

Increasing plasma collection by blood establishments to reach European plasma strategic independence



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EUROPEAN
BLOOD
ALLIANCE

ABOUT EBA:

Membership organization

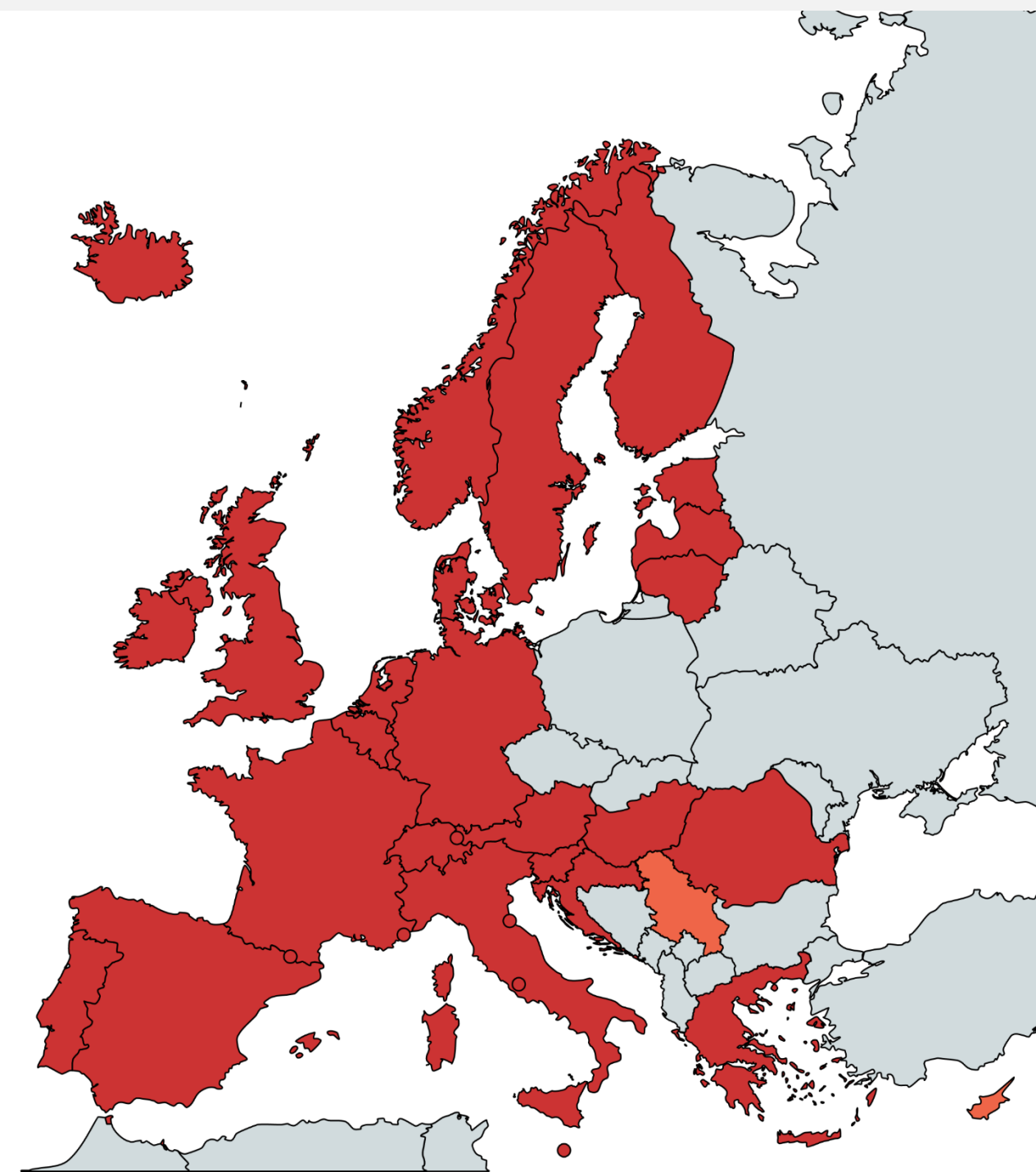
Representing non-profit Blood
establishments across Europe

26 members, 2 observers

17 million blood donations,
serving 470 million people

EBA Members and Observers

- EBA Members
- EBA Observers



Mission of EBA

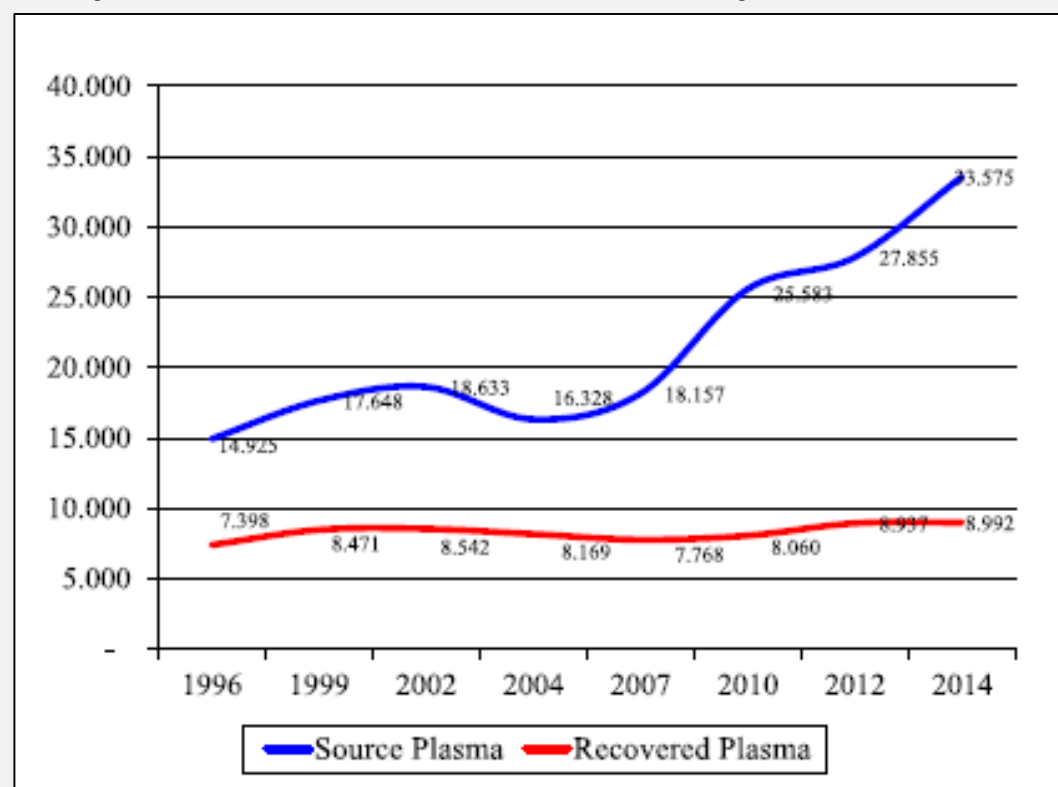
“To contribute to the safety, security and cost effectiveness of the blood and tissue and cell supply for the citizens of Europe by developing and maintaining an efficient and strong collaboration amongst European blood and tissue and cell services”.

EBA core values

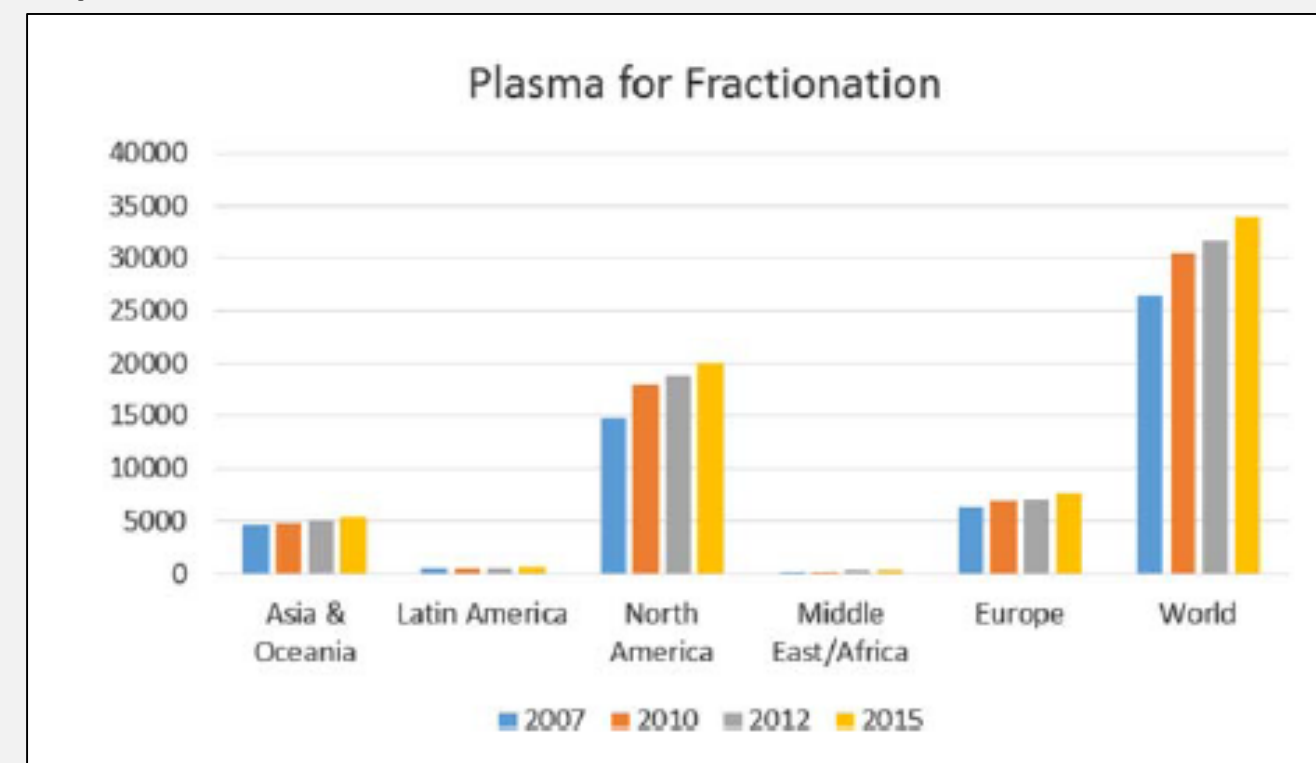


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- The need for plasma to produce plasma-derived medicinal products (PDMP) is increasing.
- Europe is increasingly dependent on plasma collected in the USA.
- Availability of PDMP is driven by a world-wide competitive market.



Worldwide plasma processed (x1000 L)
(Strengers and Klein, Transfusion, 2016)



Global plasma collection volume (x1000 L)
(Strengers and Klein, Transfusion, 2016)

Increasing plasma collection by blood establishments to reach European plasma strategic independence

- **Meeting the patients needs today and tomorrow : a public health mandate**

In the law of the European Union : “A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities”, Article 168(1) of the Treaty on Functioning of the European Union

A commitment of EBA : “Through safe and sustainable supply of blood components, EBA members contribute to the patient’s care”, EBA core value

Increasing plasma collection by blood establishments to reach European plasma strategic independence

- **Meeting the patients needs today and tomorrow : a public health mandate**

In the law of the European Union

A commitment of EBA

- **Regarding plasma and PDMP, this essential mandate is exposed to significant risks**

Increasing needs world-wide

Disruption in plasma availability and/or collection in relation with geo-political turmoil or a emerging infectious/transmissible disease risk

Market-related, or non-evidence based use-driven inaccessibility to PDMP

Increasing plasma collection by blood establishments to reach European plasma strategic independence

- **Meeting the patients needs today and tomorrow :**

In the law of the European Union

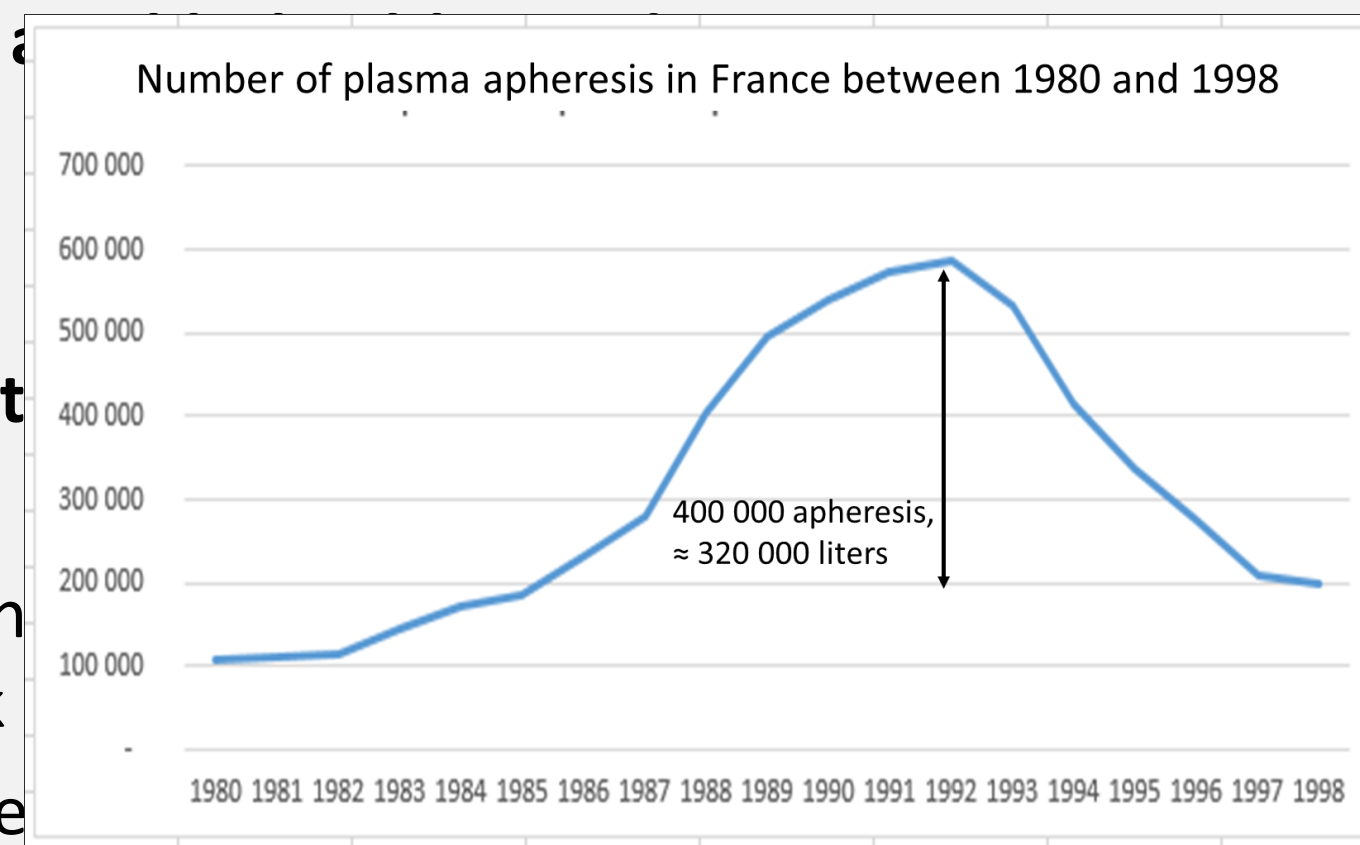
A commitment of EBA

- **Regarding plasma and PDMP, this essential mandat**

Increasing needs world-wide

Disruption in plasma availability and/or collection
emerging infectious/transmissible disease risk

Market-related, or non-evidence based use-drive



- **Therefore reaching (again) European strategic independence is essential**

Why again? Recent increased dependence: at least partly a consequence of the EU internal market law for PDMP without measures to ensure adequate plasma sourcing in EU members states

Increasing plasma collection by blood establishments to reach European plasma and PDMP strategic independence

- **Plasma collection: a donation of human bodily material and a public health resource, to be considered within the framework of blood donation**
 - One same donor : plasma, whole blood (allowing for recovered plasma), platelet (+/- plasma) apheresis donation
 - One same ethical setting: autonomy, dignity, beneficence, non-maleficence and justice, i.e. within the remit of voluntary non-remunerated donation
 - One same safety setting: optimal prevention and treatment of donation-related adverse events, one same donor hemovigilance
 - One same donor base:
 - Preventing the erosion and/or fragmentation of a community-based donor population
 - Preventing competition and cherry-picking versus a mandate to continuously provide therapeutic solutions for all patients wherever they live

Increasing plasma collection by blood establishments to reach European plasma and PDMP strategic independence

- **Achieving European strategic independence must therefore rely on increased plasma collection by European blood establishments**
- **To increasingly do so, one should (1):**
 - Recognize plasma as a EU strategic resource
 - Engage European inhabitants in a reflection/conversation on plasma, PDMP and patient needs, and more generally on health solidarity and self sustainability within Europe
 - Modernize donor recruitment:
 - Improving communication and accessibility
 - Building on increased willingness for societal engagement, and focus on health issues
 - Rely on a large diverse donor base vs a narrow donor base undergoing high frequency plasma collection:
 - To reduce individual donor burden and to ensure donor safety while increasing the quality of collected plasma

Increasing plasma collection by blood establishments to reach European plasma and PDMP strategic independence

- **To increasingly do so, one should (2) :**
 - Optimally integrate plasma collection (apheresis and recovered plasma) in blood establishments operations
 - Orient toward fractionation all recovered plasma not used for direct transfusion purpose
 - Promote compliance with GMP certification, adapt PMF certification procedures for small countries
 - Increase efficiency of plasma collection: shared best practices, technological evolutions, ...
 - Ensure donor safety: obviously essential *per se*, also to guarantee continuous product availability for patients (e.g. prevent acute disruption of plasma collection in relation with an “emerging” unmanaged /poorly managed donor health issue)
 - Align EU and EU member states legislation and policies with the objective of achieving blood establishment - driven European plasma and PDMP strategic independence
- **Plasma collection and PDMP provision: to be considered a European Union « service of general interest »?**

Increasing plasma collection by blood establishments to reach European plasma and PDMP strategic independence

- **Plasma collection and PDMP provision: to be considered as a European Union « service of general interest »?**

Services of general interest (SGI) are services that public authorities of the EU member countries classify as being of general interest and, therefore, subject to specific public service obligations. Such obligations may be associated with derogations to the European internal market and competition rules.

SGI comprises « activities which deliver outcomes in the overall public good that would not be supplied (or would be supplied under different conditions in terms of quality, safety, affordability, equal treatment or universal access) by the market without public intervention”.

Examples of services of general interest include: public transport, postal services, and healthcare.

Increasing plasma collection by blood establishments to reach European plasma and PDMP strategic independence

To increase plasma collection by blood establishments and reach European plasma and PDMP strategic independence:

- Identify plasma as a strategic resource for Europe and communicate on patients dependence on life-saving PDMP
- Align EU legislation to ensure adequate plasma sourcing in EU member states within the framework of blood donation
- Invest in plasma donor safety and health
- Improve efficiency of plasma collection by blood establishments
- Promote evidence-based use of PDMP, therapeutic products relying on the generosity and commitment of a large number of donors