PPTA
Plasma Protein Therapeutics Association

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Plasma-derived medicines are different from synthesized pharmaceuticals

The unique value chain for these medicines always starts with a person's donation of plasma.

To ensure access for all patients to these life-saving plasma-derived medicines, public health authorities need to plan for stable access to plasma-derived therapies under all circumstances.

Producing plasma-derived medicines takes much longer than the process to make chemically-synthesized pharmaceutical medicines.

The unique character of plasma-derived medicines

Patient access in the plasma protein therapy value chain

The value chain for producing plasma-derived medicines is unique – it always starts with a person's donation of plasma.

The process of making specialized medicines derived from plasma takes much longer to produce chemically-synthesized pharmaceutical medicines. It takes 7-12 months to manufacture plasma-derived medicines, from the moment the donation is made until it is ready to be given to a patient.

Ensuring adequate access and supply of these medicines also requires effective planning by public health authorities to ensure that patients have stable access to their therapies under all circumstances.

A spike in need for more chemically-synthesized pharmaceuticals – for example in response to a pandemic – can be easily managed in this production process.
In contrast, the donor-to-patient plasma-derived medicine pathway needs to be planned months in advance. Obtaining large additional quantities of plasma to produce these medicines cannot be done overnight.

In planning for access to plasma-derived medicines, it is vital that sufficient plasma volumes from donors are always available.

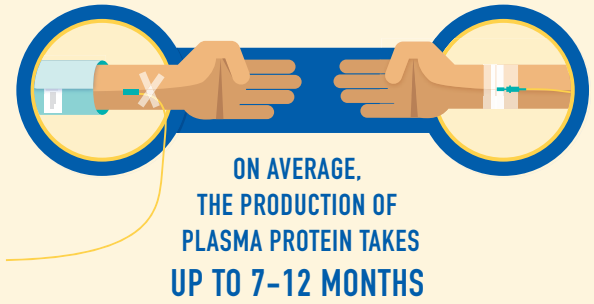
A plasma-derived medicine that is needed today has been a year in the making.
This means that, in a crisis situation where large volumes of medicines are needed rapidly, a public plasma collection system may not have the flexibility to deliver more donated plasma needed for medicines production.
A combined system where public and private plasma donation systems coexist – or with sharing of donated plasma across regions – will increase certainty for patients to have stable access to the treatments they need.

Unique and non-interchangeable medicines

Plasma-derived medicines cannot be cannot be used interchangeably to treat a patient with similar conditions, even in a same class of medicines. Each plasma protein therapy is unique due to differences in manufacturing processes, and because patients' specific responses to the therapy will differ, depending on the person's health situation.

How long does plasma protein production take?

The process to manufacture plasma protein therapies is lengthy because several complex steps must be taken to ensure products are safe and effective.



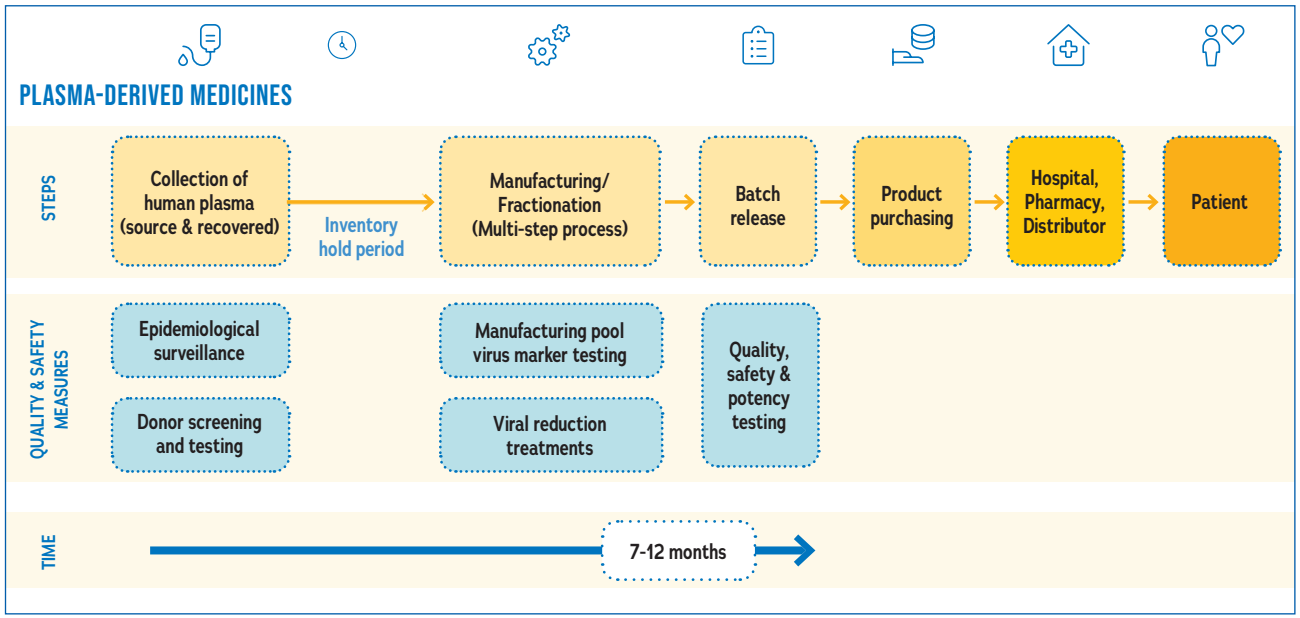
For example, a patient's tolerance of the therapy may depend on the variation in the composition of components, the dosage and routes of administration. To identify optimal treatment for each patient, physicians do complex evaluations to identify the appropriate brand, dosage and administration route.

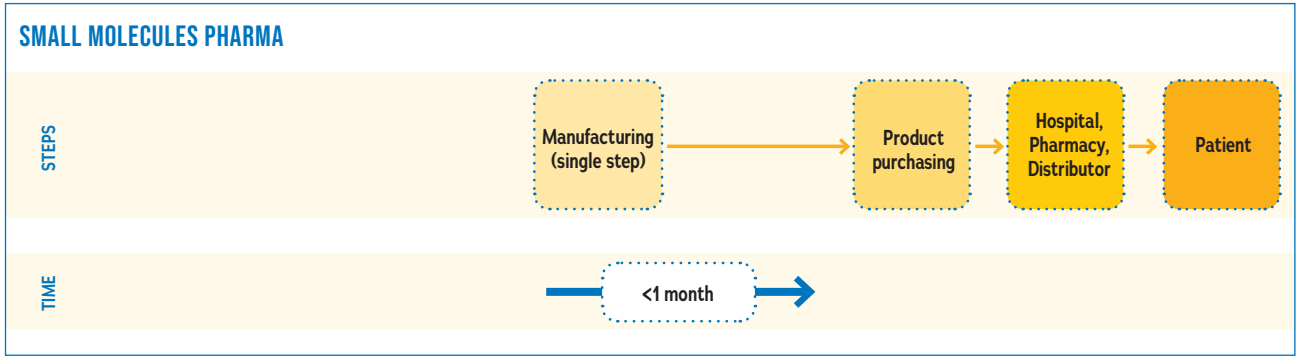
Co-morbidities will also indicate which brand therapy in a class of treatments is optimal for that patient.[10]

The donor-to-patient pathway is fundamentally different for the creation of plasma protein therapies than for chemically synthesized medicines.

- **The essential building block of plasma-derived medicines is human-donated plasma**, a material that cannot be re-created in a laboratory or by synthesis used in the pharmaceutical process for small molecule medicines.
- **The production process of medicines derived from human plasma is more complex** and expensive chemically-synthesized medicines. It takes 7-12 months from donation before a plasma-derived medicine is available. Some 57% of the cost of a plasma-derived medicine is in the manufacturing process; for small molecule medicines it is 14%.

  Source: Vintura; Grabowski and Manning 2018
- **Each medicine derived from plasma has its unique biochemical profile, and is not interchangeable with other treatments.** Medicines regulators specify them as treatments for which no generic or substitution treatments exist.





Source: Burnouf 2018, PPTA analysis, Vin 1