

1. New thinking on plasma donation for European countries

This report is intended as a resource to open a conversation with public health decision makers.

It discusses new approaches and offers examples of how countries can build on current plasma donation structures; to increase the donations which are needed to produce plasma-derived medicines for patients that need them.

European countries' challenge of increasing plasma donations to improve patient access

Attaining stable and safe access to human plasma from European donors to produce critical medicines for European patients is a goal voiced by most countries' health services.

This view has long been supported by inter-governmental recommendations of the WHO and European Union¹, whose calls for more national autonomy for donation in plasma and other blood components date back several decades. These bodies recommend the donation of whole blood and plasma on a 'voluntary unpaid donation' basis.

European countries currently have a deficit in the plasma they need to produce medicines that meet their patients' needs. Today, plasma comes from a combination of in-country and imported donations. Some 38% of this life-giving material used in Europe to make plasma-derived medicines, is given by donors in the US who are compensated. In Europe today, most countries follow the principle of Voluntary Unpaid Donations, where donors can receive reimbursement for expenses incurred or a fixed allowance that recognises the inconvenience of donating plasma.

Austria, Czech Republic, Germany and Hungary have policies that authorize different types of compensation to donors who give in private plasma donation centres.

Looking to the decades ahead, imported plasma will continue to make an important contribution needed to make plasma-derived medicines that improve the quality of life for an increasing number of patients in every European country.

But countries will also benefit from cooperating on new approaches to plasma donation. For example, in an ecosystem that offers diversified donations of plasma by growing communities of donors in all European countries.

Europe's decision makers are faced with an evolving public health landscape. There is a growing population of patients that can benefit from plasma-derived medicines. Medical research is identifying new indications that plasma can control and cure. Likewise, more precise diagnoses mean that more existing plasma-treatable conditions are being identified.



For public health decision makers, this challenge can be summarized in three imperatives:

- **Achieving improved access to plasma-derived medicines**, by building more plasmapheresis programmes across Europe.
- Doing this in a way that guarantees the **highest levels of safety for donors** and the plasma materials they give.
- **Reconciling the 'public goods' character of plasma donation**, with accepted standards for voluntary unpaid donations – by recognising and thanking plasma donors for their commitment and efforts they make to give plasma frequently.

New approaches that countries can consider to ensure more plasma donations

The good news is that there are useful examples from several European countries today. They show how the public sector blood system can work together with private sector plasmapheresis plasma donation services to increase donations at country level.

These models respect the principle of voluntary unpaid donation in national policies. They allow donors to be recognised for the costs they incur, and the considerable effort and inconvenience of donating plasma. Many plasma donors give on average 20 times yearly, and up to 50-60 times.

Toward a regional/global plasma ecosystem

Plasma is a critical source material of human origin and a global needed to make specialised plasma-derived medicines that will be needed by millions more people in the coming decade. New thinking on policies and practices for plasma donation has the potential to link countries in a regional and global ecosystem for plasma donation, exchange and the sharing of related know-how.

European countries have different options to build systems for safe and stable plasma donations. Options include fully public systems; and combined public-private plasma donation networks.

There is no single pathway; all variations of plasma donation and processing are needed.

The guiding principle is that plasma donors are protected by the highest safety standards; and patients benefit from a public health system that ensures stable access to high-quality plasma to produce safe and efficacious plasma-derived therapies – in line with national health policies and ethical and cultural norms.

