



# Contract Approval Request

## Summary Page

<b>Title:</b>	<b>Supply &amp; Delivery of a Monoclonal Antibody for Respiratory Syncytial Virus (RSV) Passive immunisation of infants HSE 24237</b>
<b>Initial Term:</b>	<b>6 months only- Pathfinder Programme</b>
<b>Extension Period:</b>	<b>N/A</b>
<b>Awarded Supplier(s):</b>	<b>Sanofi-Aventis Ireland Ltd for Nirsevimab (Beyfontus®)</b>
<b>Total Contract Value:</b>	<b>██████████ for six months for ██████████ doses</b>
<b>Annual Contract Value:</b>	<b>6 months-Pathfinder Programme</b>
<b>Savings/ Additional Costs:</b>	<b>N/A</b>
<b>Incumbent Supplier(s)</b>	<b>N/A</b>
<b>Date Submitted:</b>	<b>20 06 2024</b>
<b>Estimated Start Date:</b>	<b>01 08 2024</b>
<b>Portfolio Name:</b>	<b>Vaccines</b>
<b>Submitted by:</b>	<b>Marnie Mc Dermott</b>
<b>Summary:</b>	<p>In accordance with National Immunisation Advisory Committee (NIAC) advice, HSE Public Health: National Health Protection, with the National Women and Infants Health Programme wish to put in place a contract for a monoclonal antibody called Nirsevimab (Beyfontus®) ██████████ per dose ██████████ including VAT) for a pathfinder immunisation programme to protect all babies from RSV disease born during the RSV season from 1<sup>st</sup> September 2024 to 28<sup>th</sup> February 2025.</p> <p>This contract will supply ██████████ doses of the monoclonal antibody for passive immunisation over a six month period. It is a once only dose and will protect all eligible babies during their first season of RSV when they are at the highest risk of being ill from RSV disease as per National Immunisation Advisory Committee (NIAC).</p> <p>This contract is only for a six month period pending a Health Technology Assessment (HTA) to determine whether infant and/or adult vaccination will provide the greater benefit, due early 2025.</p>



# Contract Approval Request

---

Sanofi-Aventis Ireland Ltd is the sole supplier of this monoclonal antibody drug that has received marketing authorisation by European Medicine Agency (EMA) for use in all neonates and infants for the prevention of RSV disease.

In addition to the [REDACTED] another [REDACTED] doses of Nirsevimab (Beyfontus®) will be purchased for babies currently eligible for Palivizumab (current drug in use for high risk babies only)

**Procurement Process Type:** Direct Negotiation

**Issues encountered:** Sole Supplier. Very short time line due to sign off from Department of Health (DoH) for budget approval which was received on 18<sup>th</sup> June 2024 and the commencement of the contract 1<sup>st</sup> August 2024.

**Value for money:** The original budget estimate was [REDACTED] based on Public Health data for other countries that have commenced Nirsevimab (Beyfontus®) for their immunisation programmes.

HSE Procurement achieved a cost avoidance of [REDACTED] which equates to [REDACTED] on the original proposed price submitted by Sanofi-Aventis Ireland Ltd following direct negotiations.

NIAC have recommended passive immunisation of all infants against RSV disease during their first RSV season and noted that this monoclonal antibody drug for infants has received EMA authorisation, is safe and effective and should be considered for use in Ireland. Introducing this new drug will reduce the burden of RSV disease on babies, families and healthcare- including primary care, ED presentations, hospitalisation of infants.



# Contract Approval Request

## Tender Contract Details

### 1.0 Explanation of Requirement

RSV is a significant cause of infection every Autumn/Winter resulting in illness, increasing presentations to primary care, ED and admission to hospital and ICU. Between week 40 2023 and week 9 2024, there were 1,397 RSV hospitalisations in infants under one year of age, of which 1,017 were less than 6 months of age, with 118 paediatric intensive care unit (PICU) admissions. International trial data conducted in Europe during Winter 2022/23 involving over 8,000 infants reported an 83% reduction in RSV related hospitalisations in infants who had received Nirsevimab.

This contract will ensure that all babies will have access to this new treatment for who there is currently NO alternative to prevent the morbidity & mortality risks of RSV during the Winter.

This contract is for a pathfinder programme for Winter 2024/2025. A number of countries have made recommendations to introduce an RSV immunisation programme for infants and children and/or for older adults. Spain introduced a temporary RSV immunisation programme for infants this year, while it completes its assessment of options for a long-term programme. Preliminary results in Spain are very positive. In Ireland, a working group was established to consider developing a costed plan for a pilot programme for RSV immunisation for Autumn/Winter 2024/25, which will help to inform future plans for implementation of an RSV immunisation programme. HIQA are currently undertaking a Health Technology Assessment (HTA) which is due for release in 2025.

### 2.0 Procurement Market

Sanofi-Aventis Ireland Ltd is the sole supplier of Nirsevimab (Beyfontus®) which is the only drug with marketing authorisation for use in all neonates and infants for the prevention of RSV disease and requires one (1) dose. As a result, the HSE entered in to Direct Negotiations with Sanofi-Aventis Ireland Ltd to secure supply for this pathfinder programme pending the HTA assessment due in 2025.

### 3.0 Procurement Strategy

There is one sole supplier for this drug and as a result, Negotiated Procedure under Article 32(2) (b) of the EU Procurement Directives as there is only one supplier (sole supplier confirmed by Public Health).

Ireland expressed an interest to participate in a Joint Procurement with EU Health Emergency Preparedness and Response Authority (HERA) [REDACTED]

[REDACTED] Ireland will continue to be part of the Joint Procurement HERA to procure maternal and vaccines for over 65 on a non-committal basis.



# Contract Approval Request

## 4.0 Procurement Process

Negotiated Procedure under Article 32(2) (b) of the EU Procurement Directives as there is only one supplier (sole supplier confirmed by Public Health).

## 5.0 Value for Money

The original budget estimate was [REDACTED] based on Public Health data for other countries that have commenced Nirsevimab (Beyfortus®) for their immunisation programmes.

Sanofi-Aventis Ireland Ltd. proposed an initial price of [REDACTED] per dose ([REDACTED] including VAT) which equates to [REDACTED] (€[REDACTED] including VAT) for [REDACTED] doses for the 2024/2025 RSV season.

Following direct negotiations, a price of [REDACTED] per dose ([REDACTED] including VAT) was agreed on for [REDACTED] doses of the 50mg & 100mg. The majority of the [REDACTED] doses will be 50mg [REDACTED] and the balance [REDACTED] will be 100mg. Both strengths are the same price.

## Cost Avoidance

HSE Procurement achieved a cost avoidance of [REDACTED] which equates to [REDACTED] on the original proposed price submitted by Sanofi-Aventis Ireland Ltd.

## 6.0 Environmental Impact Statement

Sanofi has a clear understanding of the specific environmental challenges faced by their sector. They have identified major environmental challenges relating to their businesses: greenhouse gas emissions and climate disruption; water; pharmaceuticals in the environment; waste and biodiversity.

Sanofi is minimising the environmental impacts of their products and activities while strengthening their business resilience in the face of environmental changes. In 2010, initiatives are continuing and are keen to give them fresh impetus through the Planet Care program. (Environmental Sustainability and Resilience (sanofi.com)). Planet Care is a global project that involves all the Company's resources in defining objectives and engaging with external partners. Compared with 2019 figures, they are undertaking to reduce their carbon emissions by 55% by the end of 2030 and reach carbon-neutral status by 2030 on their scope 1, 2 & 3 (direct and indirect emissions for all activities). They have also set the target of achieving sustainable water resource management, especially at sites which are under hydric stress.

## 7.0 Budget

Access and Integration, Acutes is the budget holder and funded by the Department of Health.

## 8.0 Risk Management

Sanofi-Aventis Ireland Ltd is the sole supplier of this monoclonal antibody that is suitable for the passive immunisation of all babies born during the RSV season 24/25 and failure to implement this contract will impact at risk cohorts resulting in a significant burden on families and healthcare due to increased number of presentations to primary care, ED and admission to Hospitals and ICU.



# Contract Approval Request

---

Contract commencement is 1<sup>st</sup> August 2024 which is a tight time frame however this depended on DoH budget approval which was received on 18<sup>th</sup> June 2024.

## 9.0 Contract Management

This Contract will be managed by Access and Integration, Acutes. The HSE's standard terms and conditions will apply.

## 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.



# Contract Approval Request

Submitted By:

*Máirín Mc Donnell*

Procurement Team Lead

Date: 20.6.24

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

## 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
Approved By	<i>Siobhan Dunphy</i> Siobhan Dunphy	<i>Ciaran Browne</i>
Position	A/National Director, HSE Procurement	
Date	21/06/2024	<i>21/06/2024</i>



# Contract Approval Request

## Appendix A: Procurement Report Summary

Tender Procedure		Direct Negotiation		
Publication Date <a href="http://www.etenders.gov.ie">www.etenders.gov.ie</a>		N/A		
Publication Date on OJEU		N/A		
Number of Expressions of Interest Received (For Restricted Procedures Only)		N/A		
Number of Tenders Received by Closing Date		N/A		
Closing Date		N/A		
Tender Opening Date		N/A		
Tenders Opened by		N/A		
<b>Procurement Team</b>				
<b>Name</b>	<b>Title</b>	<b>Role</b>		
Augustine Pereira	HPSC	Lead/Technical		
Joan Gallagher	HPSC	Technical		
John Murphy	NWIHP	Technical		
Angela Dunne	NWHIP	Technical		
Chantal Migone	NIO	Technical		
<b>Selection Criteria</b>				
<b>Main Criteria</b>	<b>%</b>	<b>Sub-Criteria</b>	<b>%</b>	<b>Min %</b>
<b>Suppliers who Failed to Qualify at Selection Stage</b>				
<b>Name</b>	<b>Reason</b>			
<b>Award Criteria</b>				
<b>Main Criteria</b>	<b>%</b>	<b>Sub-Criteria</b>	<b>%</b>	<b>Min%</b>
<b>Suppliers who Failed to Qualify at Award Stage</b>				
<b>Name</b>	<b>Reason</b>			
<b>Financial Ranking Following Award Evaluation</b>				
<b>#</b>	<b>Name</b>	<b>Score</b>		
<b>Non-Financial Following Award Evaluation</b>				
<b>#</b>	<b>Name</b>	<b>Score</b>		
<b>Most Economically Advantageous Ranking Following Award Evaluation</b>				
<b>#</b>	<b>Name</b>	<b>Score</b>		



# Contract Approval Request

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.	





# Contract Approval Request

## Appendix B Contract Price List

		€(incl. VAT)			
Cost Element		Current Contract Cost	New Contract Cost	Diff	
Nirsevimab		N/A		N/A	
Total					
Contract Savings / Cost					

## Appendix C Supplier Savings/Cost

		€(incl. VAT)			
Supplier	Year 1	Year 2	Year 3	Year 4+	Total Cost
Sanofi-Aventis Ireland Ltd		N/A	N/A	N/A	
Total					