

CAREB

Commodity Action Report & Eps Bulletin

Intravenous Immunoglobulin (IVIgG) and Subcutaneous Immunoglobulin (IgG) Contract Reference: NP32617

Prepared by:

Hazel Johnstone Commodity Manager National Procurement 29 June 2017

CAREB **National Procurement**

Intravenous Immunoglobulin (IVIgG) and Subcutaneous Immunoglobulin (IgG)

NP32617

Document Information

Contract Name: Intravenous Immunoglobulin (IVIgG) and Subcutaneous Immunoglobulin (IgG)

Contract Reference: NP32617

National Spend: £19,034,703 **Savings Opportunity:** £214,730 Start Date: 1 August 2017 Expiry Date: 31 July 2019

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CPV Code: 33600000

Awarded Supplier (see main text for details of selection and evaluation process)

Baxalta, Bio Products Ltd (BPL), Biotest, CSL Behring Ltd, Grifols and Octapharma

Key Strategy (see main text for further details)

Due to the limited number of suppliers the market was approached using the open procedure.

Lots one to three (1 – 3) were advertised as a Ranked Multi-Supplier Framework to obtain value for money for NHSS and reward competitive pricing. A ranked framework ensures individual patient therapy needs are met where patients can't be switched to alternative products on clinical grounds.

Lot four (4) was advertised as a single supplier framework due to limited competition in the marketplace.

All framework participants are required to supply the Goods to the Scottish National Blood Transfusion Service (SNBTS), and all health boards to call off via SNBTS.

Benefit Summary (See m	ain text for full deta	ils)				
			Contract Extension			
	No Change	Optimum	Delivered	Remaining		
Health Board	Impact	Outcome	Saving	Benefit	Specific HB Comment	
Ayrshire & Arran	-£9,388	£10,398				
Borders	-£15,435	-£6,920				
Dumfries & Galloway	-£25,246	-£8,479				
Fife	-£18,799	-£7,023				
Forth Valley	-£8,311	£880				
Grampian	-£54,495	-£3,743		The optimum outcome sa	The optimum outcome saving of £214,730 has been calculated based on an	
Greater Glasgow & Clyde	-£78,516	£94,493			anticipated percentage of overall volume switching to the 1st ranked supplier,	
Highland	-£18,224	-£6,059			on a lot by lot basis, acknowledging that due to clinical requirement, Primary	
Lanarkshire	-£14,846	-£278			Immune Deficient (PID) patients will require to remain on existing product.	
Lothian	-£26,261	£70,704				
NWTC (Golden Jubilee)	-	-			Full details of assumptions and savings calculations are detailed in Sections	
Orkney	=	-			4-6 within the main body of CAREB.	
Shetlands	-	-]	
Western Isles	-£441	£3,721				
Special HBs	-	-				
Tayside	-£6,452	£67,036				
Total	-£276,414	£214,730				
Contract Extension (see m	nain text for further o	details)				
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The framework agreement has the option to extend by a further two (2) periods of up to twelve (12) months.

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1. Commodity Description

The scope of the framework was to tender for the following Intravenous Immunoglobulin (IVIGG) and Subcutaneous Immunoglobulin (IgG) plasma products.

- Human Normal Intravenous Immunoglobulin 5%
- Human Normal Intravenous Immunoglobulin 10%
- Human Normal Intravenous Immunoglobulin for subcutaneous use
- Subcutaneous Immunoglobulin with Hyaluronidase

2. Current Position

There is currently an unranked multi supplier framework agreement in place that is due to expire on 31 July 2017. There is one (1) x twelve (12) month extension option remaining on this framework; however the decision was taken to re-tender this framework due to the recent launch of new products.

There are five (5) suppliers on the Framework – Baxalta, Grifols, Biotest, CSL Behring and Octapharma.

Health boards do not deal directly with suppliers. SNBTS place the purchase orders with the suppliers and hold three (3) months buffer stock. Health boards place purchase orders with SNBTS to call off the stock.

The current annual spend for the medicines is circa £19.2M based on SNBTS sales data for the period from 1 November 2015 to 31 October 2016, split by product group as detailed below:

- 5% IVIGG £1.1M;
- 10% IVIGG £14.9M:
- Subcutaneous IgG £3.2M;
- Subcutaneous Immunoglobulin with Hyaluronidase (Hyqvia®) circa £7K (off contract).

The following table (Table 1.0) shows current spend and usage by health board across all products.

Health board	Total No. Of Grammes Issued	Current Value	
Ayrshire and Annan	23,462	£753,625	
Borders General	13,316	£394,437	
Dumfries and Galloway	17,987	£517,318	
Forth Valley	28,422	£859,851	
Grampian	81,079	£2,383,554	
Greater Glasgow Clyde	225,534	£6,801,710	
Highland	28,266	£814,418	
Lanarkshire	30,517	£968,598	
Lothian	106,798	£3,292,980	
NHS FIFE	23,055	£678,554	
Tayside	53,274	£1,661,842	
Western Isles	3,993	£122,547	
Total	635,702	£19,249,434	

Table 1.0 - Current usage and spend by health board

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3. New Contract Process and Award

A complete strategic sourcing process was followed to identify opportunities, evaluation criteria and score tender responses.

Clinical Advisory Panel Members

It was agreed by the Chair of The National Plasma Product Expert Advisory Group (NPPEAG) - Dr Rachel Green (Consultant in Transfusion Medicine), SNBTS that the following key members of the group would be consulted to represent the views of the NPPEAG group and assist with the construction and evaluation of the tender.

Dr. Richard Herriot, Immunologist, NHS Grampian Prof. Hugh Willison, Professor of Neurology, NHS Greater Glasgow & Clyde Mr Peter Mulholland, Principal Pharmacist, NHS Greater Glasgow & Clyde Mr Andy Crawford, Plasma Product Manager, SNBTS

Contract Process

The market was approached using the open procedure, as there are a limited number of suppliers.

The following table (Table 2.0) shows the agreed structure of the framework agreement and the criteria used to evaluate tender responses:

Contracting Process	NP32617 (Lots 1 - 3)	NP32617 (Lot 4)	
Type of Framework Agreement	Ranked Multi Supplier	Single Supplier	
Type of Framework Agreement	Framework Agreement	Framework Agreement	
Duration of Framework Agreement	24 Months	24 Months	
Extension Option	24 Months	24 Months	
Selection Criteria	Mandatory Requirements	Mandatory Requirements	
	85% Price	85% Price	
Evaluation Criteria	10% Range of Vial Sizes	10% Range of Vial Sizes	
	5% Storage Conditions	5% Storage Conditions	

Table 2.0 – Framework Agreement Structure

Full details of the selection criteria and individual technical scoring methodology are available on request from Hazel Johnstone, Commodity Manager.

Award

It was agreed during the Award of Business CAP that six (6) suppliers would be awarded to the Framework Agreement

The following table (Table 3.0) details the suppliers awarded to each Lot.

Supplier	Lot 1	Lot 2	Lot 3	Lot 4
Baxalta	No Award	1st Ranked	1st Ranked	Single Supplier
Bio Products Ltd (BPL)	ī	-	4th Ranked	
Biotest	1st Ranked	2nd Ranked	-	-
CSL Behring	-	4th Ranked	2nd Ranked	-
Grifols	2nd Ranked	5th Ranked	-	=
Octapharma	3rd Ranked	3rd Ranked	3rd Ranked	=

Table 3.0 - Suppliers awarded by Lot

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Lot 3 - Human Normal Intravenous Immunoglobulin for subcutaneous use

Please be aware that Baxalta have advised that they will discontinue Subcuvia by September 2018; however they have agreed to honour the current contract price for new and existing patients until July 2018, and work with clinicians to switch patients to other suitable therapies. There will be no change to Subcuvia's availability in Scotland until July 2018.

Product Details and Product Matching

Please see Appendix A – Contract Summary for full details of products awarded. This information has been shared with SNBTS who will arrange to update their catalogues and issue updated purchase order templates in advance of the framework start date.

4. Base Data Used For Contract Analysis And Benefit Calculation

The base data to determine the overall spend on these products has been collated from health board usage via SNBTS for the twelve (12) month period from 1 November 2015 to 31 October 2016.

Due to clinical requirement, Primary Immune Deficient (PID) patients will require to remain on existing product, reducing the opportunity to switch to the most cost effective product. The assumptions detailed in Table 4.0 below have been made in the calculation of the savings opportunities in Section 6.

Lot	Indicative Annual Volume (Grammes) - All Patients	Indicative Annual Volume (Grammes) PID Patients	Indicative Annual Volume (Grammes) for Non PID Patients	Comments
Lot 1 - 5% MIGG	32775	1639	31136	Based on 95% of overall usage available for competition, 5% remaining on current product
Lot 2 - 10% IVIGG	509325	50933	458393	Based on 90% of overall usage available for competition, 10% remaining on current product
Lot 3 - Sub Cut	93427	88756	4671	Based on 5% of overall usage available for competition, 95% remaining on current product
Lot 4 -Sub Cut with Hyaluronidase.	175	158	18	Based on 10% of overall usage available for competition, 90% remaining on current product, allowing for some trials etc.
Totals	635702	141484	494218	

Table 4.0 - Breakdown of indicative use for each Lot

5. Calculations of Financial Impact

The following table (Table 5.0) shows the financial impact if health boards do not switch any current non PID patients to the new first ranked product.

Health Board	Current Value	No Change Impact Value	No Change Cost Increase
Ayrshire and Annan	£753,625	£763,013	-£9,388
Borders General	£394,437	£409,873	-£15,435
Dumfries and Galloway	£517,318	£542,564	-£25,246
Forth Valley	£859,851	£868,161	-£8,311
Grampian	£2,383,554	£2,438,050	-£54,495
Greater Glasgow Clyde	£6,801,710	£6,880,226	-£78,516
Highland	£814,418	£832,642	-£18,224
Lanarkshire	£968,598	£983,444	-£14,846
Lothian	£3,292,980	£3,319,241	-£26,261
NHS FIFE	£678,554	£697,352	-£18,799
Tayside	£1,661,842	£1,668,294	-£6,452
Western Isles	£122,547	£122,988	-£441
Total	£19,249,434	£19,525,848	-£276,414

Table 5.0 No Change Impact by Health Board

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Section 6 contains details of how this increase can be mitigated.

6. Opportunity and Method of Call Off

OPPORTUNITY

The overall saving opportunity for NHSScotland from this procurement process is £214,730. Based on this the new value of the Framework Agreement has been calculated as £19,034,704.

The following table (Table 6.0) provides a breakdown of total savings by health board (based on an anticipated percentage of overall volume switching to the 1st ranked supplier, as detailed in Section 4.)

Health board	New value for PID patients	New value for Non PID Patients	Total new value	Total Saving Opportunity
Ayrshire and Annan	£548,721	£194,506	£743,227	£10,398
Borders General	£308,522	£92,836	£401,357	-£6,920
Dumfries and Galloway	£341,186	£184,611	£525,797	-£8,479
Forth Valley	£766,041	£92,930	£858,971	£880
Grampian	£1,914,398	£472,899	£2,387,297	-£3,743
Greater Glasgow Clyde	£5,109,365	£1,597,852	£6,707,216	£94,493
Highland	£707,909	£112,568	£820,477	-£6,059
Lanarkshire	£830,787	£138,089	£968,876	-£278
Lothian	£2,365,458	£856,818	£3,222,276	£70,704
NHS FIFE	£556,733	£128,844	£685,577	-£7,023
Tayside	£1,060,320	£534,486	£1,594,806	£67,036
Western Isles	£81,805	£37,020	£118,826	£3,721
Totals	£14,591,246	£4,443,458	£19,034,704	£214,730

Table 6.0 Saving/Increase by Health board

The following table (Table 7.0) provides a breakdown of this total saving on a lot by lot basis.

Category (Lot No.)	Current Supplier	New value - PID Patients	New value Non PID Patients	New Total Value	Savings
Lot 1 - 5%	Grifols	£55,685	£965,224	£1,020,908	£93,442
		£55,685	£965,224	£1,020,908	£93,442
Lot 2 - 10%	Baxalta	£1,102,607	£9,923,465	£11,026,073	-£76,305
	CSL	£232,749	£1,862,706	£2,095,455	£232,033
	Grifols	£39,848	£304,837	£344,685	£53,795
	Octapharma	£140,065	£1,156,535	£1,296,599	-£73,812
		£1,515,269	£13,247,543	£14,762,812	£135,710
Lot 3 - Sub-Cut	Baxalta	£671,817	£35,359	£707,176	£0
	Bio Products Ltd (BPL)	£193,016	£6,603	£199,619	-£14,324
	CSL Behring	£2,121,884	£106,751	£2,228,635	£4,927
	Octapharma	£103,416	£5,443	£108,859	-£5,024
		£3,090,133	£154,156	£3,244,289	-£14,421
Lot 4 - Subcut with	D It .		00.004	00.004	
Hyaluronidase	Baxalta		£6,694	£6,694	£0
			£6,694	£6,694	£0
Totals		£4,661,086	£14,373,617	£19,034,703	£214,731

Table 7.0 - Savings by Lot

<u>Lot 1 – Human Normal Intravenous Immunoglobulin 5%</u>

As detailed above, there is a savings opportunity of circa £93k within Lot 1 - 5% IVigG based on the anticipated volume of patients switching to the new 1^{st} ranked product – Intratect.

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Lot 2 – Human Normal Intravenous Immunoglobulin 10%

There is a saving opportunity of circa £285k within Lot 2 – 10% IVIgG based on the anticipated volume of patients switching to the 1st ranked product - Kiovig. This saving will help mitigate the cost increase (circa £150k) due to the price increase from PID patients remaining with current medicines, giving a net saving of circa £135k for this Lot.

Lot 3 - Human Normal Intravenous Immunoglobulin for subcutaneous use

The majority of patients receiving Subcutaneous IgG (Lot 3), are not suitable for switching and price increases have resulted in an overall cost increase of circa £14k. However, due to the availability of an alternative 20% subcutaneous IgG - Cuvitru as 1st ranked supplier and Hyqvia, awarded to Lot four (4), this will allow health boards to review any new patients, and determine the most cost effective IgG.

<u>Lot 4 - Subcutaneous Immunoglobulin with Hyaluronidase</u>

As this is a newly launched product, no savings have been calculated. However, health boards should review if this new once-a-month subcutaneous IgG to assess its cost effectiveness against current subcutaneous products.

Details of the SPC and PIL for all of the products awarded are available from Hazel Johnstone, Commodity Manager.

METHOD OF CALL OFF

Call off from the Framework Agreement shall be made by submission of orders by SNBTS to the Framework Participants awarded to the Framework Agreement as per below,

- Lot 1 3: Call off will be on the basis of the 1st ranked supplier for new or current Non PID patients, cascading to the remaining (second ranked supplier), subject to clinical requirements. Call off for current PID patients will be based on clinical requirements.
- Lot 4 -: Call off shall be by submission of orders to the Framework Participant awarded to the Lot.

SNBTS will place orders with the suppliers for all the NHS Scotland health boards ensuring that costs are kept to a minimum with one ordering and delivery point.

Health boards will place orders direct with SNBTS by submitting the completed purchase order template issued by SNBTS.

Orders will be fulfilled and distributed directly from SNBTS to health boards as and when required, with SNBTS holding a three (3) month buffer stock.

7. ePS Implementation

Contract Maintenance Process

Any changes to the framework will be directed through the Commodity Manager based on new product introduction as approved through NPPEAG.

EPS Implementation Notes

All supplier items have been loaded to CCM prior to the framework start date of 1 August 2017. All data has been provided to SNBTS.

Contractual Terms

The framework will be awarded on National Procurement's standard terms and conditions of contract for the purchase of goods. .

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8. Next Steps

Health boards should review overall usage of IVIgG and IgG and the switching opportunities outlined in this document through the appropriate clinical users group. In the following weeks National Procurement will circulate a compliance letter that will request an update on health board switching plans. This information will then be shared with SNBTS to manage future order requirements.

SNBTS will update purchase order templates and issue them to pharmacy leads within health boards. The three (3) months stock held at SNBTS will be run down and issued to ensure that old stock is used prior to new stock being purchased in line with the tender outcome and health board feedback on switching plans.

Health boards should update all appropriate catalogues as soon as possible.

Due to the increasing spend in this area; NPPEAG will continue to monitor usage of IVIgG and IgG using data extracted from the national Immunoglobulin database on a regular basis. The aim of this work is to reduce the overall demand and spend on IVIgG and IgG across NHSScotland health boards.

In conjunction with SNBTS, National Procurement will develop an overarching supplier management process across all plasma product frameworks to help monitor the performance of these frameworks, and gain a greater understanding of the cost drivers within this area to help determine ways where NHSScotland can reduce costs.

9. Contract Extensions

There is the option to extend for two (2) periods of up to twelve (12) months.

Version History

Version	Version. Date	Revised By	Description	Filename
1.0	29 June 2017	Hazel Johnstone	CAREB - NP32617 CAREB	NP32617 CAREB V01.0 (Final)

Distribution

То	Action	Date
Directors of Pharmacy Chief Pharmacists	Cascade Distribution to appropriate users	29 June 2017
POG	Cascade Distribution to appropriate users	29 June 2017
Pharmacy Procurement Staff	For implementation and logistics	29 June 2017
SNBTS	For implementation and stock management	29 June 2017
NPPEAG	For information	29 June 2017