

CAREB

Commodity Action Report & Eps Bulletin

Anti-D, Four Factor Concentrate and Hyper Immunes (AFHP) Contract Reference: NP34917

Prepared by:

Hazel Johnstone
Commodity Manager
National Procurement

Date : 6 June 2017

Document Information

Contract Name:	Anti-D, Four Factor Concentrate and Hyper Immunes (AFHP)			Contract Reference:	NP34917		
National Spend:	£2,206,116	Savings Opportunity:	Nil (Cost Increase £97,341)	Start Date:	1 August 2017	Expiry Date:	31 July 2019
Contract Manager:	Hazel Johnstone	Tel :	GRO-C	Email:	hazel.johnstone@ GRO-C		
CPV Code :	33600000						

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

Bio Products Ltd (BPL), CSL Behring Ltd, Biotest Ltd

Key Strategy (see main text for further details)

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

Lot 1: Anti-D (Rho) Immunoglobulin was advertised as a ranked multi supplier due to different presentations available from different suppliers.

Lots 2 - 6: Hyper Immunes and Lot 7: Four Factor Concentrate (PCC) was advertised as single supplier frameworks.

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

Benefit Summary (See main text for full details)

Health Board	Cost Increase	Optimum Benefit	Contract Extension		Specific HB Comment
			Delivered Saving	Remaining Benefit	
Ayrshire & Arran	-£7,524	N/A			<p>Overall there is a cost increase £97,341 as the result of the tendering process.</p> <p>There is a national saving of £89,970 across the three (3) presentations of Four Factor Concentrate (PCC) due to a price reduction received from the incumbent supplier (CSL Behring). This saving has helped mitigate cost pressures against the Hyper Immunes of £137,336 and the higher dose Anti- Anti-D (Rho) Immunoglobulin £49,975.</p> <p>Further details are contained within Section 6 'Calculation of Benefits' within the main body of the CAREB.</p>
Borders	-£415	N/A			
Dumfries & Galloway	£375	N/A			
Fife	-£1,784	N/A			
Forth Valley	-£10,399	N/A			
Grampian	-£24,750	N/A			
Greater Glasgow & Clyde	-£26,484	N/A			
Highland	-£8,518	N/A			
Lanarkshire	-£4,690	N/A			
Lothian	-£8,128	N/A			
NWTC (Golden Jubilee)	£1,770	N/A			
Orkney	-	N/A			
Shetlands	-	N/A			
Western Isles	-£667	N/A			
Special HBs	-	N/A			
Tayside	-£6,127	N/A			
Total	-£97,341	N/A			

Contract Extension (see main text for further details)

The framework agreement has the option to extend by a further two (2) periods of up to twelve (12) months.

Table of Contents

1. Commodity Description	4
2. Current Position	4
3. New Contract Process and Award	5
4. Base Data Used For Contract Analysis And Benefit Calculation	7
5. Method of Call Off	7
6. Calculations of Benefits	8
7. ePS Implementation.....	10
8. Next Steps	10
9. Contract Extensions	11

1. Commodity Description

There are two (2) types of human immunoglobulin preparations available, normal immunoglobulin and disease specific immunoglobulin. The scope of the framework was to tender for disease specific immunoglobulin, as detailed below.

- Anti-D (Rho) Immunoglobulin (either in a pre-filled syringe or vial)
- Hyper Immunes:
 - HBIG Hepatitis B Immunoglobulin intramuscular use (IM)
 - HBIG Hepatitis B Immunoglobulin intravenous use (IV)
 - HTIG Tetanus immunoglobulin intramuscular use (IM)
 - Anti Rabies immunoglobulin for intramuscular use (IM)
 - VZIG Varicella - Zoster immunoglobulin intramuscular (IM)
- Coagulation Factor Four Factor Prothrombin Complex Concentrate (PCC)

2. Current Position

There is currently a national framework agreement in place that is due to expire on 31 July 2017. There are no remaining extension options available on this framework.

The current framework agreement is a single supplier framework with each line awarded as a separate lot apart from the three (3) presentations of Four Factor Concentrate which were treated as one (1) Lot due to administration protocols requiring medicines from the same supplier.

There are nine (9) lots awarded to three (3) suppliers – Bio Products Laboratory Ltd (BPL), CSL Behring Ltd and Biotest Ltd.

BPL have since withdrawn the product awarded to Lot one (1) - Anti-D (Rho) immunoglobulin intramuscular use (IM) 250iu and there are no other manufacturers of this vial size, therefore this was not re-tendered as part of the new framework. There was no impact by withdrawal from market as dosing requirements are met by other strengths.

Health boards do not deal directly with suppliers. SNBTS, currently at Ellen's Glen Road in 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.

The current annual spend for the medicines is circa £2.1M based on SNBTS sales data for the period from 1 November 2015 to 31 October 2016.

C A R E B	Anti-D, Four Factor Concentrate and Hyper Immunes (AFHP)	NP34917
National Procurement		

The following table (Table 1.0) shows current spend by Lot and supplier.

NP34917 Anti D, Four Factor Concentrate and Hyper Immunes (AFHP) - Current spend by Lot and Supplier				
Lot No.	Type	Supplier	Product Description	Total Current Spend
1	Anti D	CSL Behring	Rhophylac 1500iu Anti-D	£339,830
		BPL	D-Gam 500iu	£356,636
2	Hyper Immunes	BPL	Hep B	£97,732
3		Biotest	Hepatect	£9,250
4		BPL	Tetanus	£139,000
5		BPL	Rabies	£44,507
6		BPL	Zoster	£282,100
7	Four Factor Concentrate	CSL Behring	Beriplex 250iu	£3,500
			Beriplex 500iu	£744,660
			Beriplex 1000iu	£91,560
Totals				£2,108,775

Table 1.0 – Current spend by Lot and Supplier

The following table (Table 2.0) shows spend by Lot and health board.

NP34917 Anti D, Four Factor Concentrate and Hyper Immunes (AFHP) - Current spend by Lot and Supplier				
Health Board	Anti D (Lot 1)	Hyper Immunes (Lots 2 - 6)	Four Factor Concentrate (Lot 7)	Total
Ayrshire and Arran	£50,979	£38,446	£56,980	£146,404
Borders General	£9,653	£8,065	£22,120	£39,838
Dumfries and Galloway	£17,096	£7,650	£32,900	£57,646
Forth Valley	£40,568	£41,361	£29,120	£111,049
Golden Jubilee			£16,520	£16,520
Grampian	£81,300	£105,410	£56,840	£243,550
Greater Glasgow Clyde	£179,748	£168,641	£228,200	£576,588
Highland	£30,230	£36,827	£25,760	£92,817
Lanarkshire	£66,350	£59,905	£138,880	£265,135
Lothian	£121,812	£60,947	£143,640	£326,399
NHS Fife	£44,695	£18,341	£49,000	£112,036
Tayside	£49,289	£23,263	£32,760	£105,312
Western Isles	£4,748	£3,733	£7,000	£15,480
Total	£696,466	£572,589	£839,720	£2,108,775

Table 2.0 – Current spend by Lot and Health Board

3. New Contract Process and Award

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

CAP 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, representing Neurology, Immunology, Haematology clinicians and specialist clinical pharmacists views would be consulted to represent the views of the NPPEAG group and assist with the construction and evaluation of the tender.

Dr Henry Watson, Haematology Consultant, NHS Grampian
Dr Richard Soutar, Consultant Haematologist, NHS Greater Glasgow & Clyde
Dr Alan Mathers, Clinical Director for Obstetrics and Gynaecology, NHS Greater Glasgow and Clyde

TENDER WEIGHTINGS

All tender submissions were assessed against the advertised qualification criteria, detailed below:

All lots - Evaluate Price 90%, Technical 10% lot specific as below:

- Anti D: Presentation of Product - 10%
- Hyper Immunes: Range of Vial Sizes - 10%
- Four Factor Concentrate: Range of Vial Sizes - 10%

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

CONTRACT PROCESS

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

Lot 1: Anti-D (Rho) Immunoglobulin (either in a pre-filled syringe or vial).

This Lot was tendered as a ranked multi-supplier framework with overall usage of the two (2) presentations combined and evaluated based on £/IU due to the different presentations available across suppliers.

Lots 2 – 6: Hyper Immunes (single supplier framework on a Lot by Lot basis):

The number of suppliers that manufacturer specialist Immunoglobulin's is limited with only one supplier able to provide a licensed product for each of the Hyper Immunes, as detailed below:

- Lot 2 - HBIG Hepatitis B Immunoglobulin intramuscular use (IM)
- Lot 3 - HBIG Hepatitis B Immunoglobulin intravenous use (IV)
- Lot 4 - HTIG Tetanus immunoglobulin intramuscular use (IM)
- Lot 5 - Anti Rabies immunoglobulin for intramuscular use (IM)
- Lot 6 - VZIG Varicella - Zoster immunoglobulin intramuscular (IM)

Lot 7: Coagulation Factor Four Factor Prothrombin Complex Concentrate (PCC)

This Lot was tendered as a single supplier framework due to administration protocols requiring medicines from the same supplier. Overall usage across the three (3) current vial sizes was combined and evaluated on a £/IU with a wastage calculation added to any supplier's bid for the non-supply of a 250iu vial.

Selection Criteria

The following Selection Criteria were used;

- Confirmed that the product holds a valid and current UK European Medicines Agency (EMA) or Medicines and Healthcare products Regulatory Agency (MHRA) market authorisation
- Quality system ISO 9001 or equivalent.
- Requirement to meet conditions of participation questions within the ITT.

Condition of Tender

- Fixed pricing for the initial period of the framework agreement.
- Ability to meet tender specification.

Eight (8) suppliers expressed interest, with four (4) suppliers submitting bids.

AWARD

It was agreed during the Award of Business CAP that three (3) suppliers would be placed on the National Framework.

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

Lot	Product Description	Supplier
1	Anti-D (Rho) Immunoglobulin (High Dose) 1500iu pfs	CSL Behring - 1st Ranked
	Anti-D (Rho) Immunoglobulin intramuscular use (IM) 500iu vial	BPL - 2nd Ranked
2	HBIG Hepatitis B Immunoglobulin intramuscular use (IM)	BPL - Single Supplier
3	HBIG Hepatitis B Immunoglobulin intravenous use 100ml (IV)	Biotest -Single Supplier
4	HTIG Tetanus immunoglobulin intramuscular use (IM)	BPL - Single Supplier
5	Anti Rabies immunoglobulin for intramuscular use (IM)	BPL - Single Supplier
6	VZIG Varicella - Zoster immunoglobulin intramuscular use (IM)	BPL - Single Supplier
7	Coagulation Four Factor Prothrombin Complex Concentrate (PCC) 250iu	CSL Behring - Single Supplier
	Coagulation Four Factor Prothrombin Complex Concentrate (PCC) 500iu	
	Coagulation Four Factor Prothrombin Complex Concentrate (PCC) 1000iu	

Table 3.0 Award Details

PRODUCT DETAILS AND PRODUCT MATCHING

Please see Appendix A – Contract Summary for full details of products awarded. There is no change to current supplier or products awarded.

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 12 month period from 1 November 2015 to 31 October 2016.

There are no secured savings from this tendering exercise. The procurement process has resulted in an overall annual cost pressure of £97,341.

5. Method of Call Off

The method of call off remains unchanged from the current arrangement. 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: Call off will be on the basis of the first ranked supplier, cascading to the remaining (second ranked supplier), subject to clinical requirements.
- Lots 2 - 7: 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 via the EMIS and JAC computer systems (Non PECOS) as soon as the framework commences.

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.

6. Calculations of Benefits

There are no secured savings from this tendering exercise.

The following table (Table 4.0) provides a breakdown of the total saving/increase for each product

Product Description	Sum of Quantity Issued	Total Current Value	Current Unit Price	New Unit Price	New Value	Difference
Anti D (Rho) Immunoglobulin						
Rhophylac 1500iu Anti-D	9995	£339,830	£34.00	£39.00	£389,805	-£49,975
D-Gam 500iu Igg	10567	£356,636	£33.75	£33.75	£356,636	£0
Hyper Immunes						
Zoster Igg 250iu	806	£282,100	£350.00	£450.00	£362,700	-£80,600
Tetanus 250iu Igg	1390	£139,000	£100.00	£125.00	£173,750	-£34,750
Rabies Ig	108	£44,507	£412.10	£500.00	£54,000	-£9,493
Hep B Igg For Im 500iu	367	£97,732	£266.30	£300.00	£110,100	-£12,368
Hepatect 100ml 5000iu	5	£9,250	£1,850.00	£1,875.00	£9,375	-£125
Four Factor Concentrate (PCC)						
Beriplex 500iu 4fpcc	5319	£744,660	£140.00	£125.00	£664,875	£79,785
Beriplex 250iu	50	£3,500	£70.00	£62.50	£3,125	£375
Beriplex 1000iu	327	£91,560	£280.00	£250.00	£81,750	£9,810
Overall Totals	28934	£2,108,775			£2,206,116	-£97,341

Table 4.0 Saving/Increase by Product

Lot 1: Anti-D (Rho) Immunoglobulin (either in a pre-filled syringe or vial)

Following receipt of the tender submissions and subsequent discussions with Dr. Rachel Green and Dr. Alan Mathers, it has been agreed there will be no change to current prescribing protocols. Therefore, the Lot value and cost increase for Anti-D have been calculated based on the following assumptions - 55,000 cases per annum, with approx 17% of expectant mothers receiving Anti D:

- Immunising events in pregnancy will receive 500iu (assumed 10% of cases)
- Prophylaxis of 1500iu between 28-32 weeks and then
- At delivery 500iu if the baby is RhD positive (assumed 60% of cases)

Product Description		No. of cases	Current Price	New Price	Current Value	New Value	Difference
Rhophylac 1500iu	100%	9350	£34.00	£39.00	£317,900	£364,650	-£46,750
D-Gam 500	Assumed 10%	935	£33.75	£33.75	£31,556	£31,556	£0
60% of cases will receive additional D-Gam 500iu	Assumed 60%	5610	£33.75	£33.75	£189,338	£189,338	£0

Table 5.0 Lot 1 Anti-D clinical pathway usage calculation

The difference between the above calculation of £46,750 and the cost increase of £49,975 shown in Table 4.0 above is due to additional usage based on previous sales data. Therefore the overall price increase is estimated to be between £45k and £50k.

The following table (Table 6.0) provides a breakdown of the overall increase by health board for Lot 1 Anti-D:

Lot 1: Anti D (Rho) Immunoglobulin			
Health Board	Previous Value	New Value	Price Increase
Ayrshire and Arran	£50,979	£54,679	-£3,700
Borders General	£9,653	£10,328	-£675
Dumfries and Galloway	£17,096	£18,146	-£1,050
Forth Valley	£40,568	£43,273	-£2,705
Grampian	£81,300	£87,300	-£6,000
Greater Glasgow Clyde	£179,748	£191,798	-£12,050
Highland	£30,230	£32,060	-£1,830
Lanarkshire	£66,350	£70,350	-£4,000
Lothian	£121,812	£132,777	-£10,965
NHS Fife	£44,695	£47,595	-£2,900
Tayside	£49,289	£52,939	-£3,650
Western Isles	£4,748	£5,198	-£450
Totals	£696,466	£746,441	-£49,975

Table 6.0 Lot 1 – Anti D: Overall price increase by health board

Lots 2 – 6: Hyper Immunes

The following table (Table 7.0) provides a breakdown of the overall increase by health board for Lots 2 – 6 Hyper Immunes:

Lots 2 - 6: Hyper Immunes			
Health Board	Previous Value	New Value	Price Increase
Ayrshire and Arran	£38,446	£48,375	-£9,929
Borders General	£8,065	£10,175	-£2,110
Dumfries and Galloway	£7,650	£9,750	-£2,100
Forth Valley	£41,361	£52,175	-£10,814
Grampian	£105,410	£130,250	-£24,840
Greater Glasgow Clyde	£168,641	£207,525	-£38,884
Highland	£36,827	£46,275	-£9,448
Lanarkshire	£59,905	£75,475	-£15,570
Lothian	£60,947	£73,500	-£12,553
NHS Fife	£18,341	£22,475	-£4,134
Tayside	£23,263	£29,250	-£5,987
Western Isles	£3,733	£4,700	-£967
Totals	£572,589	£709,925	-£137,336

Table 7.0 Lots 2 – 6 Hyper Immunes: Overall price increase by health board

Lot 7: Coagulation Factor Four Factor Prothrombin Complex Concentrate (PCC)

The following table (Table 8.0) provides a breakdown of the overall savings by health board for Lot 7 Four Factor Concentrate (PCC):

Lot 7: Four Factor Concentrate (PCC)			
Health Board	Previous Value	New Value	Savings
Ayrshire and Arran	£56,980	£50,875	£6,105
Borders General	£22,120	£19,750	£2,370
Dumfries and Galloway	£32,900	£29,375	£3,525
Forth Valley	£29,120	£26,000	£3,120
Golden Jubilee	£16,520	£14,750	£1,770
Grampian	£56,840	£50,750	£6,090
Greater Glasgow Clyde	£228,200	£203,750	£24,450
Highland	£25,760	£23,000	£2,760
Lanarkshire	£138,880	£124,000	£14,880
Lothian	£143,640	£128,250	£15,390
NHS Fife	£49,000	£43,750	£5,250
Tayside	£32,760	£29,250	£3,510
Western Isles	£7,000	£6,250	£750
Totals	£839,720	£749,750	£89,970

Table 8.0 Lot 7 Four Factor Concentrate (PCC) Overall savings by health board

There is no change the current supplier of Coagulation Factor Four Factor Prothrombin Complex Concentrate (PCC), therefore there is no change to clinical guidelines required.

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. Health boards should ensure that all orders are placed with SNBTS, Edinburgh and quote contract Reference NP34917 on all purchase orders.

8. Next Steps

There will be no requirement for SNBTS to run down current stock or manage the introduction of new stock to meet the tender outcome as there is no change to current products or suppliers, however SNBTS will update purchase order templates and issue them to pharmacy leads within health boards to reflect change in prices.

Each health board should review this contract and CAREB through the appropriate clinical users group and implement the best value for money product selection.

C A R E B National Procurement	Anti-D, Four Factor Concentrate and Hyper Immunes (AFHP)	NP34917
--	---	----------------

Health boards should update all appropriate catalogues as soon as possible

SNBTS must be notified in advance of any planned changes in demand that may affect existing requirements.

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 No.	Version. Date	Revised By	Description	Filename
1.0	7 June 2017	Hazel Johnstone	C A R E B - NP34917 CAREB	NP34917 CAREB AFHP V1.0

Distribution

To	Action	Date
Directors of Pharmacy Chief Pharmacists	Cascade Distribution to appropriate users	7 June 2017
POG	Cascade Distribution to appropriate users	7 June 2017
Pharmacy Procurement Staff	For implementation and logistics	7 June 2017
SNBTS	For implementation and stock management	7 June 2017
NPPEAG	For information	7 June 2017