6. New plasma donation approaches in Europe

There is no single pathway for providing access to plasma-derived medicines.

Whatever the choice, the guiding principle is that patients benefit from a system that contributes to stable access to plasma-derived medicines to ensure their treatment, in-line with national health policies and accepted cultural norms.

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Plasma donation approaches

Current donation practices in Europe

Plasma-derived medicines help patients living with a range of rare diseases that can only be treated by these therapies. They are also used in everyday medicine, emergency and critical care situations and in preventive medicine.

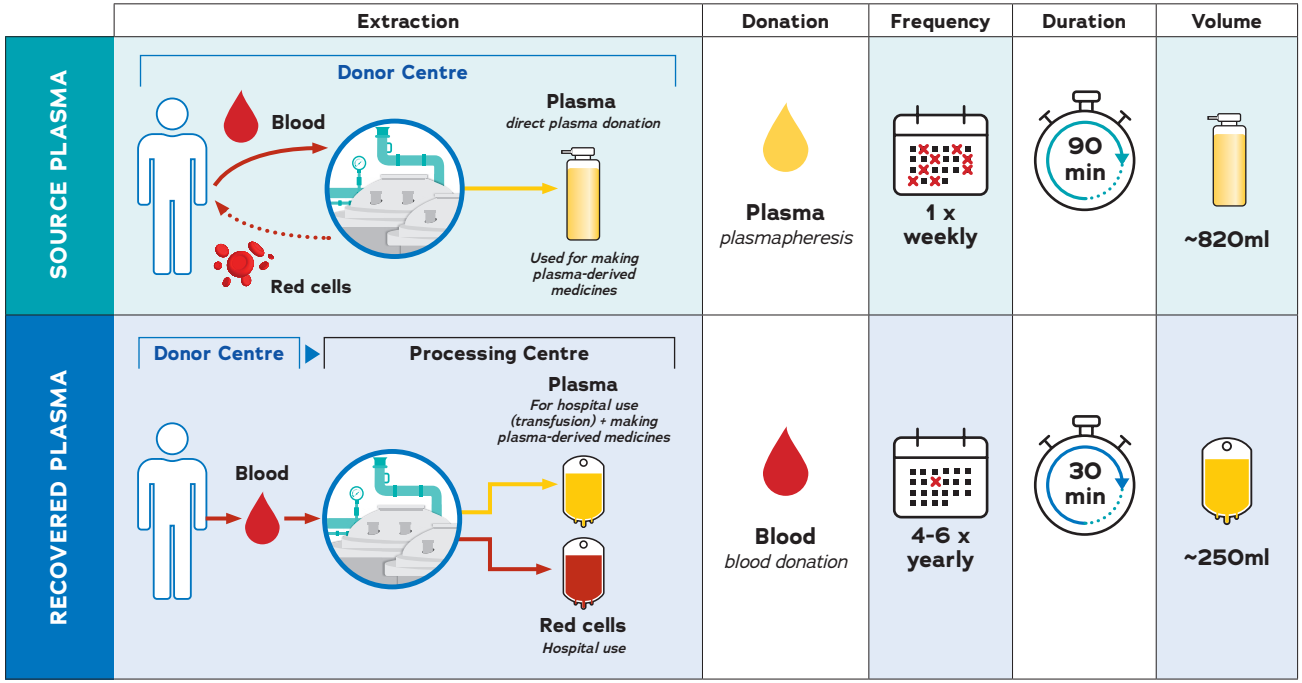
Most European countries authorize specific organisations to collect whole blood and plasma. For example, France and Finland have one approved national plasma collection body; Poland authorizes collection in state-certified public hospitals. The UK has recently reversed its decades-old ban on using plasma from the public blood system for medicines, making local production with plasma from UK blood donors possible again.[11]

Several countries – Austria, Czech Republic, Germany and Hungary – have systems where public blood and plasma services coexist with private sector plasma donor centres. Depending on national regulations, a plasma donation centre that collects plasma from donors who use 'plasmapherisis' can be public, non-profit or private.

Plasma is obtained in two ways:

- **'Direct' donation in dedicated plasma centres** that use the 'plasmapheresis' process **(source plasma)**. Here, the donor's blood runs through a medical device that separates plasma from other blood cellular components, which are then returned to the donor.
- **Separated from whole blood donation made by people to the national blood bank system (recovered plasma).** After donation, blood is separated into different components; plasma is one of these.

In both approaches, collected plasma is pooled, purified and specific proteins are separated in the 'fractionation' process. These proteins are then used by medicines producers in the plasma protein therapies that are prescribed to treat patients living with rare and debilitating conditions. In a nutshell, this is the pathway from plasma donor to patient.



Creating public-private plasma donation partnerships that benefit patients and the public health system

How can countries best align the interests of public health services with private sector partners for the benefit of all patients that need plasma protein therapies?

This is a central question for public health decision makers as they explore strategies to secure plasma donations from a wider donor community.

The global picture of plasma-derived medicines points to a continually growing need for these therapies. Better diagnosis broadens the patient population that can benefit from them, and medical research is discovering new treatment areas. While demand for blood components for transfusion remains relatively stable, a European Commission survey (2014) shows that demand for plasma derivatives is increasing by some 6% per year.

To meet this need, medicines' producers will need more donated plasma to deliver the therapies that health services and patients need.

Plasma has a unique place in the medicines development landscape. It is a finite source material that cannot be made synthetically in a laboratory. It can only come from healthy, committed donors.

New approaches to ensuring national plasma donations call for partnerships between the public health system, medicines producers and patient organisations – all focused on delivering to patients' optimal access to the plasma-derived medicines that need.[12]

Novel plasma donation policies are in place in several European countries

Current public-private plasma donation approaches brokered by public authorities specify:

- A requirement for private sector partners that establish plasma donation centres to provide the health service with access to a specified volume of plasma-derived medicines at an agreed price, in return for authorization to operate.
- Access to pooled plasma for local medicines producers at an agreed cost.
- Agreement on the volume of plasma to remain in the country for national medicines production.
- Transfer of technology and know-how to the local medicines industry.

Country cases – the combined public/private approach

	AUSTRIA	CZECH REPUBLIC	GERMANY	HUNGARY
Population	8.8 million	11 million	83 million	10 million
Approach	Combined system: Austrian Red Cross collects plasma from whole blood donations; direct plasma donation (using plasmapheresis) by Red Cross and private sector plasma donation centres.	Combined system: Public blood/plasma system from whole blood donations; direct plasma donation at private sector plasma donation centres.	The German system has three pillars, active in both whole blood and plasmapheresis donation: Red Cross collection centres; municipal and hospital centres; private donation centres.	Combined system: National blood/plasma system from whole blood donations; direct plasma donation at private sector plasma donation centres.
Public plasma system	Whole blood collection for transfusions is exclusively public; by Red Cross and national hospitals. A small amount of plasma collection is public.	Public system for blood collection – reserved to blood banks and hospitals.	Whole blood and plasma collection: centres established at city, communal level and in hospitals and by the Red Cross..	Government-run whole blood collection.
Direct plasma donation (using plasmapheresis)	Plasma donors give in dedicated donation centres; owned by mix of international and national companies.	Plasma donors give in dedicated donation centres; owned by mix of international and national companies.	Plasma donors give in dedicated donation centres; owned by mix of international and national companies.	Plasma donors give in dedicated donation centres; owned by mix of international and national companies.
Direct plasma donation (using plasmapheresis)	**20 centres nationwide**	**50 centres nationwide**	**80 centres nationwide** **Dedicated donation centres in 11 Länder**	**35 centres nationwide**
Legislation on donation frequency	– 50 plasmapheresis donations/year – 3 donations in a 2-week period – 2 donations in 7 days – 1 donation in 72 hours – Max 700 ml/donation (without coagulant)	– Plasmapheresis donation not more than every 14 days – Max 650 ml/donation(without coagulant) – Not more than 1.5l /week/person – Total plasma donation/person/year: max 25l	– 60 plasmapheresis donations in 12 months – 2-day interval between donations Between 650ml-850 ml per donation (Depending on donor weight)	– 33 plasmapheresis donations in 12 months – 1 donation within 72 hours – Max 800ml per donation (including coagulant)
Total amount of plasma collected/ per annum	– 590,000 liters, in slight decline – 67 liters per 1000 inhabitants	– 500,000 liters – 45 liters per 1000 inhabitants	– 3.1 million liters per year – 36 liters per 1000 inhabitants	– 600,000 liters per year – 60 liters per 1000 inhabitants
Incentives	Financial compensation implicitly allowed, but financial profit explicitly not allowed.	Financial compensation allowed, capped at €12 per donation to cover donor costs (linked to minimum wage and varies per year); can be deducted from personal income tax.	Financial compensation is allowed for every entity collecting blood or blood components.	Financial compensation allowed – capped at €10 per donation – linked to minimum wage and can vary per year.
Observations	Pragmatic blood donation law. Allows covering of donor expenses, and similar costs as part of 'voluntary unpaid compensation'. Advertising for plasma donation is allowed.		Pragmatic plasma donation law. Donors can be compensated for both whole blood and plasma donations.. Non-compensation also allowed. Plasma donation volumes in Germany are relatively flat (not growing). Advertising for blood/plasma collection is allowed (not for compensation).	This national framework is a good example of public/ private collaboration to encourage stable donation of whole blood and plasma in sufficient quantities. Plasma donation law for private plasma centres requires each donor to also donate whole blood for transfusion once yearly, uncompensated.

Setting-up a plasma donation centre: key considerations

Putting in place or expanding a public plasma donation scheme requires investments in infrastructure and network-building activities to inform the public and attract a community of donors interested in giving frequently.

Infrastructure development requires detailed planning and forecasting to ensure that operating costs are covered. Whether the centre is a publicly-funded facility or privately-owned, its establishment is subject to strict laws and regulations that govern facilities that handle materials of human origin.

Public blood/plasma collection architecture

A public plasma collection can have a centralized or distributed architecture, depending on a country's public health strategy, its blood/plasma policies and regulations, and the investment climate.

A centralized plasma infrastructure is typically composed of one or several large-scale donation centres. Some European countries collect whole blood only, later separating plasma from blood.

In other countries public blood centres also offer plasma donation with plasmapheresis equipment, accommodating some 30 donors at a time. Creating larger-scale plasmapheresis centres is a major public sector investment project, of the order of 250 million euro, plus a staff of salaried medical and technical professionals.

The operational plan for this type of centre requires an effective strategy and business plan that ensures sufficient throughput and donation volumes to offset the investment over a 25-year period. France, Italy and some other European countries operate this type of infrastructure.

Typically, of plasma recovered from donated blood, 75% is used for manufacturing plasma-derived medicines, with the remaining 20-25% is used for direct transfusion.

Making plasma protein therapy medicines

Depending on national regulations, dedicated plasma donation centres can be a part of the public health system, non-profit entities, or privately owned. In all cases they will be governed by health regulations for donor safety, product purity and compensation.

Producing a plasma protein therapy is a lengthy and complex process. It takes up to one year from the moment a donation is made until the therapy is ready for patients. Collected plasma is held in frozen storage for 60 days, pooled, and processed following a strict safety and purification regime.

It is then sent to a manufacturing facility that makes plasma-derived medicinal products. Here plasma is further tested; the manufacturing process uses fractionation to extract therapeutic proteins from the plasma. These protein fractions are further purified to extract proteins of interest, which are then cleared of potential viruses by additional steps.

The purified proteins are formulated into ready-to-use medicine, tested for sterility, packaged, labeled, and distributed through public health systems.