# Statement on the UK Plasma for Medicines Programme

# Update 21.08.2024

This statement was received from the NHS England's Medicines Procurement and Supply Chain (MPSC) team.

## Background

In 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines (CHM) approved the removal of the ban on UK-sourced blood plasma for the manufacture of immunoglobulins. Following this decision, the government appointed NHS England to develop and lead a procurement to select a supplier to provide fractionation services for England, as well as to lead on a UK Plasma Programme.

In 2023, the MHRA and the CHM also approved UK plasma for use in the manufacturing of albumin. This followed advocacy work by NHS England and NHS Blood and Transplant (NHSBT), in collaboration with other blood services and organisations, for the safety of UK plasma.

## UK Plasma Programme

The UK Plasma Programme is being led by England, with the option for the Devolved Administrations for Northern Ireland, Scotland, and Wales to participate.

For the first time in decades, the programme provides the UK with an opportunity to establish domestic plasma for medicines collections that will improve the resilience of our supply chain that remains at risk due to the volatility of the globally sourced supply that we are solely reliant on.

By improving the supplies of albumin and immunoglobulin to the NHS, the programme will ensure patients in the UK are more likely to retain access to recommended treatments and reduce the need to be treated with an alternative product.

In England, the NHS has infrastructure in place through NHSBT to collect plasma, through whole blood donations and via plasmapheresis at three dedicated plasma donor centres, which will enable England to establish a domestic supply of plasma derived medicinal products (PDMPs) that will meet a proportion of total demand; while continuing to source products manufactured using non-UK plasma.

Over the past two years, NHSBT has been collecting source and recovered plasma, and will continue to collect more than 250,000 litres per year throughout the life of the programme. NHSBT is actively recruiting new donors to build on the donor base. By the end of March 2025, NHSBT will have doubled their donor base, ensuring that they can sustainably collect 10,000-12,000 litres of source plasma a year.

## Fractionation procurement

Following evaluation and moderation of procurement bids, NHS England has now completed a procurement process, with the support of the UK government, NHSBT, and the Devolved Administrations.

In July 2023, NHS England appointed a sole fractionator, Octapharma, to proceed into the mobilisation phase of the procurement. Octapharma, established in 1983, are one of the world's largest plasma fractionators. Octapharma have been supplying the NHS with plasma derived products for more than 30 years.

The procurement will focus manufacturing on the highest volume products: low (5%) and high (20%) strength albumin, and 10% intravenous immunoglobulin (IVIg).

The initial contract period is 5 years, which begins from the supply date of the first product, expected no earlier than Q1 2025. There is an option to extend the contract for up to an additional 2 years.

## Mobilisation

The mobilisation phase of the project began in August 2023 following contract award, and consists of:

- **Plasma Readiness**
    - This phase of the project focuses on the collection, testing, release, export, and shipping plasma collected by NHSBT.
- **Regulatory and Licensing**
    - This phase of the project includes audits at both NHSBT plasma collection and processing sites, as well as fractionator manufacturing and bottling locations. During this stage, regulatory import and manufacturing and product licenses are granted.
- **Operational Readiness**
    - This phase of the project surrounds the receipt of plasma and fractionation, packaging, importation, and distribution of finished goods.
- **Implementation**
    - This phase of the project centres on the clinical engagement to deliver uptake of the products, system readiness for ordering, receipt, and distribution, creation of product allocations and uptake tracking tools, and commencing patient treatments on the new products.

In August 2024, the MHRA completed the regulatory process, granting approval for the UK Plasma Master File and Marketing Authorisations for low (5%) and high (20%) strength albumin and 10% intravenous immunoglobulin (IVIg), to include the use of UK plasma.

Substantial progress has been made and NHS England has already started working with clinicians, pharmacists, transfusion, and nursing staff to plan for implementing these new products from Q1 2025.

The Medicines Procurement and Supply Chain (MPSC) team will provide updates on progress against the mobilisation plan to Clinical Reference Groups (CRGs), expert speciality working groups and patient representative groups.

## Donating Plasma

There is a growing need for the unique medicines made from plasma. NHSBT works in collaboration with patient groups to promote UK plasma, recruit more donors and educate other stakeholders on why self-sufficiency of UK plasma is essential.

People can donate plasma more often than they can donate blood, because the recovery time is shorter. For more information about Plasma donation or how to donate, visit: www.nhsbt.nhs.uk/what-we-do/blood-services/plasma-donation/.

People can also help by donating blood if a Plasma Donation Centre is not near them, because NHSBT will remove the plasma from the blood donation to freeze and use to make medicines.

Should there be any queries regarding this project please contact: scm.procurements@nhs.net