Italian regulation on plasma self-sufficiency programme

Giancarlo Maria Liumbruno (MD)
Director general
Italian National Blood Centre
Rome, Italy

Strasbourg, January 29, 2019
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; ≈ 6.4% of GNP)
Italy’s Blood System: founding principles

Voluntary, periodic, responsible, anonymous and not-remunerated donation of blood

Blood activities can be performed only by public blood transfusion organizations (qualified blood donor Associations specifically licensed and accredited)

Civic & social function and strategic role of the Donor Federations and Associations institutionally recognised

Donor Federations and Associations participate in the institutional scheme of the national and regional blood network

Human blood is not a source of profit

Transfusion medicine activities as well as blood donation promotion & development are recognised as “basic healthcare services”

BEs (and HBBs) are exclusively public and hospital-based

The transfusion process is subject to specific accreditation that complies with European regulations

The transfusion process is unitary and “indivisible”

to be delivered equitably, impartially and free of charge to any citizen needing them
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
Agenda

• Founding principles and main figures

• **Italy’s self-sufficiency**

• The Plasma and Plasma-Derived Medicinal Products National Plan 2016 - 2020
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.

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

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.
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

Source: Adapted by the Italian National Blood Centre on data from Fractionation industries, January 2019
Agenda

- Founding principles and main figures
- Italy’s self-sufficiency
- The Plasma and Plasma-Derived Medicinal Products National Plan 2016 - 2020
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
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.
PfF 2015

Adapted by the Italian National Blood Centre on data provided by Kedrion. June 2016.
PfF 2000-2018 and PNP 2020 target

- 2.1 plasma donations/donor/year
- 12 litres/year
- 24 donations/year
- 600-700 mL volume

- Adapted by the Italian National Blood Centre on data from Fractionation Industries. January 2019
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.
Improvement of the efficiency of plasma collection, with particular regard to plasmapheresis procedures

<table>
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<tr>
<th>Country</th>
<th>% plasma from WB</th>
<th>% plasma from plasmapheresis</th>
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<tr>
<td>Slovakia</td>
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<tr>
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<td>France</td>
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<tr>
<td>Italy</td>
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<tr>
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<td>Germany</td>
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<tr>
<td>Czech Republic</td>
<td>12</td>
<td></td>
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</tbody>
</table>
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)
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!)
Thanks for your attention!