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## Letter of Support: Priority Assessment Application for Abrysvo (RSVpreF, Pfizer) Maternal Indication

From: Te Kāhui Mātai Arotamariki o Aotearoa | Paediatric Society of New Zealand (PSNZ)

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PSNZ writes in support of Pfizer's application for priority assessment of Abrysvo (bivalent RSVpreF vaccine) by Medsafe, specifically for the indication of active immunisation of pregnant women between 24 and 36 weeks of gestation for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.

PSNZ is the representative body for paediatricians and child health professionals in Aotearoa. RSV prevention is among our highest current priorities.

### Unmet Need in Aotearoa

RSV is the leading cause of bronchiolitis in infants, accounting for 60–80% of presentations globally. New Zealand data suggest RSV is responsible for approximately 40% of infant bronchiolitis hospitalisations, though this is likely an underestimate given that viral testing is not routinely performed in clinical practice, as it does not alter management. The burden is substantial and growing: hospitalisation rates for acute respiratory conditions in children have increased by 60% since 2000 and are now at record highs, with infants under one year of age accounting for around half of all child respiratory hospitalisations.<sup>1 2</sup>

These admissions are not benign events; they are associated with significant distress, potential long-term respiratory complications, disruption to breastfeeding and bonding, and considerable psychosocial and financial strain on whānau.

The burden falls disproportionately on our most vulnerable communities. Pacific children experience the highest rates of respiratory hospitalisation, followed by tamariki Māori; RSV hospitalisation rates in Māori and Pacific children have been estimated to be at least twice those of infants of European descent, reflecting persistent structural determinants of health

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<sup>1</sup> Dalziel SR et al. (2022). Bronchiolitis. *Lancet*. 400(10349):392–406.

<sup>2</sup> Tustin K, Fleming J. (2026). State of Child Health in Aotearoa New Zealand 2026. Auckland: Cure Kids.

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and systemic barriers to access that carry direct Te Tiriti o Waitangi obligations to achieve equity and actively protect the health of tamariki Māori. Socioeconomic deprivation compounds this inequity further.<sup>3</sup>

At present, there is no licensed RSV preventive product available in Aotearoa for infants, representing a significant and inequitable gap in child health protection compared with comparable countries. Australia has offered free maternal RSV vaccination for all pregnant women alongside infant nirsevimab through its National Immunisation Program since February 2025,<sup>4</sup> and Chile introduced universal infant nirsevimab in 2024, with the maternal vaccine also now approved.<sup>5</sup> New Zealand currently has neither, further widening inequities for our children, particularly those already at greatest risk.

## Clinical Evidence

The case for priority assessment of Abrysvo is supported by clinical trial evidence and a growing body of real-world data. The phase 3 MATISSE trial, conducted across 18 countries, found that a single dose of RSVpreF vaccine administered at 24–36 weeks of gestation reduced severe RSV-associated lower respiratory tract illness in infants by 81.8% through three months of age, and by 69.4% through six months of age, with no safety signals identified in mothers or infants.<sup>6</sup>

These findings appear consistent with emerging real-world evidence. In Scotland, a national population-based study found an adjusted vaccine effectiveness of 82.2% against RSV-related lower respiratory tract hospitalisation in infants under 90 days.<sup>7</sup> Similar effectiveness of approximately 71–79% has been observed in Argentina's national programme.<sup>8</sup>

The World Health Organisation's prequalification of Abrysvo in March 2025, following global recommendations by the Strategic Advisory Group of Experts on Immunisation, further underscores its international standing as a safe and effective maternal RSV vaccine.<sup>9</sup>

Importantly, maternal immunisation provides protection from birth, including for infants at the highest risk of early severe disease and those who may face barriers to accessing timely

<sup>3</sup> Turner N, et al. (2024). Comparison of the burden and temporal pattern of hospitalisations associated with respiratory syncytial virus (RSV) before and after COVID-19 in New Zealand. *Influenza Other Respir Viruses*. 18:e13346.

<sup>4</sup> Barnett ST et al. (2025). Respiratory syncytial virus preventives for children in Australia: current landscape and future directions. *Med J Aust*. 222(11):579–586.

<sup>5</sup> Torres JP et al. (2025). Effectiveness and impact of nirsevimab in Chile during the first season of a national immunisation strategy against RSV (NIRSE-CL). *Lancet Infect Dis*. 25(11):1189–1198.

<sup>6</sup> Kampmann B, et al. (2023). Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. *N Engl J Med*. 388(16):1451–64.

<sup>7</sup> McLachlan I, et al. (2026). Effectiveness of the maternal RSVpreF vaccine against severe disease in infants in Scotland, UK: a national, population-based case–control study and cohort analysis. *Lancet Infect Dis*. 26:362–73.

<sup>8</sup> Pérez Marc G, et al. (2025). Real-world effectiveness of RSVpreF vaccination during pregnancy against RSV-associated lower respiratory tract disease leading to hospitalisation in infants during the 2024 RSV season in Argentina. *Lancet Infect Dis*. 25:1044–54.

<sup>9</sup> World Health Organization. (2025). WHO prequalifies first maternal respiratory syncytial virus vaccine.

healthcare. This makes it a particularly powerful and equitable intervention for reducing disparities in infant outcomes.

### Support for Priority Assessment

PSNZ supports Pfizer's application for priority assessment of Abrysvo. The criteria for priority review (significant unmet medical need, seriousness of the condition, and absence of alternative preventive options) are clearly met. RSV causes substantial preventable morbidity and hospitalisation among infants in Aotearoa, with the burden falling disproportionately on Māori, Pacific, and socioeconomically deprived communities.

Medsafe registration is the essential **first step** toward PHARMAC considering public funding for this vaccine.

PSNZ's goal is equitable, funded access to RSV prevention for all infants in Aotearoa. Maternal vaccination and the long-acting monoclonal antibody nirsevimab represent complementary strategies that together could offer broad protection for infants. PSNZ strongly recommends that both be progressed through regulatory and funding pathways as a matter of urgency.

Ngā mihi nui,

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