NHS National Services Scotland

Document Title: Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy

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Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

Table of Contents:

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

Executive Summary:

Normal Human Immunoglobulins (Ig) are used in all acute hospitals across the UK to treat patients, whose own immune function is reduced, leaving them at increased risk of infection. Patients using Ig may be prescribed the treatment for a number of reasons including inability to make immunoglobulins themselves, as a result of autoimmune disorders or a bone marrow transplant or following acquired immunodeficiency. Due to clinical requirements for some groups of existing patients there is a requirement to remain on their current product.

Ig is now the most widely used plasma component of whole blood, and usage continues to grow. The pressure on Ig supply is compounded by an ever increasing demand because of a number of factors, including the emergence of new therapeutic indications, widespread off-label use and an indefinite duration of use in some indications.

This supply/demand is creating cost pressure as seen during the term of the current framework, average price paid per gram has increased by 21%. Annual SNBTS issue data shows an overall value of ~£23.2m.

A key driver to minimise spend is demand management. There are established clinical guidelines regarding appropriate use of Ig, as this is an expensive therapeutic choice in disease states where other interventions may be indicated. Therefore, even if there is data that support the potential efficacy of Ig, health boards still carefully consider its use, not only because of supply issues, but because of potential and often individual risks.

The current supplier market shares for Ig presents risks to the NHS in the form of supplier failure, CSL Behring currently hold 60% of the Scottish business. There is a need to identify a solution to rebalance this market share to minimise risk to the NHS.

Through engagement with NPPEAG there is agreement to review collaborative options to establish a UK wide framework. The main aims and benefits of a national contract is to ensure continuity of supply, reduce the reliance on dominant suppliers, secure value for money, manage any supply issues and avoiding a duplication of workload across the UK for these high value medicines.

The considerations for tendering have been reviewed with a proposal that NHSS collaborate with NHSE CMU to establish a UK wide framework agreement including NHSS usage. The new agreement is proposed to be advertised for an 18-month period with options to extend up to a further 30 months, with the new framework commencing 1 July 2021. The new framework will ensure continuity of product supply for long-term patients whilst ensuring that new patients are using the most cost effective and best scoring products on the framework.

This document supplements the ongoing development of a plasma product contracting strategy Plasma Products Strategy V1, and seeks approval to enter into a UK collaborative framework agreement for Human Normal Immunoglobulin & Anti-D Immunoglobulin, led by NHSE Commercial Medicine Unit (CMU), effective from 1 July 2021.

Contract Status:

NHSS National Framework Agreement Position

There are currently 2 separate NHSS framework agreements in place that covers the products within the proposed scope of the new agreement.

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

NP32617 IVIg and SCIg - This framework agreement is due to expire on 30 June 2021 with 1-month extension option remaining. It was awarded as unranked multi supplier framework on a lot by lot basis, as detailed below:

Lot 1 - Human Normal Intravenous Immunoglobulin 5%

Lot 2 - Human Normal Intravenous Immunoglobulin 10%

Lot 3 - Human Normal Intravenous Immunoglobulin for subcutaneous use

Lot 4 - Subcutaneous Immunoglobulin with Hyaluronidase (facilitated subcutaneous (fSCIg))

NP34917 Anti-D Immunoglobulin – This is currently available via Lot 1 of framework agreement for AFHP, that commenced 1 August 2017. This framework is due to expire 30 April 2021 but will be extended to align with NP32617.

NHSE CMU National Framework Agreement Position

The current CMU framework agreement for Human Normal Immunoglobulin framework covers England and Northern Ireland and is due to expire 30 June 2021 with no extension options remaining. NHS Wales have their own agreement in place.

Anti-D Immunoglobulin is currently available via a framework for Albumin Products and Anti-D Immunoglobulin. CMU are in the process of re-tendering Albumin Products and due to clinical requirements/different end users they have agreed to include Anti-D Immunoglobulin usage within the scope of the new national tender for Normal Immunoglobulin & Anti-D Immunoglobulin.

Mid Framework Supply Issues (IVIg and SCIg)

The Rank 1 supplier of IVIg 10%, Shire Pharmaceuticals, notified NP in March 2018 that they would be unable to continue to meet overall demand across the UK, and therefore unable to fulfil the NHS Scotland monthly standing requirement for intravenous immunoglobulin for the remainder of 2018. The expectation set by Shire was that this was a temporary issue until the end of 2018. In July 2018, Shire then informed NP that contrary to previous expectations, they would only be able to provide a very limited supply of immunoglobulin in 2019 leaving a significant gap in supply.

Supply Issues Mitigation

To manage the shortage, steps were taken to significantly reduce demand via health board allocations and to switch a proportion of patients to an alternative subcutaneous formulation of the product, which Shire made available as a substitute. Following significant work undertaken to identify suitable patients to switch to Shire's subcutaneous products (Cuvitru® and Hyqvia®), and the establishment of new homecare service provision (funded by Shire), Shire then advised they were unable to supply the previously agreed volumes of Cuvitru® & Hyqvia® throughout 2019 and 2020. This resulted in further engagement with all alternative suppliers to source additional product and a review of the clinical guidance. To manage this, agreement was reached via the NPPEAG, that no new patients could be transitioned onto Shire's subcutaneous products, thus increasing the demand on available IVIg products.

As a contingency, three months' worth of stock had previously been stockpiled at SNBTS, which helped buffer the impact.

A claim for compensation from Shire (the recovery of direct losses under the Framework) was pursued with assistance from CLO. Takeda made a without prejudice offer of £343,500 in full and final settlement of any claims NHSS may have in connection with the supply shortage of

Immunology products by Shire, without any admission of liability. The full £343,500 was disbursed to health boards and reported via the delivered saving process.

Mid Framework Price Increases

Working closely with the NPPEAG, NP were able to secure sufficient supply of IVIg for 2019 and 2020 from alternative suppliers to meet current demand, however the global constraint on supply has driven prices up significantly.

The additional IVIg that was sourced was from Lot 2 of the current framework. The lower ranked suppliers on the framework were unable to meet the gap in supply under their current terms. Therefore, in order for them to secure stock for NHSS from their global supplies, those that were able to supply product stated they could only supply the additional volume at an increased price based on a commitment to purchase. This was due to a combination of the manufacturing lead time (between 9 – 12 months), global demand outstripping supply and increasing global price, which has seen an increase in the current benchmark global price from £28.90 to ~£43 per gram (g).

The UK price point has historically fallen below the global and more importantly European average price. Since 2017 the UK price has risen steadily to a point more in line with Europe (~€50 per gram), but still significantly behind the US (~$80 per gram). The increase in price for the UK has meant the NHS has been able to secure a more stable supply of product in the last 18 months.

Given the shortage and global competition for available alternative stock, NHSS agreed volume-commitment purchases of Intratect®, Gamunex® and Privigen® to secure stock for 2019. This stock has almost all been depleted, with only a few vials remaining at SNBTS.

Based on these commitment purchases, this resulted in a financial impact across health boards of £4.5m pa (based on previously purchasing Kiovig® from Shire).

Current Annual Spend:

Based on SNBTS issue data, the annual spend for the current NHSS frameworks (NP32617 and Lot 1 only NP34917) for the 12-month period from 1 September 2019 to 20 August 2020 is ~£23m split across 5 categories, as detailed below:

Supplier	5% IVIg	10% IVIg	SCIg	fSCIg	Anti-D	Total
Bio Products Ltd (BPL)			£178,020		£271,900	£449,920
Biotest		£238,290				£238,290
BPL	£7,020					£7,020
CSL Behring		£8,826,720	£4,718,129		£366,607	£13,911,455
Grifols	£738,360	£2,792,700				£3,531,060
Octapharma		£871,650	£493,290			£1,364,940
Shire (Takeda)		£2,673,733	£658,105	£358,737		£3,690,575
Total	**£745,380**	**£15,403,093**	**£6,047,544**	**£358,737**	**£638,506**	**£23,193,260**

Table 1 – SNBTS Current NHSS Spend

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

The following diagram (diagram 1) shows the market split by supplier based on the above overall spend.

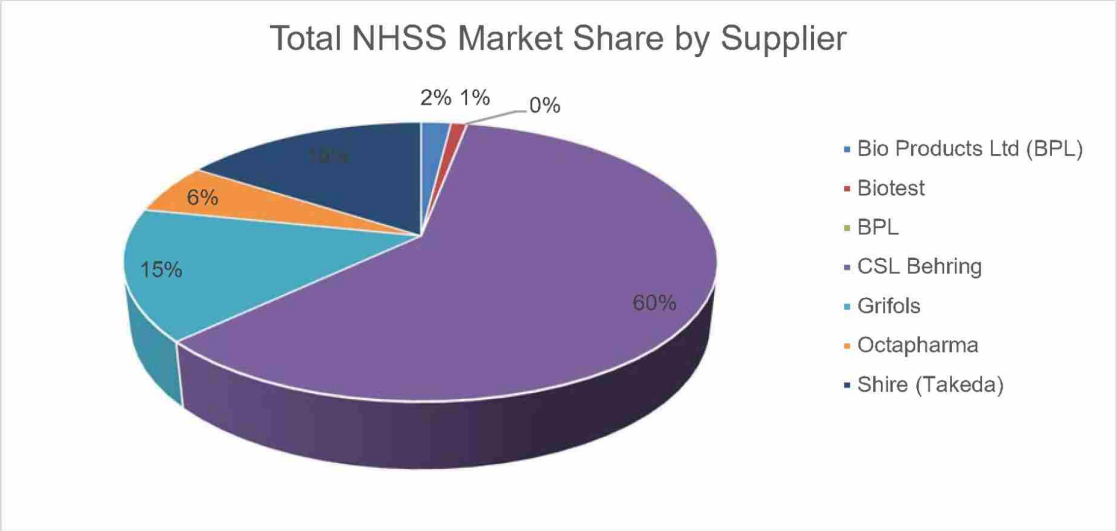

Diagram 1 – Market Share

Following extensive demand management work as a result of the severe supply disruption from 2018, all health boards are now recording usage on the national Immunoglobulin Database, managed by outsourced provider MDSAS. This data that can be extracted from this database provides details on issues by condition and brand that is not available from the SNBTS issue data.

Based on data obtained from MDSAS, for the 12-month period from 1 April 2019 to 31 March 2020, this shows a total of 507,704g of IVIg and ScIG issued (see Table 2). This is 38,214g (7%) less than the total number of grams issued by SNBTS. The difference in both data sets can be attributed to stock holding at health boards and/or delays regarding data entry, however this variance is expected to reduce as health boards have been working to improve their recording on the database.

It is proposed that the data extracted from the Immunoglobulin database will be used to inform the tender volume requirements, as this is a more comprehensive data set to determine long term and short term use by brand.

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

Brand	SNBTS Issue Data	MDSAS Data	Difference	% Diff	Comments
Privigen	210,160	173,894	36,266	17%	
Hizentra	97,281	88,603	8,678	9%	
Kiovig	89,813	108,764	- 18,951	-21%	
Gamunex	62,060	40,125	21,935	35%	
Cuvitru	19,522	21,379	- 1,857	-10%	
Octagam	19,370	21,305	- 1,935	-10%	
Flebogamma DIF	17,580	17,585	- 5	0%	
Gammanorm	10,962	7,121	3,841	35%	
Hyqvia	9,105	13,565	- 4,460	-49%	
Intratect	6,110	8,000	- 1,890	-31%	
Subgam	3,956	3,329	628	16%	
Gammaplex	-	40	- 40		
Panzyga	-	1,760	- 1,760		Withdrawn
Subcuvia	-	1,766	- 1,766		Discontinued
Vigam	-	470	- 470		
Total	545,919	507,705	38,214	7%	

Table 2 – Comparison of SNBTS v MDSAS data

New Product Launches:

The following products that are not currently used in NHSS are expected to be available as part of a new national agreement:

Gammaplex® 10% IVIg - Following a successful launch in the US, BPL have recently introduced Gammaplex® 10% to the UK market. This will be available to purchase via the current IVIg and SCIg framework agreement once all the necessary approvals are received. This is made in the same process as BPL's Gammaplex® 5% IVIg, however the 10% product is more concentrated and is stabilized with glycine that may offer clinical benefits.

Gammagard® – This is a specialist product with low usage across the UK available from Takeda. Gammagard contains only trace amounts of IgA and is used for patients with antibodies to IgA or with IgA deficiencies that are part of their underlying Primary Immunodeficiency's (PID). These patients require IVIg treatment with as low a concentration of IgA as possible to reduce the risk of allergic reaction to the IgA in the IVIg. Takeda will continue to supply this specialist product; however, they don't have any plans to expand volumes unless there is an unmet patient need. This is not currently available via the existing NHSS framework.

There are no other new entrants or products expected.

Stakeholder Map

The areas within scope of these framework agreements are currently overseen by the NPPEAG. See Plasma Product Strategy Documentation (Plasma Products Strategy V1) for further details on this group.

The CMU has conducted extensive stakeholder engagement, including representation from NHSS by the Chair of NPPEAG/Consultant Haematologist, Dr. Rachel Green NHS GG&C and Dr. John Goodfellow, Consultant Neurologist, both from NHS GG&C. They have taken on board the lessons learned from previous tender exercises and stakeholder feedback and have

developed a proposal to sustain all existing patients on their current treatment, while competitively tendering the business available for new patients.

Within NPPEAG membership, the Scottish Government (SG) representative, Samantha Baker (Donation and Abortion Policy) is aware of the proposed approach to market and is currently seeking approval from Ms Jean Freeman (Cabinet Secretary for Health and Sport) with confirmation anticipated to be received by 31 December 2020.

Benchmarking

The following table shows a comparison against current NHSE, NHS Wales (NHSW) and NHSS pricing where pricing information is available.

Category	Brand	NHSE	NHSS	NHSW
IVIg 5%	FlebogammaDIF (5%)	£39.50	£42.00	£51.60
	Gammaplex	£41.60	£45.00	£41.75
	Intratect (5%)	£39.00	£39.00	£39.00
	Octagam 5%	£45.50	n/a	n/a
	Vigam (off-contract)	£36.50	£41.80	
IVIg 10%	Gamunex (10%)	£39.50	£45.00	£49.80
	Intratect (10%)	£39.00	£39.00	£39.00
	Iqymune	£42.50	n/a	£45.65
	Kiovig	£39.00	£29.77	£39.00
	Octagam 10%	£45.50	£45.00	£47.90
	PrIVIgen	£42.00	£42.00	£47.14
SCIg	Cuvitru	£45.00	£33.48	£45.00
	Gammanorm	£45.50	£45.00	£47.90
	Hizentra	£48.50	£48.50	£54.44
	Subgam	£43.50	£45.00	£47.73
fSCIg	HyQvia	£48.50	£39.40	£48.50

Table 3 – UK Benchmarking Pricing

Note – Due to the significant supply issues as a result of Shire inability to supply NHSS volume requirements, Shire agreed to maintain their framework pricing for the remainder of the current NHSS framework agreement and not impose price increases incurred in other UK regions, including NHSE. At the end of the current NHSS framework agreement, Shire (Takeda) are expected to impose the increased pricing to NHSS as well.

Business Requirements

Where we are…

IVIg & SCIg (NP32617) and Anti-D (NP34917)

NP32617 Expiry Date – 30 June 2021
NP34917 Expiry Date – 30 April 2021
NP32617 Extension Option – 1 month
NP34917 Extension Option – 3 months

Where we want to be

Continuation of access to products from framework or contract agreement, following compliant process following the transition arrangements from the European to British regulatory legislation following the end of the EU exit transition period on 31 December 2020

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

Structure NP32617 – Ranked multi supplier on a lot by lot basis (3 lots and single supplier – Lot 4) NP34917 Anti D – Ranked multi supplier	Access to products to meet clinical requirements / specification and encourage competition between suppliers
Evaluation Criteria NP32617 – Price 85%, Range of Vial Sizes 10% and Room Temperature 5% NP34917 Anti D - Price 90% and Presentation of Product 10%	Achieve best value while achieving security of supply Evaluation of non-commercial elements ensure Health Board input to award process and ensures best fit product for NHSS
NP32617 - Ability for existing patients to remain on their current product for certain therapy areas including Immunology as per clinical guidance.	Ability for existing patients to remain on current product where clinically appropriate. Plurality of supply that supports clinical and patient needs, and provides committed volumes to suppliers and boards, assuring supply

Common

3 months' supply held at SNBTS
One ordering and delivery point through SNBTS
Agreement on contract specification
All contract spend captured

Strategic Options Considered

Contracting Authority	
No change – NP re-tender IVIg, SCIg and Anti-D Immunoglobulin on behalf of NHSS	
Benefits	**Disadvantages / Risks**
Maintain control of procurement timelines / specification and communications	On-going resource required to manage procurement and supplier engagement/management process Limited ability to agree commitment contracts to achieve best price and continuity of supply
Including Anti-D Immunoglobulin in a single tender allows the most commonly used normal immunoglobulin products to be merged into one framework agreement and align the expiry date.	NHSS currently have preferential pricing on Rhopylac® which may be as a result of the single delivery location to SNBTS, however given that pricing across all plasma products has increased and stabilised over recent years, it is expected that the supplier would aim to offer price parity across the UK, regardless if tendered separately or as a collaborative agreement.

On-going stakeholder clinical engagement during tender process and framework duration via well-established networks (NPPEAG). Good relations established with current supply base (including SNBTS staff)	
Suppliers currently alert NP and/or SNBTS regarding any supply issues	Access to stock during period of shortage if Scotland only
Established complaints escalation process	
NHSS currently receives price parity with other UK regions for the majority of products, with the exception of Shire products due to the on-going supply issues and their decision to minimise the financial impact to NHSS within the current framework period.	Increased pricing due to current market conditions and due to lower volumes within NHSS that may not be as attractive to suppliers in a globally competitive market. Increased pricing due to lower volumes spread across multiple suppliers to reduce the impact of any future supply problems Increased pricing due to shortage of raw material, current market conditions and impact of legislative changes to the statutory scheme to control the prices of branded health service medicines Increased pricing due to smaller market share These combined factors could result in further shortages and increased costs in a globally competitive marketplace
IVIg, SCIg and Anti-D Immunoglobulin Collaborate with CMU	
Benefits	**Disadvantages / Risks**
Enable NHSS to aggregate purchasing power with UK regions to increase available market share, resulting in the UK paying the same price	Loss of visibility and control of tender timelines and communications Reliance on CMU to disseminate information in a timely manner and within their timescales
Better assurance of product in the event of future supply issues, as UK collective volumes are more competitive	Increased pricing across all UK regions as suppliers adapt to meet any 'niche' UK requirements
The UK market is a more attractive market for suppliers and supplying the entire NHS is a significant badge of honour, therefore, may encourage better pricing	

Potential for NHSS to gain access to a wider range of products without significant price variation	
Opportunity for NHSS to input into the tender specification and structure of the tender, thus meeting any clinical requirements.	Need buy in from NSS, NHS and SG to collaborate
Increased clinical and procurement engagement leading to reduction in variation/standardisation of clinical protocols	
UK able to leverage purchasing power with suppliers to driver innovation and changes based on clinical requirements	
Ability for procurement staff to concentrate on other areas due to reduced admin time to manage current tender processes	Reduction in market awareness as strategic engagement not as focused
Potential to split usage across a number of suppliers to spread the market and reduce the reliance on a single supplier thus reducing the impact of any future supply disruption. This allows a number of suppliers to bid against an advertised volume that can be confident they will have the capacity to supply	Increased pricing from individual suppliers due to an overall lower market share
UK in a stronger position to enforce penalty clauses more robustly in the event of significant shortages by enforcing the anticipated clauses to be incorporated within the Standard Terms and Conditions: 'failure to deliver' and 'maintaining a minimum stock level'	Suppliers may be reluctant to agree to enter a framework agreement with enforceable clauses.
Coordinated management of shortages by DH / CMU, reducing NHSS resource to manage	Delay in information sharing

Strategic Recommendations & Reasoning:

- Collaborate with NHSE CMU to establish a national framework agreement. By aggregating purchasing power with UK regions this will offer a better assurance of product in the event of future supply issues, as UK collective volumes are more competitive due to increased market share. This will result in the UK paying the same price and minimise potential price increases that NHSS may incur due to small volume of available new business based on the clinical requirements to maintain existing long term patients on established product.

- Create an unranked multi supplier framework to obtain access to a wider range of products. A multi supplier framework ensures individual patient therapy needs are met where patients can't be switched to alternative products on clinical grounds.
- Provide a split of the total volume in 2 categories; Long Term Use and Short Term Use.
- It is intended that long term patients will not switch products unless there is a clinical requirement to do so as there are a number of patients who have long term conditions that require them to stay on the same product.
- This approach maintains clinician's flexibility in their prescribing and allows the market to respond to competition for new and potential switch patients.
- Agree existing volume + or –x% to account for organic growth or decline.
- National Procurement, in conjunction with SNBTS will liaise with CMU and suppliers to agree a forecasted usage for each framework year. These volumes will then be used by suppliers to project the NHS requirement to their global business to secure stock.
- Create a national contract with 18-month duration with an option to extend by up to 30 months. This will allow an appropriate timeframe to determine the future requirements for increased usage of subcutaneous products across a range of therapy areas and for homecare use. 18 months will also allow a review of the impact on GBP against the $ and € due to the EU exit and changes to the Branded Medicines Pricing scheme.
- Suppliers will be asked to maintain a level of stock holding sufficient to meet 12 week's anticipated demand from the commencement of the framework. This will be calculated based on the awarded market share (pro-rata) for 12 weeks' usage, unless it is the non-committed volume band. For this band, stockholding will be discussed with the relevant supplier to establish the level of stock required. The CMU will monitor monthly volumes to ensure the minimum volumes are being achieved. Any amendments will be done on a quarterly basis in conjunction with the supplier and in accordance with the terms of the framework agreement. If a supplier fails to maintain the required level of stockholding for 3 consecutive months, this will be deemed a breach of contract and as per the T&C's.
- Include liability penalties for failure to supply committed volumes as per the T&C's.

Anti-D (Rho) Immunoglobulin (either in a pre-filled syringe or vial).

- Include this requirement as part of the UK procurement as based on current benchmarking, there is no differential in pricing across the UK for D-Gam, however, NHSS currently pay 3% less for Rhophylac®. Discussions will be held with the manufacturers to ensure any preferential pricing for NHSS can be retained due to the different delivery model i.e. SNBTS.

Scope:

The scope of the UK procurement will cover the supply of Normal Human Immunoglobulin and Anti-D Immunoglobulin, split across 5 lots.

- Lot 1 - 5% Intravenous Immunoglobulin (5% IVIg)
- Lot 2 - 10% Intravenous Immunoglobulin (10% IVIg)
- Lot 3 - Subcutaneous Immunoglobulin (SCIg)
- Lot 4 - Facilitated Subcutaneous Immunoglobulin (fSCIg)
- Lot 5 - Anti-D Immunoglobulin (Anti-D)

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

Shape of Proposed Contract

The following outlines the shape of the proposed contract

Structure	Multi Supplier unranked framework
Lots	5
Duration	18 months
Selection Process	Open process with minimum standards (see main plasma product strategy) and note specific requirements
Terms & Conditions	CMU Framework Agreement for the Supply of Goods
Pricing Structure	Pricing to be held for initial 18 period
Award Criteria	Price – 60% Security of Supply – 30% Usability – 10%
Evaluation Process	The evaluation process will be made up of 2 stages: 1 – Mandatory requirements – PASS / FAIL 2 – Adjudicated award criteria – bidders will be scored and awarded based on the award criteria that will be outlined within the tender documentation

Proposed Evaluation Process & Award Criteria:

The award of the framework will be based on the most economically advantageous tender (MEAT) for each Lot. The approach to market will be based on CMU's standard processes with an approved Business Case, as per attached (CM&D IG Paper - CMU Business Case Human Normal and Anti-D Immunoglobulin). The evaluation process and award criteria will be in line with the attached draft Document No. 05b Scoring Methodology (Tabs: Scoring Methodology, Price Scoring and Vial Scoring).

Method of Call Off

Health Boards do not deal directly with suppliers. The Scottish National Blood Transfusion Service (SNBTS), Edinburgh place the purchase orders with the suppliers and hold 3 months' buffer stock. Health boards place purchase orders with SNBTS to call off the stock based on their requirements.

In order to secure NHSS volume requirements, if appropriate SNBTS could place an annual purchase order to each supplier with annual volume requirement split over multiple deliveries/timescales, managed by the SNBTS Plasma Product Manager. This would support any enforcement of the 'failure to deliver' clause within the CMU T&C's.

There are 14 patients (2 NHS Borders and 12 NHS Grampian) that currently receive subcutaneous home therapy. These patients are expected to remain on this treatment. Health boards should continue to place purchase orders with Healthnet.

Arrangements for any new patients that are identified as suitable for home therapy will be agreed with the relevant supplier and subject to internal process to establish a new NHSS commissioned homecare service, or manufacturer funded.

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

CLO Engagement Strategy

CLO will not be involved in the tender as this will be led by CMU with input from their own legal office.

Any Major Barriers to Success:

See Plasma Product Strategy Documentation (Plasma Products Strategy V1) detailed information on global market conditions, including impact of reduced plasma donations that could have a negative effect on manufactured plasma derived products from the second half of 2021.

In addition to these market conditions, based on clinical requirements, the National Plasma Product Expert Advisory Group (NPPEAG) have agreed that all long term patients should remain on their current product. This reduces the opportunity for health boards to switch to the most cost effective product.

Plasma Derived Blood Products have been included in the Voluntary scheme for branded medicines pricing and access and the Statutory scheme to control the costs of branded health service medicines for the first time from January 2019. Suppliers, excluding Takeda who are in the Voluntary scheme, have indicated that they would need to offset a large proportion, if not all, of the scheme's rebate payment against the product costs for this new tender. The rate for the 2021 Statutory scheme is 10.9%.

Financial Impact:

There are no secured savings anticipated from the proposed re-tender of this framework, due to a number of factors including:

- The majority of plasma collection is met by the US commercial plasma industry (~82%) Due to this imbalance, this could result in regional and global shortages of plasma
- There has been a global reduction in plasma donations, reducing manufacturing capacity that has resulted in increased pricing over recent years.
- As a result of the current Covid-19 pandemic, the full impact of the reduction in plasma donations is still unknown, and while the pandemic remains this may cause further unknown disruption within the collection and manufacturing process that could influence pricing.
- Uncertainty regarding the terms of the withdrawal agreement following the UK's exit from the EU and the impact this could have in the value of GBP versus $ and € resulting in increased manufacturing and shipping costs.
- This is becoming an increasingly competitive market place and the UK historically received low pricing. In order to compete for a share of the global market, suppliers are passing on price increases to compete with other countries to ensure sustainability of supply to the UK.
- All suppliers with the exception of Takeda are liable to pay the UK government an additional premium following legislative changes to the statutory scheme to control the prices of branded medicine. Takeda were previously part of the voluntary scheme. As a result of this legislative change, suppliers have indicated they will pass on a proportion of this increase in order to sustain their profits that is necessary in order to secure product for the UK market.
- There is uncertainty over the percentage increase that will be applied under the new scheme, with suppliers not receiving final confirmation until ~March each year.

– Decline in value of GBP versus $ and € resulting in increased manufacturing and shipping costs.

Benchmarking shows NHSScotland is currently receiving competitive pricing compared to CMU in England and several European markets. Germany and France continue to pay a higher price.

Potential Financial Impact Analysis

Based on existing long term patients remaining on their established product, compared against the latest NHSW pricing, this is expected to result in a cost increase of ~£2.8m, as detailed below:

Category	Manufacturer	Brand	Total Grams	NHSS Current Value	Anticipated Value	Financial Impact
5%	Grifols	Flebogamma 5%	16,635	£ 698,670	£ 858,366	-£ 159,696
	Octapharma	Octagam 5%	2,845	£ 128,025	£ 136,276	-£ 8,251
10%	Biotest	Intratect 10%	1,910	£ 74,490	£ 74,490	£ -
	CSL Behring	Privigen	146,864	£ 6,168,288	£ 6,923,169	-£ 754,881
	Grifols	Gamunex 10%	7,370	£ 331,650	£ 367,026	-£ 35,376
	Octapharma	Octagam 10%	14,243	£ 640,935	£ 682,240	-£ 41,305
		Panzyga	1,540	£ 69,300	£ 70,301	-£ 1,001
	Takeda	Kiovig	97,446	£ 2,900,967	£ 3,800,394	-£ 899,427
SCIg	BPL	Subgam	3,329	£ 149,783	£ 158,869	-£ 9,087
		Vigam Liquid	470	£ 19,646	£ 19,646	£ -
	CSL Behring	Hizentra 20%	88,473	£ 4,290,941	£ 4,816,470	-£ 525,530
	Octapharma	Gammanorm	7,013	£ 315,585	£ 335,923	-£ 20,338
	Takeda	Cuvitru	21,379	£ 715,769	£ 962,055	-£ 246,286
		Subcuvia 16%	1,766	£ 59,139	£ 79,488	-£ 20,349
fSCIg	Takeda	HyQvia	13,520	£ 532,688	£ 655,720	-£ 123,032
Total			**424,803**	**£ 17,095,875**	**£ 19,940,432**	**-£ 2,844,557**

Table 6 – Financial Impact, Long-Term Use only

The following table (Table 7) shows the anticipated financial impact breakdown by health board.

Health Board	Total Grams	NHSS Current	Anticipated Val	Financial Impac
NHS AYRSHIRE AND ARRAN	17,031	£ 734,789	£ 840,605	-£ 105,816
NHS BORDERS	8,677	£ 355,616	£ 411,838	-£ 56,222
NHS DUMFRIES AND GALLOWAY	6,504	£ 227,877	£ 281,914	-£ 54,037
NHS FIFE	19,300	£ 753,762	£ 883,927	-£ 130,164
NHS FORTH VALLEY	27,681	£ 1,038,223	£ 1,241,663	-£ 203,440
NHS GRAMPIAN	49,922	£ 2,094,289	£ 2,426,752	-£ 332,463
NHS GREATER GLASGOW AND CLYDE	141,852	£ 5,474,934	£ 6,478,102	-£ 1,003,168
NHS HIGHLAND	20,752	£ 828,156	£ 950,537	-£ 122,381
NHS LANARKSHIRE	22,608	£ 950,193	£ 1,095,144	-£ 144,950
NHS LOTHIAN	62,355	£ 2,604,684	£ 2,999,293	-£ 394,609
NHS SHETLAND	1,140	£ 49,310	£ 55,346	-£ 6,036
NHS TAYSIDE	46,981	£ 1,984,041	£ 2,275,312	-£ 291,271
Total	**424,803**	**£ 17,095,875**	**£ 19,940,432**	**-£ 2,844,557**

Table 7 – Financial Impact by Health Board (Long-Term Use only)

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

The financial impact of anticipated short term usage cannot be fully determined until the outcome of the tender is known as this usage is expected to be split across a minimum of 3 suppliers based on the most economically advantageous tender.

Risk Analysis

Description of risk	Likelihood	Impact	RAG	Implications to NHSS	Measures to Minimise / Eradicate Risk
There is a risk that SNBTS stockpile could exceed the agreed 3 month's buffer stock level to meet any volume commitments	1	3	3	Increased financial outlay by NSS due to increased acquisition cost of stock held at SNBTS Increased storage capacity required at SNBTS to store excess stock Increased risk of wastage if stock is not utilised prior to expiry date Potential increased resource required by SNBTS Plasma Product Manager to monitor health board usage versus available supply	Being part of a national collaborative agreement allows the potential opportunity to divert stock to other regions across the UK, subject to agreement Annual forecasting will allow any adjustment to volume requirements to be undertaken on a quarterly basis and allow any excess stock to be utilised first and allow the SNBTS stock pile to return to the agreed 3 months' level
There is a risk of further supply disruption across all suppliers	2	2	4	Further demand management processes have to be implemented, impacting directly on patient care	All awarded suppliers will be mandated to hold a minimum of 12 weeks of stock based on their awarded market share (pro-rata) Annual volume requirement will be stated within the tender documentation with established confirming the anticipated volume of patients who will remain on their established product. This gives supplier's sufficient visibility to manage their forecasting and delivery schedule. If an awarded supplier fails to meet their delivery requirements due to a 'stockout' (a 'stockout' is where a

					supplier does not have product available to fulfil an order on-time in full) this will be deemed a 'Delivery Failure' and T&C's can be applied. Suppliers will be required to submit monthly KPI reports including stock levels

Contracting Timeline (Proposed Timelines)

The following milestones dates are based on current CMU timelines, and are subject to change.

Tender Milestone	Date
Stakeholder procurement group meeting	03/09/2020
Supplier engagement	07/09/2020
Draft tender specification and offer schedule	01/11/2020
Submit Business Case - CM&D IG	05/11/2020
CM&D IG meeting / sigh-off of BC	24/11/2020
Pre-tender supplier meetings	01/12/2020
Tender open	15/01/2021
Tender dead-line	19/02/2021
Evaluation open	22/02/2021
Evaluation close	08/03/2021
Stakeholder award meeting	08/03/2021
Submit Business Award Case report - CM&D IG	11/03/2021
CM&D IG meeting / sign-off of BCA	23/03/2021
Prep for award	23/03/2021
Intent to award	30/03/2021
Final award	09/04/2021
Framework commence date	01/07/2021

Implementation and Roll-Out

- As existing long term patients are expected to remain on their current product, initial implementation at Health Board will only require an update of their local records of any new pricing.
- Due to SNBTS holding ~3 months' worth of stock for NHSS health boards, based on the tender outcome, the Plasma Product Manager at SNBTS will manage demand accordingly, in particular during the transition period for any change of product/suppliers.
- There is not expected to be any change to existing homecare therapy patients as Takeda have agreed to continue their manufacturer funded homecare service via Healthnet. Health boards should continue to place purchase orders with Healthnet.

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

- The outcome of the tender evaluation will be shared with NPPEAG members at the earliest stage to enable any issues to be highlighted to NP, CMU and SNBTS to support a smooth transition for any change of suppliers or products.
- A Buyers' Guide and Contract Summary will be issued to health boards in April 2021.
- The Plasma Products Manager at SNBTS will update purchase order templates and issue them to pharmacy leads within health boards in advance of the framework start date.
- Health board compliance will be monitored through SNBTS issue data and data extracted from the MDSAS database, although, it is acknowledged that there will be a delay in this being updated to reflect any significant changes.
- NP and SNBTS will engage with suppliers and CMU procurement lead throughout the duration of the framework to ensure that any committed volumes are being adhered to and any indication of failure on a suppliers' part to deliver the agreed volume will be raised with CMU.
- The CMU will also monitor monthly volumes to ensure the minimum volumes are being achieved. Any amendments will be done on a quarterly basis in conjunction with the supplier and in accordance with the terms of the framework agreement. If a supplier fails to maintain the required level of stockholding for 3 consecutive months, this will be deemed a breach of contract. See 'Supplier Performance Management' section below for further details.
- CMU is in continual dialogue with stakeholders and suppliers. Formal meetings are held with stakeholders once a year. Supplier review meetings are held monthly. NP and/or SNBTS can attend arranged supplier meetings, or conduct separately as required.
- PCM will be updated prior to the framework commencing on 1 July 2021.

Appendix A – Human Normal Immunoglobulin & Anti-D Immunoglobulin Commodity Strategy, NP32621

Definitions

Ig	Normal Human Immunoglobulin
IVIg	Intravenous Immunoglobulin
SCIg	Subcutaneous Immunoglobulin
fSCIg	Facilitated subcutaneous Immunoglobulin
NPPEAG	National Plasma Product Expert Advisory Group
SNBTS	Scottish National Blood Transfusion Service
PID	Primary Immunodeficiency's

Associated Documented Information

Version	Document Title
V1	Appendix 1 SNBTS Issue Data
V1	Plasma Products Strategy V1
V1	CM&D IG Paper - CMU Business Case Human Normal and Anti-D Immunoglobulin
V1	Document No. 05b Scoring Methodology

Document Revision History

Version	Description of Amendments
D0.01	On-going work in progress to create initial draft with various updates until final approval
D0.02	
D0.03	
D0.04	Category Manager Review
D0.05	Category Manager comments incorporated
D0.06	Final Draft
V1	Final Version for NPD Approval