

# EU needs effective measures to facilitate access to lifesaving medicines made of human plasma (PDMPs)

## PPTA position statement on stockpiling

The COVID-19 pandemic highlighted the vulnerability of the EU's reliance on US plasma. Uninterrupted access to plasma-derived medicinal products (PDMPs), which are life-saving, essential medicines made from human plasma, is critical to patients relying on these therapies. Whilst PPTA supports the European Commission's and Member States' efforts to ensure patient access to treatments, it is important to note that one of the measures examined by policymakers to prevent medicine shortages, stockpiling, is not an appropriate mechanism to ensure access to PDMPs.

While the production of some pharmaceuticals can be scaled up rapidly to meet clinical needs, this is not the case for PDMPs. Human plasma donated by healthy volunteers serves as an essential starting material for PDMP production. Moreover, given the restrictive policies and regulatory frameworks that exist in most EU countries regarding plasma collection, EU relies on the US for plasma needs. Therefore, additional stockpiling requirements risk diverting PDMPs from patients who need them and would consequently lead to more severe access challenges.

### **PPTA calls on all decision-makers to support thoughtfully-tailored policies that:**

1. Recognise the unique nature of PDMPs.
2. Address the root causes of access challenges to these essential medicines, such as the inadequate plasma collection volumes in the EU.
3. Consider fit-for-purpose measures to address root causes of PDMPs access issues and meet the growing clinical need for PDMPs.

### **PDMPs are unique medicines that depend on the limited availability of human donated plasma.**

The starting material for the manufacture of PDMPs is blood plasma, which is a scarce resource of human origin. Unlike chemical medicines or those made by biotechnological processes (e.g., monoclonal antibodies, recombinant proteins), PDMP production cannot be immediately scaled upon demand but requires increased plasma collection capabilities.

While the global clinical need for PDMPs has been growing,<sup>1</sup> access issues surrounding PDMPs, in particular immunoglobulins (IGs), have been reported repeatedly in the EU. Thus, PPTA calls on EU policymakers to address the root causes of PDMP access issues by ensuring reliable plasma collection in the EU. The EU Pharmaceutical Strategy, the review of the pharmaceutical legislative framework and the current [revision of the EU Blood, Cells and Tissues legislation](#), provide an opportunity to address these core shortcomings.

#### **Example**

*A two-month stockpile requirement for immunoglobulins (IG) for France is equivalent to more than the total annual supply for Belgium or Sweden. Were this to be increased to four months, it would exceed the total annual volume of IG used in Poland, the Czech Republic, Slovakia, Hungary, Romania, Bulgaria, Slovenia, Croatia and Greece combined [1]. Thus, recognising the unique nature of PDMPs, France recently reduced stockpiling requirements for PDMPs (for IGs - 4 weeks, for other PDMPs - 6 weeks).*

## Unilateral country stockpiling requirements may impact patient access in the other EU Member States

The introduction of mandatory stockpiling requirements by individual EU Member States would either necessitate a scale-up of PDMP production to build the stockpile or require the diversion of products from other EU Member States and patients who may need them immediately. As PDMP production cannot be scaled up in the short-term, stockpiling requirements could affect the free movement of goods in the EU and consequently, limit supplies, rather than directing them to where they are needed most, thereby putting patient health at risk.

## The EU should address the root causes of PDMPs patient access challenges

At present, EU's plasma for the manufacture of plasma therapies comes largely from four countries – Austria, the Czech Republic, Germany and Hungary. These countries permit the co-existence of the private and public sectors to collect plasma and allow donors to be compensated using a fixed-rate allowance, with conditions set by the national government. Nonetheless, despite the plasma industry sector's strong European manufacturing footprint, the EU relies on the US for 38% of its plasma for manufacturing.<sup>2,3</sup> Therefore, to ensure patient access to these therapies, it is crucial to accelerate plasma collection efforts in the EU.

### Example:

*Until recently, Finland had mandatory stockpiling of six months of sales for immunoglobulins and 10 months of sales for albumin. Due to COVID-19 pandemic, the plasma collection has significantly decreased. The Finnish authorities, however, recognising the unique nature of PDMPs, reduced stockpiling requirements.*

- » Stockpiling is **NOT** an appropriate measure to address access challenges to plasma-derived therapeutics.
- » The unique nature of PDMPs should be considered when issuing any assessments, recommendations, or guidance related to PDMP supply chain management.
- » To ensure the availability of PDMPs, it is necessary to strengthen the entire PDMP supply chain, including the collection of the starting material.
- » Policy-makers should address the root causes of EU PDMP access issues, through specific policies, at the European level.<sup>4</sup>

### References

1. The Market Research Bureau (2017) (annual volume supplied to France of 10.87 tonnes). [www.marketingresearchbureau.com](http://www.marketingresearchbureau.com).
2. Vintura (2020). White paper: Key Economic and Value Considerations for Plasma-Derived Medicinal Products (PDMPs) in Europe.
3. Copenhagen Economics (2021). The impact of plasma derived therapies in Europe: The health and economic case for ensuring sustainable supply.
4. PPTA BTC position paper. [www.EUNeedsMorePlasma.com](http://www.EUNeedsMorePlasma.com).