



Contract Approval Request

Summary Page

Title:	Supply and Delivery of Meningococcal Group B vaccine
Initial Term:	48 months
Extension Period:	N/A
Awarded Supplier(s):	GlaxoSmithKline(Ireland) Limited
Total Contract Value:	██████████ (incl Vat)
Annual Contract Value:	██████████ (incl VAT)
Savings/ Additional Costs:	-██████████ (incl VAT)
Incumbent Supplier(s)	GlaxoSmithKline(Ireland) Limited
Date Submitted:	29 04 024
Estimated Start Date:	01 10 2024
Portfolio Name:	VACC
Submitted by:	Marnie Mc Dermott
Summary:	<p>This contract is for the supply of up to ██████████ doses (+/-15%) of Meningococcal Group B Vaccine over a four year period. The annual requirement is for ██████████ doses which equates to ██████████ doses in a four year period. The drawdown may vary by 15% depending on the birth cohort which is decreasing and the uptake of the Primary Childhood Immunisation Programme. The last supply of Men B vaccines on the current contract is due to be supplied in October 2024 therefore a new contract needs to be put in place. This contract will ensure compliance with National Financial Regulations and continuity of supply for the Primary Childhood Immunisation Programme.</p>

Procurement Process Type: Direct Negotiation

Issues encountered: Sole supplier of Meningococcal Group B Vaccine

Tender Contract Details

1.0 Explanation of Requirement

In accordance with the National Immunisation Advisory Committee (NIAC) Immunisation Guidelines of Ireland, a National Contract for the Supply of Meningococcal B Vaccine to the HSE is required to vaccinate relevant cohorts and provide protection against Meningococcal B. The Meningococcal B vaccine is indicated for active immunisation of babies from two months of age and older against invasive meningococcal disease caused by *Neisseria Meningitidis* Group B. The Men B vaccine was introduced in Ireland for all children born on or after 1 October 2016 because children under one year are at the highest risk of meningococcal B disease and forms part of the Primary Childhood Immunisation Schedule. Since the introduction of this vaccine along with the Meningococcal C Vaccine in 2010, cases of meningococcal meningitis have dropped more than 80%.

Of the people who get meningococcal disease:

- 1 in 20 will die
- 1 in 10 people who recover will have a major disability such as deafness, brain damage or loss of fingers, toes, hands, feet, arms or legs.

Meningococcal disease may occur at any age but the highest rate of meningococcal disease occurs in children under 1 year of age. In Ireland the risk of infection is highest in winter and early spring.

Meningococcal B disease is prevented by vaccination.

2.0 Procurement Market

The Irish market for Meningococcal B Vaccine is populated by one supplier only, GlaxoSmithKline (Ireland) Limited, that is suitable for the Primary Childhood Immunisation programme. There is a second Men B vaccine but this is indicated for active immunisation of individuals 10 years and older therefore does not meet NIACs Immunisation guidelines. As a result, the HSE entered in to Direct Negotiations with GSK to secure supply for the Primary Childhood Immunisation Scheme.

3.0 Procurement Strategy

Negotiated Procedure under Article 31(1) (b) of the EU Procurement Directives as the contract may only be awarded to one supplier (sole supplier confirmed by the NIO).

4.0 Procurement Process

Negotiated Procedure under Article 31(1) (b) of the EU Procurement Directives as the contract may only be awarded to one supplier (sole supplier confirmed by the NIO).

5.0 Value for Money

- The current contract cost is [REDACTED] (€[REDACTED] including VAT) per dose of Bexsero® vaccine.

- GSK proposed a price of [REDACTED] ([REDACTED] including VAT) per dose of Bexsero® vaccine.
- Following Direct Negotiations, a price of [REDACTED] (€[REDACTED] including VAT) per dose of Bexsero® vaccine was agreed.

The original budget estimate was [REDACTED] over a four year contract which was based on the current contract as per the National Immunisation Office. This was based on the previous tender cost, which had a higher quantity than required for this tender. The reduced volume for this tender is due to the fall in the birth rate cohort by 15k and the development of a new combined vaccine for diseases including Meningococcal B. The increase in price can be attributed to the reduced volume guaranteed to be purchased and the shorter duration

The main cost drivers for this tender is low volume and short duration. The previous contract was for [REDACTED] vaccines over a seven year period which equates to [REDACTED] doses per annum. This tender is for [REDACTED] vaccines over a four year period which equates to [REDACTED] doses per annum. .

The original contract was tendered in 2015 (nine years ago) was [REDACTED] per dose which was also procured utilising Direct Negotiation as GSK was the only supplier in 2015. Ireland was one of the first countries to start using the Meningococcal B vaccine as part of the Primary Childhood Immunisation Programme from babies born after 2016. There was no increase in the cost per dose during the lifetime of the contract.

A result of the Direct Negotiation for this process, the cost per dose has increased from [REDACTED] to [REDACTED] which equates to an increase in price per dose of 21% approximately. The Consumer Price Inflation from December 2015 to March 2024, is 21.3% which is in line with the price increase negotiated with GSK.

The National Immunisation Office requested a shorter duration for this contract as there is a combined vaccine in the development stage which includes Men B. it is anticipated that the combined vaccines will be available in the Irish market place in four to five years approximately. This will increase competition in the market place as well as providing greater immunity for a number of diseases not just Meningococcal B.

- Pre Direct Negotiation, the cost for [REDACTED] doses of Men B vaccine was [REDACTED] over four years. This equates to [REDACTED] per vaccine
- Post Direct Negotiation, the cost for [REDACTED] doses of Men B vaccine was [REDACTED] over four years. This equates to [REDACTED] per vaccine

Cost Avoidance

HSE Procurement achieved a Cost avoidance of [REDACTED] %/[REDACTED] was achieved by HSE Procurement direct negotiations on the tendered price submitted by GSK.

There was also a cost avoidance of [REDACTED] by switching from a single dose pack to a 10 pack. The cost avoidance will be achieved in the National Cold Chain Service over the four years of the contract.

Total of cost avoidance by Direct Negotiation is [REDACTED].

6.0 Environmental Impact Statement

GSK is committed to environmental sustainability with a commitment to be net zero carbon, nature positive, healthier plant with ambitious goals for 2030 and 2045.

- 100% imported renewable electricity by 2025 and 100% renewable electricity (imported and generated) by 2030
- 80% absolute reduction in greenhouse gas emissions from a 2020 baseline across all scopes and investment in nature-based solutions for the remaining 20% of their footprint by 2030
- Net zero greenhouse gas emissions across their full value chain by 2045

GSK is addressing major sources of emissions with a plan to reduce carbon emissions by 80% by 20230 and 90% by 2045, with a need to off-set the residual emissions in line with the Science Based Target net zero standard.

Packaging- There is no PVC in Primary pack or tertiary packs; blisters and carton trays are assimilated to secondary pack items. PVC in secondary packaging is expected to be phased out by 2025. 95% of secondary packaging materials are from FSC/PEFC certified sources.

ePIL- GSK supports the adoption of regulatory frameworks which allow marketing authorisations holders to replace package insert leaflets with electronic patient information leaflets (ePIL) in all product types.

Freshwater- reduce overall water use by 20% by 2030

Land- 100% of agricultural and forestry derived materials sustainably sourced and deforestation free by 2030

Oceans- 100% of marine-derived materials sustainably sourced by 2030

Waste and materials-Zero operational waste including eliminating single use plastics by 2030.

7.0 Budget

The National Immunisation Office is the budget holder and funded by the Department of Health.

8.0 Risk Management

There is only one manufacturer of Meningococcal B vaccine that is suitable for the Primary Childhood Immunisation Programme and failure to implement this contract will impact continuity of supply of the Men B vaccine for the and at risk cohorts programme resulting in cessation/interruption to the programme.

9.0 Contract Management

This Contract will be managed by the National Immunisation Office. The HSE's standard terms and conditions will apply.



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10.0 Approval

The Procurement Team recommends the award of this contract as detailed above and confirms:

1. The procurement process detailed above complies fully with Statutory Instrument No. 284 of 2016 EUROPEAN UNION (AWARD OF PUBLIC AUTHORITY CONTRACTS) REGULATIONS 2016 giving effect to Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC; HSE Procurement Policy; and HSE National Financial Regulations;
2. No member of the Evaluation Team or anyone else involved in the above procurement process had any registered interest or conflict of interest with any of the tenderers;
3. Award of contract(s) is subject to the receipt of satisfactory tax and insurance certificates;
4. Award of contract will be governed by legally binding contracts which protect HSE interests. The contract will include appropriate confidentiality clauses;
5. Funding is available to meet the cost of this contract.
6. Total life cost analysis has been carried out and the recommended contract represents best value for money;
7. The business benefits identified will be tracked to ensure that they are realised and will in due course be available to Board/CEO/National Director etc. and C&AG;
8. A contract will not be concluded within the standstill period required under European Communities (Public Authorities' Contracts) (Review Procedures) Regulations 2009.

Submitted By:

Procurement Team Lead

Date: 29 04 2024

The undersigned accepts and supports the recommendation of the Procurement Team.
Recommendation Accepted & Supported by:

AND Strategic Sourcing & Contracting

Date: 02/05/2024

Approval

In accordance with HSE Purchase to Pay National Financial Regulations Board/CEO/National Director etc., (edit as appropriate) approval is requested

	Procurement Process Approval	Budget Holder Approval
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Approved By		
Position	National Director of Procurement	
Date	21/05/2024	



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Appendix A: Procurement Report Summary

Tender Procedure		Direct Negotiation		
Publication Date www.etenders.gov.ie		N/A		
Publication Date on OJEU		N/A		
Number of Expressions of Interest Received (For Restricted Procedures Only)		1		
Number of Tenders Received by Closing Date		1		
Closing Date		22.3.24		
Tender Opening Date		22.3.24		
Tenders Opened by		Marnie Mc Dermott		
Procurement Team				
Name		Title		Role
Lucy Jessop		Director of the National Immunisation Office		Lead/Chairperson
Mr. Achal Gupta		Chief Pharmacist, National Immunisation Office		Technical/Commercial Evaluator
Ms. Leah Gaughan		Senior Pharmacist, National Immunisation Office		Technical/Commercial Evaluator
Ms. Cora Kerrigan		Senior Pharmacist, National Immunisation Office		Technical/Commercial Evaluator
Ms. Linda Slevin		Vaccine Business Team, HSE National Immunisation Office		Technical/Commercial Evaluator
Ms. Marnie Mc Dermott		General Manager, HSE Procurement		Commercial Team
Selection Criteria N/A Direct Negotiation				
Main Criteria		%	Sub-Criteria	% Min %
Suppliers who Failed to Qualify at Selection Stage				
Name		Reason		
Award Criteria N/A Direct Negotiation				
Main Criteria		%	Sub-Criteria	% Min%
Suppliers who Failed to Qualify at Award Stage				
Name		Reason		
Financial Ranking Following Award Evaluation				
#	Name			Score
1	GlaxoSmithKline (Ireland) Limited			
Non-Financial Following Award Evaluation				
#	Name			Score
Most Economically Advantageous Ranking Following Award Evaluation				



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#	Name	Score
1	GlaxoSmithKline (Ireland) Limited	

Cost Drivers		
Element	%	Influencing Factors
Energy (excluding transport)		
Transport		
Process		
Material		
Labour		
Margin		
Total	100%	

Budget Savings or Cost (Calculate both columns based on pre contract full year volumes)		
Pre Contract Full Year Cost	Post Contract Full Year Cost	Full Year Benefit / (Cost)

See Appendix B for detail

Procurement Process Assurance		Tick to Confirm
The Procurement Team Confirms <input type="checkbox"/>		
1	The Procurement process detailed above complies fully with Statutory Instrument No. 284 of 2016 European Union (Award of Public Authority Contracts) Regulations 2016 giving effect to Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public Procurement and repealing Directive 2004/18/EC; HSE Procurement Policy; and HSE National Financial Regulations.	√
2	No member of the Evaluation Team or anyone else involved in the above procurement process had any registered interest or conflict of interest with any of the tenderers.	√
3	Total life cost analysis has been carried out and the recommended contract represents best value for money.	
And subject to recommended contract being approved:		
4	A contract will not be concluded within the standstill period required under European Communities (Public Authorities' Contracts) (Review Procedures) Regulations 2009.	
5	Award of contract(s) will be subject to the receipt of satisfactory tax and insurance certificates.	√
6	Award of contract will be governed by legally binding contracts which protect HSE interests.	√
7	A contract award notice will be published on eTenders.	



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Appendix B Contract Price List

		€(incl. VAT)			
Cost Element		Current Contract Cost (per annum)	New Contract Cost (per annum)	Diff	
Men B Vaccine					
Total					
Contract Savings / Cost					

Appendix C Supplier Savings/Cost

		€(incl. VAT)			
Supplier	Year 1	Year 2	Year 3	Year 4+	Total Cost
GSK					
Total					