HSE Board Briefing Template

Subject: Request for approval for Supply & Delivery of a Monoclonal Antibody for Respiratory Syncytial Virus (RSV) Passive immunisation of infants HSE 24237
Submitted for meeting on: 26th July 2024
Name & title of author: Siobhan Dunphy, Acting National Director, HSE Procurement
Why is this information being brought to the Boards attention? Board approval is required for: • The award of a contract to Sanofi-Aventis, sole supplier, for the supply and delivery of Nirsevimab (Beyfontus®) for a six pathfinder immunisation programme for prevention of RSV on behalf of the HSE and all other Public Services • The value of this contract over six months is [redacted]. Cost per dose [redacted] including VAT) • This six month contract will provide the HSE [redacted] doses of Nirsevimab (Beyfontus®
Is there an action by the Board required, if so please provide detail? Board Approval is sought for the award of a Contract for the provision of Nirsevimab (Beyfontus®) on behalf of the HSE and all other Public Services to Sanofi-Aventis who is the sole supplier of this drug.
Please indicate which of the Board's objectives this relates to; ▪ The development and implementing of an effective Corporate Governance Framework, incorporating clinical governance and a performance management and accountability system; ☐ ▪ Developing a plan for building public trust and confidence in the HSE and the wider health service; ☐ ▪ Ensuring the HSE's full support for and implementation of the Government's programme of health reform as set out in the Sláintecare Implementation Strategy; ☐ ▪ Exercising effective budgetary management, including improving the value achieved with existing resources and securing target saving, with the objective of delivering the National Service Plan within Budget. √
Brief summary of link to Board objectives. The HSE is required to comply with the Procurement Regulations and Guidelines. The Award of a Contract in excess of €10 million requires Board Approval. .
What actions are required by the Board? Approval is sought for the award of a Contract for the provision of Nirsevimab (Beyfontus®) on behalf of the HSE and all other Public Services to Sanofi-Aventis sole supplier of this drug.
Background - provide context in order to ensure that the Board fully understand the issue.

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®) for a pathfinder immunisation programme to protect all babies born during the RSV season from 1st September 2024 to 28th February 2025.

This contract will supply [redacted] doses of the monoclonal antibody for passive immunisation of all eligible babies born over a six month period.

It is a once only dose and will protect 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).

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.

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)

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.

Conclusion:

The Procurement Evaluation Group is satisfied that the process is robust and we can defend any challenges to the outcomes.

Approval of the Contract Award to the provider is recommended.

Recommendation:

The award of a contract to Sanofi-Aventis is recommended for approval.