NHS National Services Scotland

Scotland Plasma for Medicines Programme

Clinician leaflet

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

This pack has been provided to clinicians in Scotland by The Scottish National Blood Transfusion Service (SNBTS) in conjunction with the National Plasma Product Expert Advisory Group (NPPEAG). It aims to provide information on the forthcoming changes to the supply of immunoglobulin and associated plasma products for patients in Scotland. The leaflet will summarise the rationale for these changes and outline what action clinicians / Health Boards should take at this point.

What is the Plasma for Medicines Programme?

The global clinical demand for plasma derived medical products (PDMPs) continues to increase. In response to this, Scotland and England have introduced Plasma for Medicines (PfM) programmes and Wales and Northern Ireland are in the planning stage of developing their PfM programmes. This is to provide a level of selfsufficiency in PDMP supply within the UK and build resilience into the supply of these treatments for patients within the NHS. UK plasma products are for UK patients only securing a proportion of this life saving treatment despite the continuing global shortages.

What are Plasma Derived Medicinal Products (PDMPs)?

PDMPs are pharmaceutical products made from human plasma. PDMPs are crucial for treating a wide range of life-threatening conditions. Many patients rely on these lifesaving and life enhancing treatments.

Examples of PDMPs:

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

How does Scotland currently obtain PDMPs?

All PDMPs, including, immunoglobulin and albumin, are currently made from non-UK plasma and imported into the UK. 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. The National Services Scotland (NSS) National Procurement team manage this framework and procure the PDMPs which are then held at the Jack Copland Centre in Edinburgh, ready to be distributed to Health Boards. Any changes to the commercial products available

What is the aim of the Plasma for Medicines Programme?

The aim of the programme is to achieve a level of self-sufficiency in Scotland for 20% immunoglobulin and 80% albumin from July 2025. The level of self-sufficiency will hopefully increase in the future.

How will plasma be collected in Scotland?

The SNBTS started to collect plasma from donors for the programme in April 2024 and this plasma is tested and processed for freezing. The frozen plasma is then distributed onto the PDMP supplier for fractionation.

What changes will be delivered through the Plasma for Medicines Programme?

Plasma collected in the UK will be sent to the PDMP supplier to be manufactured into 10% intravenous immunoglobulin and 5% and 20% albumin. These products will be returned to the UK at the beginning of 2025 and made available to distribute out to the Health Boards to treat patients.

Producing PDMPs from UK plasma provides a guaranteed level of supply for our patients with life-threatening conditions.

Why is this change necessary?

Immunoglobulin is now the most widely used plasma component. As usage continues to increase there has been growing concerns over availability of immunoglobulin to the NHS because of a global supply shortages. 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 self-sufficiency in the UK is of great importance to build resilience in UK healthcare.

What regulatory changes have there been for this to happen?

There has been no evidence of any UK clinical cases of vCJD being linked to a blood transfusion given after 1999.

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 risk is now negligible.

As a result, in 2021, the Medicines Health and Regulatory Authority (MHRA) and the CHM recommended that UK sourced blood plasma should be able to be used for the manufacture of immunoglobulins (www.gov.uk - Immunoglubulin) In 2023, the MHRA and the CHM recommended UK plasma for use in the manufacturing of albumin (www.gov.uk - Albumin). These recommendations led Ministers to lift the ban on using UK sourced plasma for the manufacture of immunoglobulin and albumin.

PDMPs derived from UK plasma have had the same rigorous regulatory oversight as imported plasma products. For this reason, albumin and immunoglobulin products manufactured using UK plasma will, in functional terms, exhibit the same efficacy as existing products manufactured from global plasma.

What changes will clinicians be required to make?

Some patients on intravenous immunoglobulins might be required to switch to UK intravenous immunoglobulin . Work is ongoing to understand which patients may be impacted by this change and further communications from National Procurement will be provided if your patients may be affected.

Will it be necessary to make appointments with patients to swap to the UK plasma product?

Yes, standard procedures for switching immunoglobulin products will need to be followed for all patients who are switching to UK intravenus immunoglobulin. Please use the switching leaflet for support.

https://bit.ly/IGSwitching

Further information:

For more information on UK intravenous immunoglobulin please visit the website below:

https://bit.ly/EMCGamten

For more information on the Scotland Plasma for Medicines Programme visit our FAQs:

https://bit.ly/PfMFAQsV2

Contact

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This document was designed by NHS National Services Scotland Creative Services team.

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