Agenda Item
5.3

Joint Commissioning Committee

Velindre University NHS Trust (Welsh Blood Service) Recovered Plasma from Whole Blood Donations for Medicines

Dyddiad y Cyfarfod / Date of Meeting	20/05/2025
Statws Cyhoeddi / Publication Status	Open/ Public
	Not Applicable
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Pwrpas yr Adroddiad / Report Purpose	For Approval

Engagement (internal/external) undertaken to date (including receipt/consideration at Committee/Group)		
Committee / Group / Individuals	**Date**	**Outcome**
Collective Commissioning Leadership Group (CCLG)	29/06/2025	Noted
Chief Executive Management Team (CEMT)	06/05/2025	Endorsed: i. supply of plasma recovered from whole blood for the manufacture of medicines

		ii. VUNHST use of price savings from Octapharma contract procured immunoglobulins & albumin to fund additional costs of testing, processing, warehousing & logistics and lost plasma sale income.

Acronyms / Glossary of Terms	
FY	Financial Year
PYE	Part Year Effect
VUNHST	Velindre University National Health Service Trust
WBS	Welsh Blood Service

1. SITUATION

The purpose of this report is to seek support from the Joint Commissioning Committee (JC) members for the Velindre UNHST:

Policy

i. Welsh Blood Service (WBS) to commence the supply of plasma recovered from whole blood donations (recovered plasma) for the manufacture of Immunoglobulin and Albumin products for clinical use in Wales under the terms of a UK-wide contract with Octapharma AG.

Financial

ii. Welsh Blood Service (WBS) to use the price savings from the UK-wide Octapharma contract compared to the commercially sourced equivalent NHS Wales contracts, to cover the additional costs of testing, processing, warehousing and logistics of recovered plasma, as well as income lost from supply of plasma to diagnostic industry. Once a break-even point has been reached, VUNHST will share future savings with Health Board commissioners.

2. BACKGROUND

2.1 Following the emergence of prion diseases in the mid/late 1990's, the UK stopped using plasma from UK donors for plasma-derived medicines in 1997. This led to reliance on imported plasma-derived medicines, primarily

from the United States and other countries where donors are paid. Plasma collected in the UK has been sold to the diagnostics industry, supporting core blood and transplant services. Global demand for these medicines has grown, causing price increases and supply chain issues, leading to rationing in parts of the UK. In Wales, plasma-derived medicines are centrally purchased and distributed by the Welsh Blood Service, allowing for better supply chain management.

2.2 The reliance on a few countries for plasma from paid donors poses risks, similar to the emergence of HIV and Hepatitis C in the United States. This has created a need for countries to reduce reliance on paid donor plasma and establish national strategic independence. Investments have been made in Europe, Australia, New Zealand, and Canada to establish plasma donation programs. In 2021, the UK lifted the ban on using plasma from UK donors for medicines, followed by similar actions in Australia and the United States. Government investments in England and Scotland have allowed their blood services to restart plasma supply for medicines, with plasma processed under a 'Toll Fractionation' contract by Octapharma, resulting in significant savings compared to commercially sourced products.

2.3 Recently, the EU announced a €200 million investment fund to increase plasma collection in member states, aiming for long-term strategic independence from the USA.

2.4 The move towards supplying plasma for medicines should be seen as a medium to long-term project. Italy took 20 years to meet 90% of its need for immunoglobulins, and Australia took 10 years to achieve 60% self-sufficiency.

2.5 There is an urgency to start the journey. High self-sufficiency is desirable to mitigate risks, but regulatory and quality hurdles need to be addressed. The immediate investment aim for supplying plasma recovered from whole blood (Recovered Plasma) is:

- Achieve regulatory permission and accreditation to supply plasma for medicines.
- Achieve 10% self-sufficiency in immunoglobulins supply for Wales.
- Release limited revenue savings to recoup the up-front investment.

2.6 The medium-term objective for investing in additional plasma collection capacity through apheresis is:

- Achieve 25% self-sufficiency in immunoglobulins and aim for 50% self-sufficiency.
- Create opportunities for donors to contribute to health in Wales.
- Balance investment in additional capacity with potential cost savings for Health Boards.

3. KEY RISKS / MATTERS FOR ESCALATION

3.1 The time to gain regulatory approvals and accreditation will take about 8 months, with an additional 7 months between the first plasma shipment to Octapharma and the receipt of products for clinical use. During this period, WBS will incur costs for leucodepletion, infectious disease testing, processing, storage, and logistics. There will also be a reduction in income as WBS exists contracts to supply plasma to the diagnostics industry.

3.2 Once products are received from Octapharma, the savings compared to commercially sourced equivalents will outweigh the costs and lost income. The programme based on recovered plasma will break even by the end of year 2026/27. VUNHST has approached the Welsh Government for financial support to cover initial impacts in 2025/26 & 2026/27, but they have responded that Health Boards should fund since the benefits of reduced immunoglobulin and albumin prices will accrue to them.

3.3 it is proposed that VUNHST and Health Board commissioners proceed at financial risk to supply excess plasma to Octapharma instead of the diagnostics industry. VUNHST will recover the initial investment by retaining savings from the products supplied by Octapharma. Once a break-even point is reached, VUNHST will share future savings with Health Board commissioners.

3.4 Expanding collection capacity to increase plasma supply through apheresis will require capital funding for collection facilities and ongoing revenue funding for staffing, overheads, and running costs. This second phase will not proceed without a commitment from the Welsh Government and/or Health Board Commissioners to provide funding.

3.5 The introduction of plasma from UK donors into the Welsh medicines supply chain represents a significant change, and Velindre UNHST is seeking a policy decision with Cabinet Secretary approval for this change.

Expected Benefits

Benefits	Timeline
• Reduced reliance on international markets for albumin and immunoglobulin products used in Wales (actual benefit proportional to investment but minimum 10% self-sufficiency)	August 2026
• Greater assurance over the safety of plasma-derived products/plurality of supply in the event of new risks emerging.	August 2026
• Financial benefits expected to exceed the up-front investment in supply of plasma recovered from whole blood	FY 2027/28

Funding and Affordability

3.6 Velindre UNHS Trust will cover the up-front costs and lost income in 2025/26 and 2026/27 until products are available from Octapharma for clinical use. If Welsh Government funding is not available, commissioners and VUNHST will bear the costs of supplying plasma recovered from whole blood donations for Immunoglobulin and Albumin products in Wales. These costs include:

- Additional testing and processing for donated plasma
- Warehousing and logistics operations required by Octapharma
- Lost income from existing contracts to supply plasma to the diagnostics industry

Year	2025/26 (PYE)	2026/27
Cost	£279,819	£509,759
Lost plasma diagnostics income	£600,000	£1,400,000
Octapharma price benefit	£0	-£2,032,236
Net Cost (+'ve) / Benefit (-'ve)	£879,819	-£122,477

3.7 Immunoglobulin and Albumin products from plasma donated in Wales will be supplied to Health Boards at the average price of equivalent commercially procured products (£63.55 per gramme of immunoglobulin and £2.54 per gramme of albumin for 2025). VUNHST will retain the difference between the price paid to Octapharma and the price charged to Health Boards until the project breaks even.

3.8 Once the investment is recouped (estimated by 2027/28), VUNHST will pass on savings to Health Boards by reducing product prices.

3.9 Expanding plasma collection through apheresis will require additional funding of c£2.4m for collection facilities, staffing, overheads, and running costs. This work will not proceed without funding commitment from the Welsh Government and/or Health Board Commissioners.

4. ASSESSMENT

Objectives / Strategy	
Dolen i Amcan (au) Strategol CBC / Link to JCC Strategic Objectives(s)	Maximise Value Ensure Quality
Dolen i Ddeddf Llesiant Cenedlaethau'r Dyfodol – Nodau Llesiant / Link to Wellbeing of Future Generations Act – Wellbeing Goals *150623-guide-to-the-fg-act-en.pdf (futuregenerations.wales)*	A Healthier Wales If more than one applies please list below:
Dolen i Hwyluswyr Ansawdd *(Canllawiau Statudol Dyletswydd Ansawdd (llyw.cymru)) /* **Link to Enablers of Quality**	Whole-systems Perspective If more than one applies please list below:

(Duty of Quality Statutory Guidance (gov.wales))	
Dolen i Feysydd Ansawdd *(Canllawiau Statudol Dyletswydd Ansawdd (llyw.cymru)) /* **Link to Domains of Quality** *(Duty of Quality Statutory Guidance (gov.wales))*	Effective
	If more than one applies please list below: Efficient Equitable
Effaith Amgylcheddol/ Cynaliadwyedd (5R) / Environmental /Sustainability Impact (5Rs)	Yes - Repurpose
	Reduce Reuse

Impact Assessment		
Ansawdd *Ydych chi wedi ymgymryd â Sgrinio Asesiad o'r Effaith ar Ansawdd? /* **Quality** *Have you undertaken a Quality Impact Assessment Screening?*	Yes: ☒	No: ☐
	Outcome: Overall positive impact across all quality domains and enablers	If no, please include rationale below:
Cydraddoldeb *Ydych chi wedi ymgymryd â Sgrinio Asesiad o'r Effaith ar Gydraddoldeb? /* **Equality** *Have you undertaken an Equality Impact Assessment Screening?*	Yes: ☐	No: ☒
	Outcome:	If no, please include rationale below: The switch in use of plasma for medicines manufacturer does not impact adversely on any protected characteristics
Cyfreithiol / Legal	There are no specific legal implications related to the activity outlined in this report.	

	However, VUNHST is also seeking Cabinet Secretary approval for the switch of use of plasma derived from whole blood from diagnostic to manufacture of medicines.
Enw da / Reputational	There is no direct impact on the reputation of the Joint Committee as a result of the activity outlined in this report.
	However, England, Scotland and NI have either commenced or are in the process of implementing the use of plasma collected from their populations to supply Octopharma for manufacture of medicines.
Effaith Adnoddau *(Pobl /Ariannol) /* **Resource Impact** *(People / Financial)*	Yes (Include further detail below)
	The financial impact of this case is set out in the report

5. RECOMMENDATIONS

The Joint Commissioning Committee is asked to

- **Approve** that the Velindre University NHS Trust (VUNHST) / Welsh Blood Service (WBS):
  i. commence supply of plasma recovered from whole blood donations for the manufacture of Immunoglobulin and Albumin products for clinical use in Wales under the terms of a UK-wide contract with Octapharma AG; and
  ii. use the price savings from the UK-wide Octapharma contract compared to the commercially sourced equivalent NHS Wales contracts, to cover the additional costs and lost income.

6. NEXT STEPS

Project Plan / Timelines

Deliverables	Timeline
• Welsh Blood Service staff to engage with Octapharma in Q1 of FY 2025/26 with a view to commencing due diligence and contractual assurance activities.	May 2025
• Welsh Blood Service to exit existing contracts to supply excess plasma to the diagnostics industry commencing Q3 FY 2025/26	October 2025

• WBS/VUNHST agree a Quality Technical Agreement and sign a fractionation contract that allows VUNHST to be listed as a plasma supplier under the Octapharma Plasma Master File.	January 2026
• WBS to Commence Supply of Plasma to Octapharma for fractionation. Future supplies will be made quarterly thereafter.	January 2026
• Immunoglobulin and Albumin products for clinical use received at WBS from Octapharma. Future deliveries to be received quarterly thereafter.	August 2026