WB donations
85.8% of total donations
42.6 per 1,000 pop

427,288 apheresis
(348,486 plasmapheresis)
14.2% of total donations
5.6 per 1,000 pop

1.8 WB donations/donor/year
2.1 plasma donations/donor/year

Blood components transfused in 2017

2,960,643 units
48.8 per 1,000 pop

2,457,300 units of RBCs
40.6 per 1,000 pop
(98.8% leucodepleted)

218,937 units of platelets*
3.6 per 1,000 pop
(25.2% apheresis)

284,406 units of plasma**
4.7 per 1,000 pop
(of which 119,404 virus-inactivated plasma)

8,111 blood components transfused per day

1 donation every 10 seconds guarantees transfusion therapy for 1,806 patients a day

* Adult therapeutic dose; ** apheresis + WB

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The annual national self-sufficiency programme

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.



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 programme**, which identifies:

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

Since 2008, 10 annual national **self-sufficiency programmes** have been published and became **law**

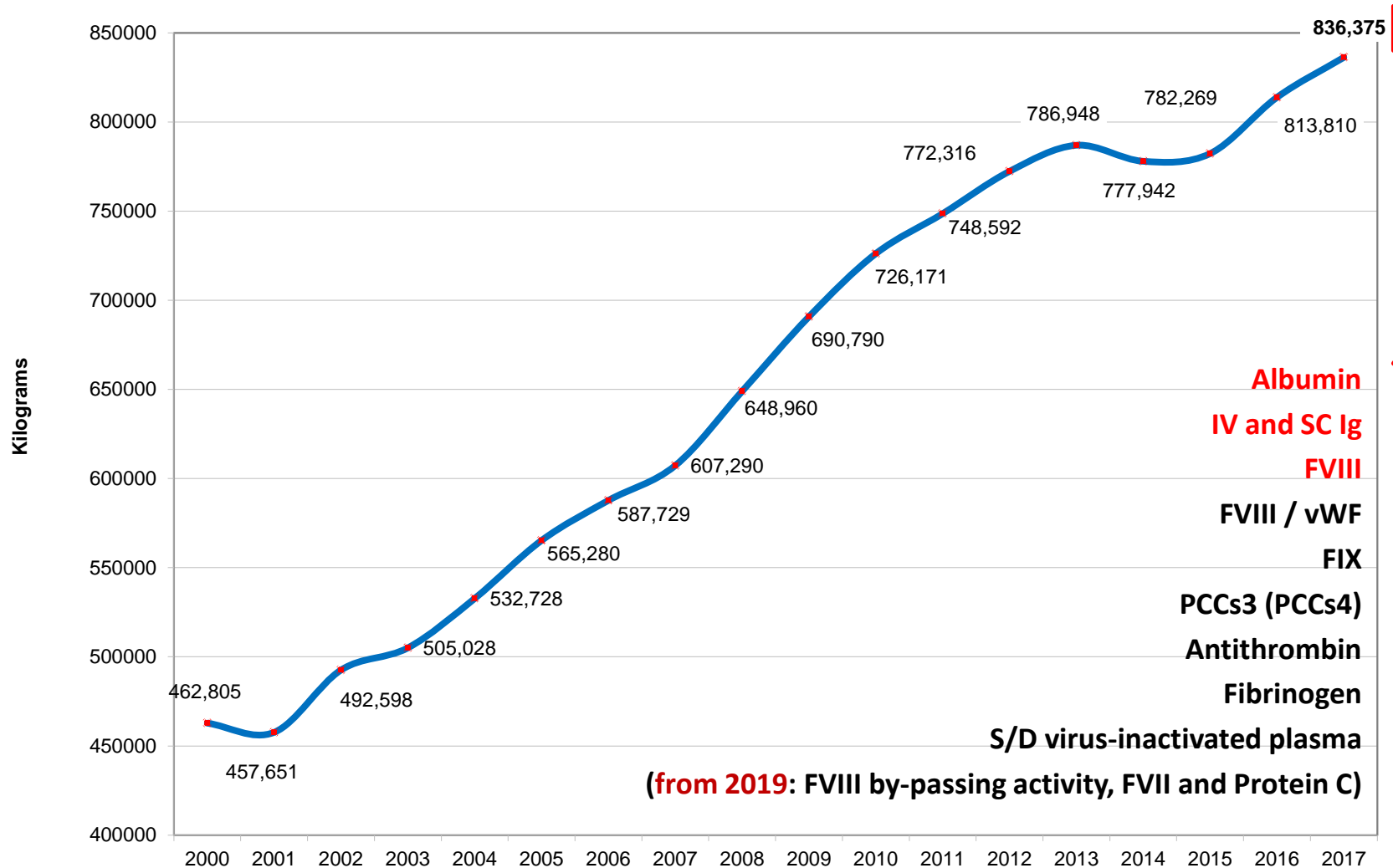


National self-sufficiency of PDMPs

- “[...] 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 VNRDs with the contribution of PDMPs shares acquired on the market.”

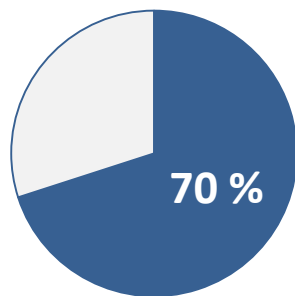


Plasma for fractionation (Pff) 2000-2017

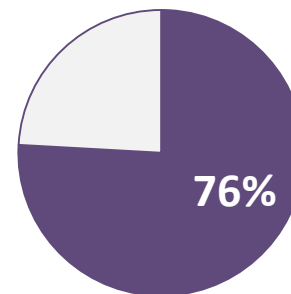


Italy's self-sufficiency in 2017

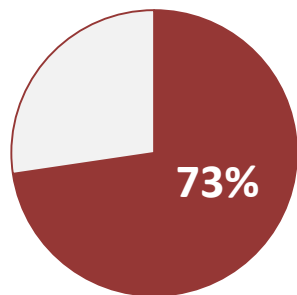
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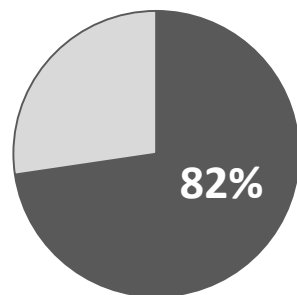
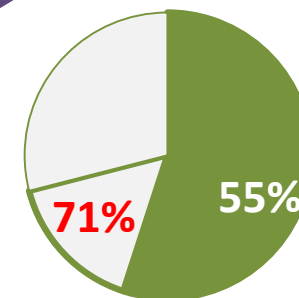
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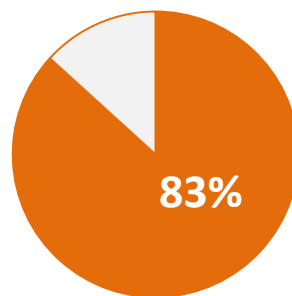
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FACTOR VIII

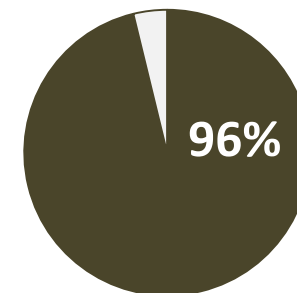


S/D-TREATED PLASMA



FACTOR IX

PCCs3



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Plasma and PDMP National Plan

Main goals

- the adoption of measures for promoting the **appropriate use of PDMPs**;
- the **promotion of the collection**, with particular regard to the Regions that have low plasma donation levels;
- the **improvement of the efficiency** of the plasma collection system, with particular regard to plasmapheresis procedures.



Promoting the appropriate use of PDMPs

Regional demand for

- Albumin shall not exceed 400 grams per 1,000 pop
- AT shall not exceed 1 IU *per capita*
- Polyvalent immunoglobulins shall not exceed 110 grams per 1,000 pop
- FFP shall not exceed 1,600 mLs per 1,000 pop
- in the absence of documented epidemiological and clinical peculiarities

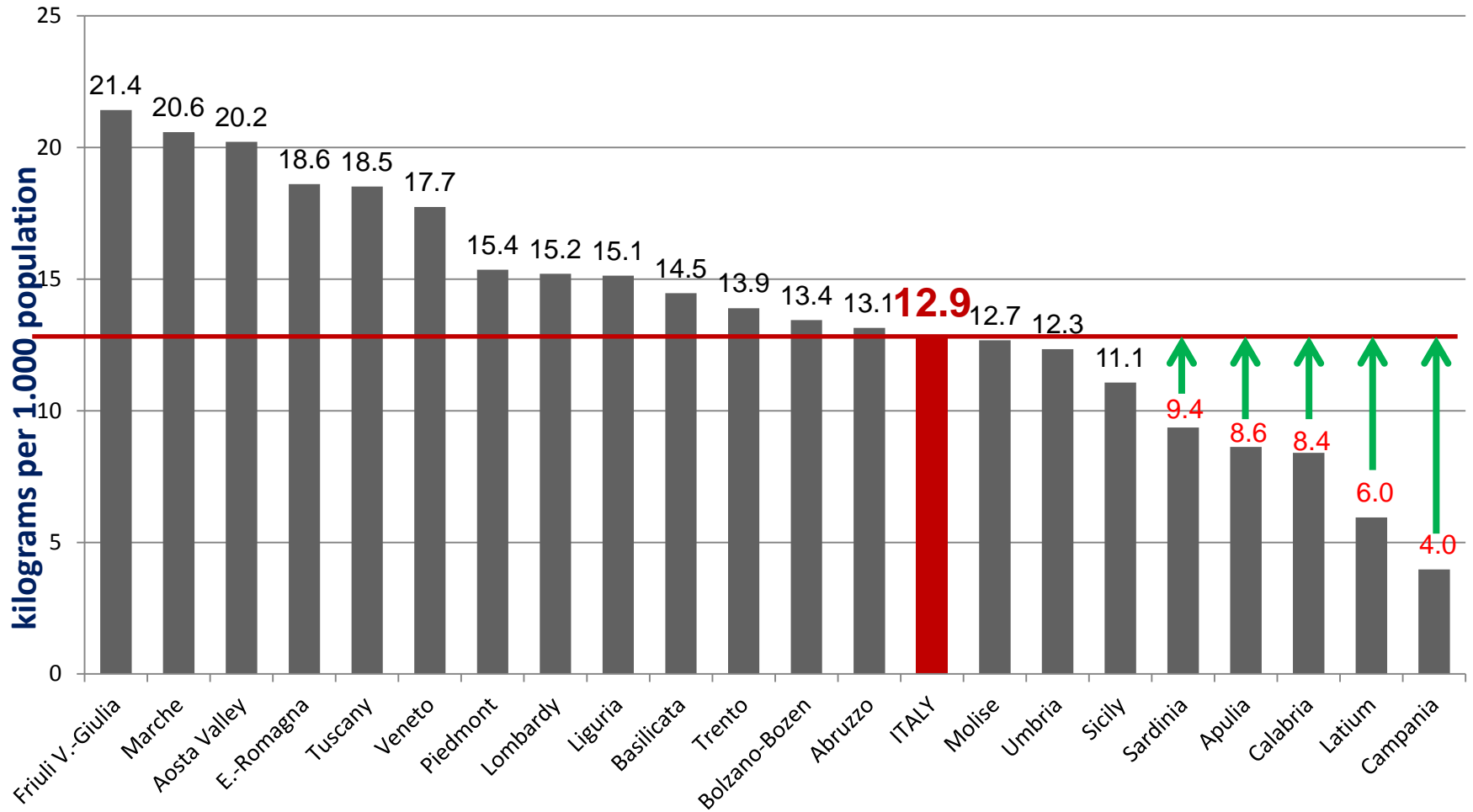
Plasma and PDMP National Plan

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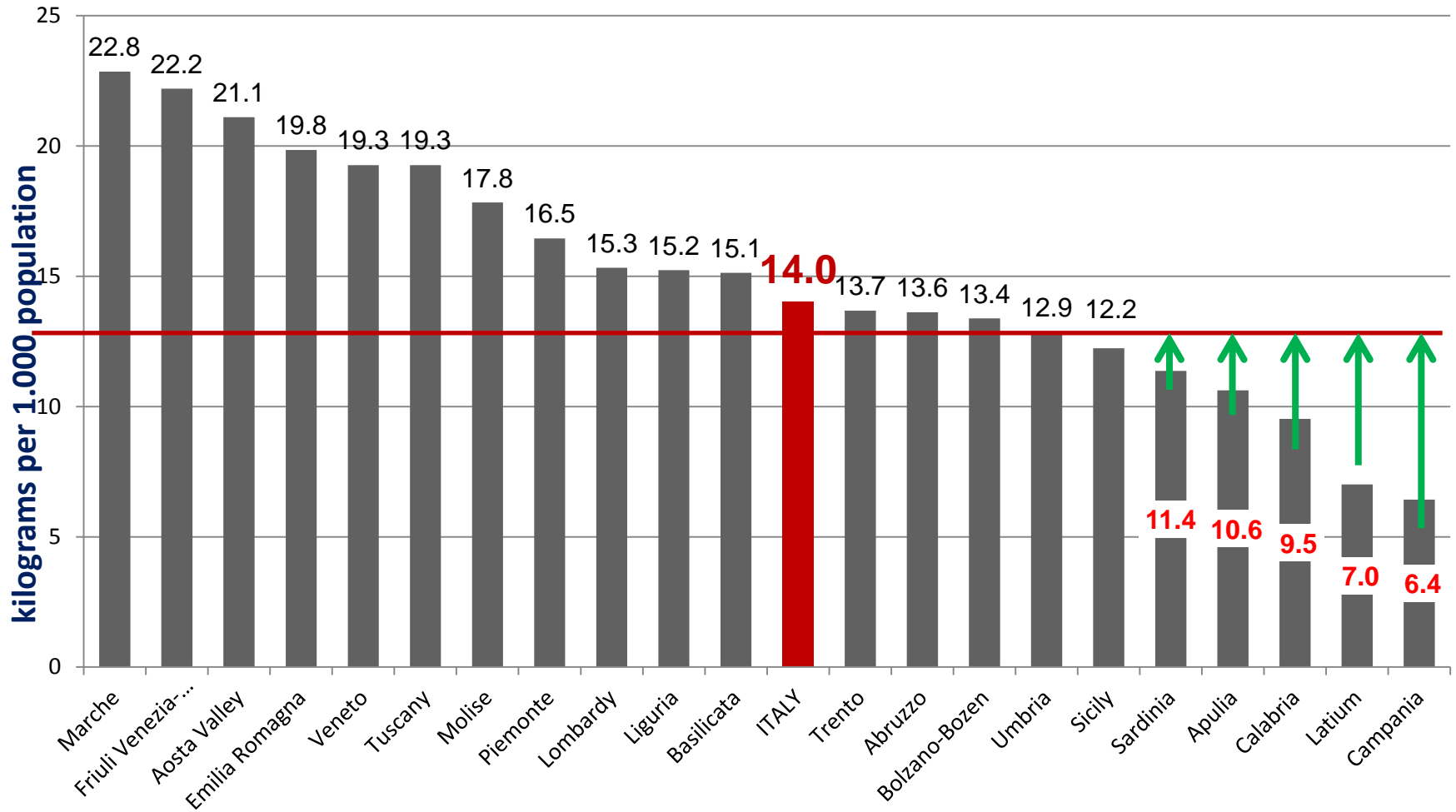
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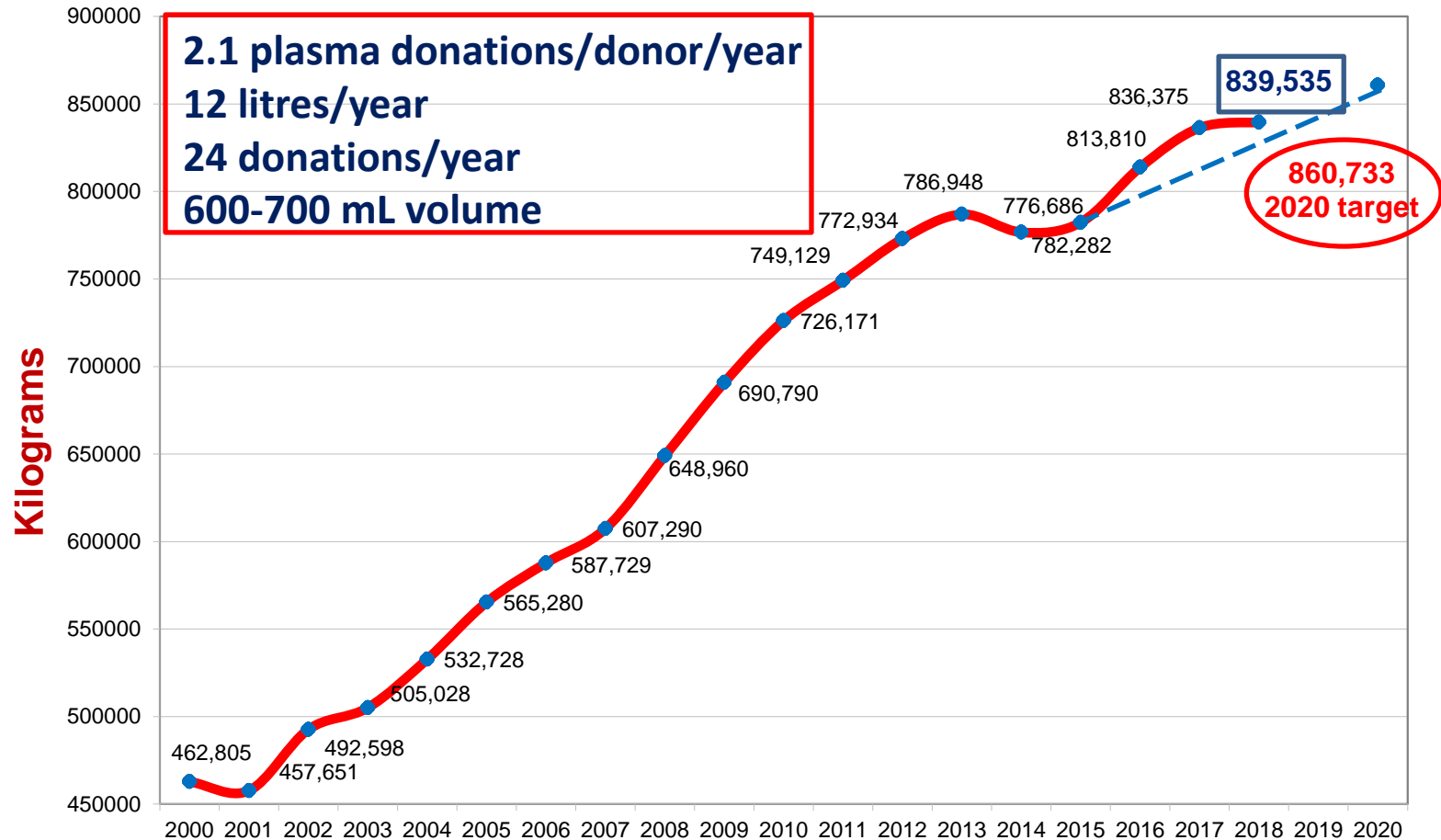
PfF 2015



PfF 2018



PfF 2000-2018 and PNP 2020 target



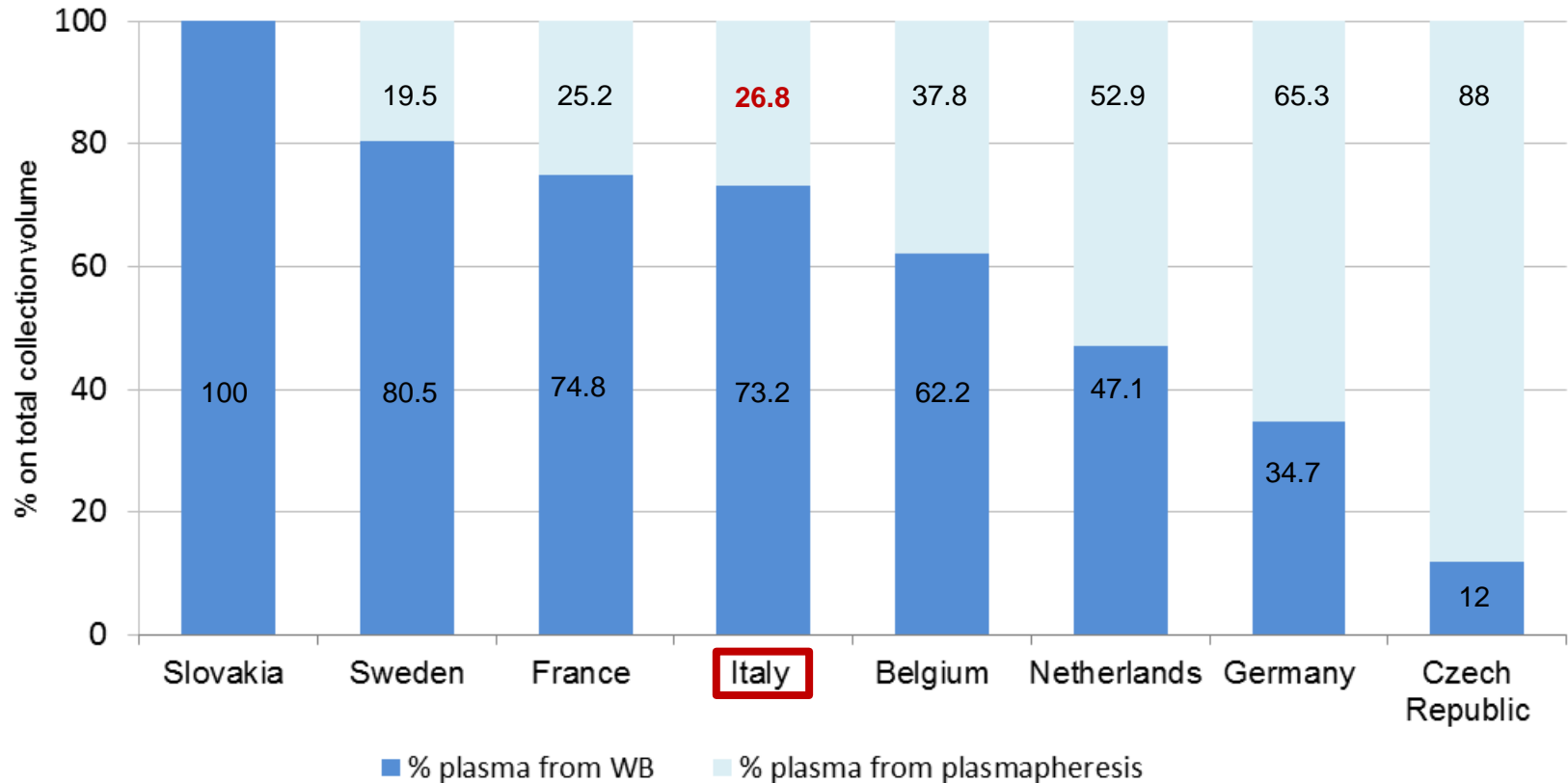
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Improvement of the efficiency of plasma collection, with particular regard to plasmapheresis procedures



Actions aimed at improving the efficiency and sustainability of plasma collection

- **Increasing procedures per apheresis machine**
 - **600 procedures** per machine per year (Regional average)
 - **Minimum: 250 procedures** per machine per year
- New partnerships and agreements with voluntary blood donor Associations and Federations
- **Increasing the accessibility** to BEs and blood collection sites
- **Increasing volumes collected** through apheresis procedures (min 600 – max 700 mL: +18%; up to 12 L/year and 24 plasma donation/year)
- **Reducing discarded plasma units** (< 2% of collected units)

} 2020 targets

Conclusions 1

- In Italy, Plasma and PDMPs are part of a **specific national regulation** which defines **levels of collection** for each Region and **appropriate levels of demand** for PDMPs, aligned with expected scenarios, and **includes several areas of improvement and measures to intensify plasmapheresis**
- **VNRDs and donor Associations** as part of the Italian blood and plasma system, which is entirely public, **are able to provide** as much plasma as needed to obtain significant levels of PDMP self-sufficiency despite "relatively low" levels of plasma donation



- **EU legislation is an opportunity** for strategic independence of PfF [VNRDs, blood donor health and safety]

Conclusions 2

- An **EU Plasma and PDMP self-sufficiency plan based on VNRDs** could integrate single Member State plans and include shared (and more easily adopted) «Proposals for a way forward to intensify plasmapheresis»
- **PDMP self-sufficiency based on VNRDs** could/should be a **common European strategic objective**
- The main **obstacle** to the **independence of PfF in Europe** is possibly the **lack of awareness** that:
 - Plasma itself is a strategic resource as “raw material” for the production of life-saving medicinal products
 - Currently, the global plasma and PDMP-market depends almost entirely on plasma collected in the USA
 - **PDMP self-sufficiency based on VNRD is possible** (Yes, we can!)





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*Thanks for your
attention!*

