National Plasma Product Expert Advisory Group (NPPEAG)

NHS National Services Scotland

Plasma for Medicines
Frequently Asked Questions (FAQs)

1. What are Plasma-Derived Medicinal Products (PDMPs)?

Plasma-derived medicinal products (PDMPs) are pharmaceutical products made from human plasma.

Examples of PDMPs include:

- **Immunoglobulins:** Used to treat immune deficiencies, autoimmune diseases, haematological disorders and neurological disorders.
- **Albumin:** Used in replacement fluid in plasma exchange and liver disease.

PDMPs are crucial for treating a wide range of life-threatening conditions. Many patients rely on these lifesaving and life enhancing treatments.

2. How are PDMPs made?

Whole blood or plasma is collected from a donor, tested and processed in a laboratory for freezing. The plasma is then sent to a plasma product manufacturer and put through a process called fractionation. Plasma fractionation separates out the different components of the plasma and includes steps which inactivate viruses. These components, such as immunoglobin or albumin, are then treated and purified ready to be packaged for distribution.

3. Why did the UK stop making Plasma-Derived Medicinal Products (PDMPs)?

In 1998, the Committee on Safety of Medicines (CSM) advised against the use of UK plasma for manufacture of Plasma-Derived Medicinal Products (PDMPs) due to concerns around the potential risk of transmission of variant Creutzfeldt-Jakob Disease (vCJD). Between 1998 and 2008 the UK bought in plasma from outside of the UK for fractionation in Edinburgh. Since 2008 all plasma products have been purchased and imported into the UK for use.

4. What is MHRA?

The Medicines and Healthcare products Regulation Agency (MHRA) is responsible for the regulation of medicines (including PDMPs), medical devices and blood components for transfusion used in healthcare in the UK. The MHRA is also responsible for the regulation of blood establishments which are authorised for the collection, testing, processing, storage and distribution of blood and blood components intended for transfusion. Blood establishments can also be authorised to collect and test blood intended for further manufacture of medicinal products.

5. What is the Commission on Human Medicines?

The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. CHM is an advisory non-departmental public body, sponsored by the UK Department of Health and Social Care (DHSC).

6. Why is the UK now able to collect plasma to make intravenous immunoglobulin and albumin?

There has been no evidence of any UK clinical cases of vCJD being linked to a blood transfusion given after 1999. From October 1999, white blood cells (which may carry a risk of transmitting vCJD) have been reduced in all blood used for transfusion, by a process known as leucodepletion or leukoreduction.

Due to increasing global demand and concerns regarding supply, the Commission on Human Medicines (CHM) was asked to carry out a new assessment of the risk of vCJD transmission by immunoglobulins. It found that risks were now negligible. As a result, in 2021, the MHRA and the CHM recommended that UK-sourced blood plasma should be able to be used for the manufacture of immunoglobulins (www.gov.uk - Immunoglobulin). In 2023, the MHRA and the CHM recommended UK plasma for use in the manufacturing of albumin (www.gov.uk - Albumin). Ministers from all four UK nations then approved the use of UK plasma for the manufacture of immunoglobulins and albumin.

In September 2023, the Biological Working Party of the European Medicines Association (EMA) completed a review and said it had no specific concerns with fractionation programmes using plasma sourced from the UK for the manufacturer of products in a European Union (EU) facility.

Following the CHM review, countries such as the United States of America, Canada, New Zealand, Australia and Ireland have all amended their policies to allow blood donors with a history of living in the UK to donate blood.

In 2023, NHS England appointed a plasma fractionator, Octapharma, to manufacture intravenous immunoglobulin and albumin from UK plasma for NHS England. The Scottish National Blood Transfusion Service (SNBTS) has joined the Octapharma service agreement to allow plasma collected in Scotland to be manufactured into intravenous immunoglobin and albumin.

7. Who is Octapharma?

Octapharma is a global healthcare company headquartered in Lachen, Switzerland. Their products are available in 118 countries and reach hundreds of thousands of patients every year. As one of the world's largest plasma fractionators they have been supplying the NHS with plasma-derived medicinal products for more than 30 years.

UK plasma will be sent to the Octapharma manufacturing sites in mainland Europe to be main into PDMPS. The PDMPs will then be shipped back to the UK for treatment of UK patients.

8. Why is it important that the UK starts to collect plasma to make PDMPs?

Immunoglobulin is now the most widely used plasma component. As usage continues to increase there has been growing concerns over availability of immunoglobulin because of a global supply shortage. As the global clinical demand for plasma products increases, there is a risk that the availability of commercial plasma products will be limited in the future and therefore using UK plasma is important to build resilience and increase security of supplies in UK healthcare. UK plasma products are for UK patients only and therefore a proportion of this life saving treatment can be secured.

9. What level of supplies of UK plasma products is Scotland aiming for?

Scotland hopes to achieve a level of 20% self-sufficiency in intravenous Immunoglobulin (IVIg) from July 2025 and 80% for albumin. In other words, Scotland will collect enough plasma to provide 20% of the immunoglobulin NHS Scotland needs.

10. Will the UK plasma products be safe to use?

Yes. Strict donor selection criteria together with donation testing form the basis of blood safety.

Every time a donor comes to give blood or other blood components such as plasma, they are asked to read our donor information leaflet, 'Giving blood: Process, risks and information' so they understand the importance of answering the donor health check accurately. The leaflet makes it extremely clear when a

donor must not give blood or blood components, for example, that individuals must never donate if they are HIV positive, have Hepatitis B, Hepatitis C, or syphilis, or where a donor has ever injected, or been injected with, drugs.

The donor must also fill in a donor health check. This questionnaire asks about medical history, lifestyle and recent travel. It helps us work out whether it's safe for the donor to give blood, and whether the blood is safe to be given to someone else. If a donor is identified as being at a higher risk of infection, they will not be able to give blood at that time.

All new blood donors are sent a welcome pack, which signposts them to the donor information leaflet, 'Giving blood: Process, risks and information'.

Donors are selected according to UK wide guidelines set by The Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC).

At every donation, blood samples from donors are tested for infections which we know can be passed on in blood. This includes tests for HIV, Hepatitis A, B, C and E, Syphilis, Parvovirus and Human T-lymphotropic virus (HTLV). To meet the special needs of some patients we also test some donations for CMV (Cytomegalovirus). Extra tests can also be carried out depending on a donor's travel history, for example, for the West Nile virus or malaria.

National regulatory authorities evaluate the safety, efficacy and tolerability of each plasma product; all products have to go through regulatory approval before they can be used to treat patients.

During manufacturing of the PDMPs, the plasma goes through purification processes to filter out contaminants and pathogens. Viruses are removed or inactivated through solvent detergent and nanofiltration and the products are then purified into the final products such as Immunoglobulin and albumin.

The UK 10% intravenous immunoglobulin product Gamten is a duplicate of the 10% intravenous immunoglobulin Octapharma product Octagam®. The 5% and 20% UK albumin product Octalbin® is a duplicated of the 5% and 20% albumin Octapharma product Albunorm®. UK plasma products are produced exactly the same as non-UK plasma products and therefore the same level of safety and tolerability should be expected as non-UK plasma products.

More detailed information on the UK plasma products can be found at the links below:

EMC - Gamten

EMC - 5% Octalbin

EMC - 20% Octalbin

11. What is the surveillance for vCJD in the UK?

The National CJD Research & Surveillance Unit (NCJDRSU, formerly NCJDSU) undertakes CJD surveillance in the UK and research into prion disease and related problems. Based at the Western General Hospital in Edinburgh, the Unit brings together a team of clinical neurologists, neuropathologists, scientists and others as part of the University of Edinburgh's College of Medicine and Veterinary Medicine, School of Clinical Sciences (Centre for Clinical Brain Sciences). They work closely with the UK Health Departments, the National Blood Authorities, Public Health England (PHE) and Public Health Scotland (PHS), as well as local public health teams, to provide advice where needed.

12. When does Scotland plan to start introducing UK plasma products?

UK plasma products will be available in the UK at the beginning of 2025 and will be ready to order in Scotland from April 2025

13. Do patients have to use the UK plasma product?

If patients are currently on the 10% IvIg Octapharma product Octagam®, this will be replaced with Gamten. These are the same products with different names. Octagam® is manufactured using non-UK plasma and Gamten is manufactured using UK-sourced plasma. The frequency, dosage and supply of Gamten is expected to remain the same for patients who are currently on Octagam®.

Some patients who are not prescribed Octagam® but instead alternative intravenous immunoglobulins might be required to swap to Gamten. Work is ongoing to understand what patients may be impacted by this change and further communications will be provided if your patients might be affected. In the first instance it is likely that Gamten will mainly be used for either existing patients prescribed Octagam® or for new patients who are starting intravenous immunoglobulin treatment.

14. What happens when a patient swaps to the UK plasma product?

Standard procedures for switching immunoglobulin products will need to be followed for all patients who are switching to Gamten.

15. How does procurement of PDMPs work in Scotland?

In Scotland, the procurement of PDMPs involves the establishment of a framework agreement for the supply of PDMPs over a specified period. The framework agreement outlines the terms and conditions, including pricing, quality standards, and delivery terms.

Before entering into any new framework agreement for PDMPs, Scotland decides whether to collaborate with NHS England or to conduct a standalone procurement process. Various factors are considered when making this decision, including buying power and security of supply.

In recent years, collaboration with NHS England has been the preferred approach for the procurement of PDMPs in Scotland. With this approach, Scotland "calls-off" from the framework agreement, without having to undergo a separate procurement process, as the terms have already been agreed upon. There is close coordination between NHS Scotland and NHS England, especially in agreeing the terms of the framework agreement and managing the supply chain, which ensures that Scotland benefits from economies of scale and consistent quality standards.

16. What is NPPEAG?

National Plasma Product Expert Advisory Group (NPPEAG) was established in 2009 and meets 3-4 times a year. It is a Scotland wide group which was set up by NHS Board Chief Executives to provide advice on the use, prescribing and procurement of plasma products for NHS Scotland. NPPEAG is working alongside colleagues at SNBTS to support the Plasma for Medicines Programme.

17. What is SNBTS role in PDMP?

SNBTS will be collecting plasma (from whole blood and plasma only donations) from donors, then testing and processing it for freezing. The frozen plasma will then be distributed on to Octapharma for fractionation.

18. What monitoring is there for adverse events relating to PDMP?

Adverse events relating to PDMPs are reported via the Yellow Card Scheme Yellow Card | Making medicines and medical devices safer (mhra.gov.uk). The MHRA runs the Yellow Card scheme, which collects and monitors information on any suspected safety concerns involving healthcare products, like a side effect with a medicine or an adverse medical device incident. The scheme relies on voluntary reporting of any problems by the public (including patients, parents and carer givers) as well as from healthcare professionals.

19. Where do I email if further questions or feedback on PfM Programme?

If you have any questions or feedback, please contact us at nss.nppeag@nhs.scot