



National Immunisation Advisory Committee

Minutes of Meeting	
Full NIAC meeting Date: 24 November 2025	Time: 3-5.30pm Venue: Hybrid (Board Room, HIQA Office, Smithfield and Online via MS Teams)

Attendance	Apologies
Chair: Edina Moylett Deputy Chair: Corinna Sadlier	
Committee Members (and Alternates) Brian Cleary, Karn Cliffe, Cillian De Gascun, Ashwin Delmonte Sen, Aoife Fallon, Daniel Hare, Sujil Jacob, Patrick Kelly, Cliona Murphy, Patrick Stapleton, Mary Ward Barrett	Alan Baird, Michelle Flood, Bridget Freyne, Juliette Lucey, Cathal O'Bróin, Ruth O'Riordan, Lois O'Connor, Scott Walkin, Astrid Weidenhammer
In Attendance DOH: Bearach Reynolds HPRA: Ronan Donelan HPSC: Lisa Domegan HSE: Áine McNamara NIO: Lucy Jessop Medical Secretary: Ellen Walsh Trainee review group: Michael Hanrahan, Muireann de Paor, Áine Varley Observers: Patricia Harrington Others: N/A	Ellen Crushell Finnuala Lonsdale Michael Carton Chantal Migone
Secretariat Clinical Lead: Sarah Geoghegan Special Advisors: Ellen Cosgrave, Fiona Cullinane, Karen McCarthy, Helena Murray Programme Manager: Melissa Jones Programme Coordinator: Trish Clarke Senior Analysts: Valerie Power, Gillian Walsh	Bryony Treston



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1	<p>Introductions</p> <ul style="list-style-type: none"> • Apologies • Welcome from HIQA CEO, Angela Fitzgerald • Welcome to Dr Bearach Reynolds (DCMO alternate) • Thank you to Aine Varley outgoing medical secretary 	
2	<p>Minutes of previous meetings</p> <ul style="list-style-type: none"> • Review of September 2025 Full Committee Meeting action items 1) Rabies recommendations update to be communicated to HSE Task and Finish group. (Complete) 2) Draft and circulate finalised rabies post-exposure prophylaxis recommendations. (Complete) 3) Respond to HPSC correspondence re mpox booster programme. (Complete) 4) Finalise NIAC ToR and SOP. (Complete) 	
3	<p>Statement of Interests</p> <ul style="list-style-type: none"> • No conflicts of interest were declared 	
4	<p>Clesrovimab (RSV)</p> <p><i>Background:</i></p> <ul style="list-style-type: none"> • Current NIAC nirsevimab recommendations were reviewed. • A review of clesrovimab was requested by the Department of Health (DoH) in the context of the EMA adopting a positive opinion for marketing authorisation in September 2025. • The main differences between nirsevimab and clesrovimab include: <ol style="list-style-type: none"> 1. Nirsevimab is licensed up to 24 months of age for those with increased risk of RSV disease in their second RSV season. Clesrovimab is currently only licensed for use in infants during their first RSV season. 2. Nirsevimab dosing is weight-based, with two different doses recommended for infants based on a cut-off of 5kg. Clesrovimab dosing in the first season is the same for all infants and is not dependent on weight. 3. Nirsevimab targets the site 0 PreF protein which may have higher neutralisation potency. Clesrovimab targets site IV of the PreF and 	



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	<p>PostF proteins which may offer broader protection against virus mutation. No head-to-head comparisons have been performed and the clinical significance of this difference in binding site is unknown.</p> <p><i>Policy question:</i> Can clesrovimab be recommended for the prevention of RSV-associated lower respiratory tract infection (LRTI) in infant populations for whom nirsevimab is currently recommended by NIAC?</p> <p><i>Domain 1: The Problem</i></p> <ul style="list-style-type: none"> HPSC data show a large reduction in hospitalisation rates among those aged 0-6 months post-introduction of extended half-life monoclonal antibodies (EHL mAbs). <p><i>Domain 2: Benefits and Harms</i></p> <ul style="list-style-type: none"> Substantial real-world safety and effectiveness data is available for nirsevimab. There are no effectiveness data yet for clesrovimab. Phase 2b/3 CLEVER and SMART studies were reviewed. The safety profile was comparable between clesrovimab and either placebo or palivizumab. No deaths were deemed to be related to EHL mAbs. Efficacy and pharmacokinetics data were reviewed for clesrovimab at 5 months post-administration. The efficacy estimate increased with increasing disease severity. Outcomes were stratified by $\geq 5\text{kg}$ and $< 5\text{kg}$ body weight, with results comparable between weight groups, which led to the single dose regimen. <p>Efficacy estimates from trials for hospitalisation and medically attended LRTI (MALRTI) were comparable between palivizumab and clesrovimab, when the definition of MALRTI was adjusted in post-hoc analysis to redefine MALRTI to bring the definition more in line with that used in nirsevimab trials.</p> <ul style="list-style-type: none"> Safety and efficacy of clesrovimab is likely to be in a comparable range to nirsevimab in healthy preterm and term babies in their first RSV season. Safety and pharmacokinetics in high-risk infants are comparable to healthy preterm and term infants in clinical trials. 	



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	<ul style="list-style-type: none"> There has been no evidence of increased RSV-associated MALRTI in the second season in those who received clesrovimab during a first season. Duration of protection is at least 6 months. Safety in high-risk infants re-dosed in second season was comparable to a first season in interim analysis. Pharmacokinetics are not yet reported. <p><i>Domains 3 & 6: Values and preferences and acceptability</i></p> <ul style="list-style-type: none"> Nirsevimab uptake in the birth cohort for 2024/2025 was 83% and was 99% in high-risk infants. <p><i>Domain 7: Feasibility</i></p> <ul style="list-style-type: none"> If two products (nirsevimab and clesrovimab) were in use concurrently there would be potential for confusion around dosing given different dosing regimens. The timing of the decision on authorisation of clesrovimab for use in the second RSV season is not known, but is unlikely to occur in time for planning for 2026/2027 season. <p>Noting international recommendations; ACIP recommends clesrovimab as an alternative agent. JCVI has not made a formal recommendation to date. Clesrovimab has been introduced in US and UAE for this RSV season which may produce clinical effectiveness data.</p> <p>A point was raised that pausing a recommendation for clesrovimab at this time might allow real-world effectiveness data to be generated prior to introduction in Ireland. Dosing differences were discussed. It was noted that having two products with different dosing schedules administered in many different settings may be challenging. Overall this was deemed to be a manageable challenge. However, set dosing may improve ease of administration, particularly for catch-up groups in the community. Introduction of a second product may introduce competition to tender procedure. The cost of each product is not yet known to NIAC. With respect to preterm babies, there are no data for babies <1kg in SmPCs for nirsevimab or clesrovimab. The median weight at randomisation of all study participants in the SMART trial (which included 50 infants <29 weeks gestational age) was 3.3kg with a range of 1.1 to 9.6kg. The mean body weight</p>	



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	<p>of infants in the CLEVER trial (preterm and full-term infants) was 5.8kg with a standard deviation of +/- 2kg. The weight range of the infants in the CLEVER trial was not further specified.</p> <p>There were no concerns overall around safety and efficacy between the two products. Feasibility is the main consideration of the committee at this time in relation to dosing confusion and lack of real-world effectiveness data.</p> <p>It was discussed that NIAC would likely have to specify caution and discretion of the treating clinician for significantly preterm babies in NICU, similar to what is currently recommended for nirsevimab. It was noted that although the EMA adopted a positive opinion for marketing authorisation in September 2025, there was an update to the website in 2025 stating that the applicant has informed the agency about a revised dataset that will be submitted and that as a result, the Commission Decision process has been put on hold while they await this information from the applicant.</p> <p>It was concluded that a NIAC recommendation for clesrovimab would only be issued after EMA authorisation.</p>	<p>1</p>
	<p>Selective BCG programme</p> <p>A query was raised from the national TB advisory committee (NTAC) on guidance in relation to TB screening prior to BCG immunisation and the implementation of same. Specifically in relation to:</p> <ol style="list-style-type: none">1. The use of high burden versus high incidence countries as an indicator of TB risk.2. TB screening prior to administration of BCG and age cut-offs for same.3. Use of Tuberculin Skin Test (TST) or Interferon Gamma Release Assay (IGRA).	



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	<p><i>Background:</i></p> <ul style="list-style-type: none">• There has been a global BCG vaccine shortage with no national programme in Ireland since 2015. NIAC issued recommendations for selective BCG vaccination when it became available again in 2022.• Timeframe for vaccination will now be pushed beyond the neonatal period as Severe Combined Immunodeficiency (SCID) screening is being introduced for all neonates. BCG vaccination will not be administered until SCID results are available.• NIAC currently uses the WHO list of high burden countries as an indicator of TB risk. This is a fixed list of countries updated every 5 years. There is overlap between high burden and high incidence lists. Some countries however have a high burden of multi-drug resistant TB without meeting high incidence criteria. Some countries have high incidence rates but do not meet the high burden list due to small population sizes, and so some children might be missed.• NIAC is an outlier internationally in use of burden rather than incidence.• Current NIAC recommendation wording refers to locally identified high risk groups. This is to include those who may be from lower incidence country but living in a setting of higher risk, or transited through a higher risk setting. <p><i>Policy question for committee:</i></p> <ol style="list-style-type: none">1. Should the language in the recommendation be amended to refer to “high incidence,” meaning an incidence rate of $\geq 40/100,000$ population?2. Does “locally identified risk groups” adequately cover infants and children who live in higher-risk environments in Ireland or have transited through higher-risk environments on route to Ireland? <ul style="list-style-type: none">• Current NIAC recommendations for TB screening prior to BCG were reviewed. The recommendations which refer to neonates are no longer implementable as BCG is now unlikely to be administered before four weeks due to introduction of SCID screening.	



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	<ul style="list-style-type: none"> • The adverse effects of administering a BCG dose in a child with TB infection were reviewed. Administration may lead to an accelerated BCG reaction. This rate is not defined in children, but may be more common in older infants. Safety nets will need to be in place if a child has an accelerated reaction, with assessment for TB infection to take place. • The potential benefits and harms of TST/IGRA screening pre-BCG vaccination were reviewed, along with international recommendations. <p>Two options were presented for discussion:</p> <ol style="list-style-type: none"> 1. Risk-based approach irrespective of age 2. Risk-based approach only for younger children <6 years <ul style="list-style-type: none"> • It was noted that an alternative age cut-off could also be used, but that there is no evidence for an age-based approach to screening. • Including locally identified risk groups may help identify children from high burden countries that do not meet incidence criteria. There was discussion around the need to specify who is responsible for identification of risk groups. There was also discussion about inclusion of wording around congregate settings. It was noted that these children should be identified via contact tracing in outbreak settings. The terminology was originally worded to allow for changes in risk factors year-on-year. A point was raised in relation to caution not to specify regional variation in how BCG vaccination is implemented and suggested to remove the word “locally.” <p>There was agreement among the committee to amend the recommendation to refer to high incidence in place of high burden. National guidelines on testing with TST and IGRA have been updated and NIAC will bring the chapter in line with national testing guidance when updating it, but recommendations on the specific test used are beyond the remit of the committee. The term neonate will need to be removed. The consensus was for the risk-based approach in younger children (option 2) with editing in the wording regarding congregate settings,</p>	<p>2, 3</p>



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	and more explicit wording regarding those transiting through a region with a high TB incidence.	
5	<p>International updates on vaccine safety statements</p> <ul style="list-style-type: none"> The recent publication by the US CDC on a potential link between autism and vaccination was noted. There has not been discussion in Irish media to date on this publication. The HSE has prepared a holding statement should it be needed, and the NIO is moving to remove CDC links at this time including information predating 2025. There was a consensus that there is a need for unity among organisations valuing scientific accuracy and NIAC should distance itself from any organisations publishing inaccurate information. If NIAC were to prepare a statement, it should focus on highlighting known vaccine safety profiles and research. NIAC will align with other EU NITAGs in the event a position statement is prepared. NIAC will move to remove live CDC links from chapters as they are being updated. 	4
6	<p>Epidemiology updates</p> <p><u>COVID-19</u></p> <ul style="list-style-type: none"> Weekly hospitalisations were lower in 2025 than 2024 and occurred mostly in those aged 80 and over. There were three variants under monitoring in 2025. XFG eventually became predominant strain. There was no evidence of an effect on severity or immunity by the three variants monitored. Similar patterns were seen across the northern hemisphere. <p><u>Influenza</u></p> <ul style="list-style-type: none"> The 2024/2025 season was severe, prolonged, and more intense than the previous season with >27,000 cases and 245 deaths notified. There was an earlier start to 2025/2026 season. Most notified cases are influenza A, of which most are A(H3). 	



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	<ul style="list-style-type: none"> The antigenically drifted A(H3) has been identified in Ireland. This is an A(H3N2) subclade K (J.2.4.1). Low reactivity of the drifted virus with post-infection ferret antisera is noted. There were over 1,000 hospitalised cases in first five weeks of this season, which is higher than last year. ECDC has published a threat assessment. The newly emerged subclade K has been identified on all continents. It notes mismatch between H3N2 vaccine strain with the new subclade K. Vaccination is still expected to protect against severe disease and remains a public health tool. A larger epidemic may occur due to lower immunity of H3N2 as there has not been major circulation in the last 18 months. It recommends consideration of antivirals in outbreaks and review of preparedness plans. Facemasks should be used for staff and visitors to hospital. <p><u>RSV</u></p> <ul style="list-style-type: none"> Epidemiological impact of the nirsevimab programme was reviewed with significant reduction in cases, ED presentations, hospitalisation and ICU admissions. The prevented fraction of cases was 74.5%. RSV circulation remains at low levels but is increasing during the current season, with the majority of hospitalised cases in 1–4-year-olds. There have been two RSV outbreaks in nursing homes this season to date. Uptake is 45% on catch-up pathfinder programme. <p>The SARI sentinel surveillance data update was presented but noted that the situation is changing quickly and numbers presented are changing. Influenza and COVID-19 vaccine uptake data was reviewed.</p> <p><u>Avian influenza H5N1</u></p> <ul style="list-style-type: none"> There was an upsurge in animal cases across the EU from mid-September. Three animal outbreaks are ongoing in Ireland, but no human contacts have tested positive for influenza A to date. 	



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	<ul style="list-style-type: none"> The ECDC risk assessment remains unchanged with low risk to the public. There has been a total of 973 human cases since 2003 with CFR of approximately 43%. 	
7	<p>Administration and Governance</p> <ul style="list-style-type: none"> The first advocacy workshop took place on 6 November with a strategic advocacy plan to be developed. Work is ongoing. NIAC TOR-SOP has been updated and published. An EGM is scheduled for 4 December at 8am to review NIAC’s work plan for 2026. 	
8	<p>Vaccine injury redress scheme</p> <ul style="list-style-type: none"> No updates at this time. Officials at the department have updated a model for vaccine injury redress. The Minister intends to bring this to the cabinet for discussion in the future. 	
9	<p>Correspondence</p> <p>Incoming</p> <ol style="list-style-type: none"> 13 October 2025 – Email from Dr Aoife Fallon to NIAC 13 October 2025 – Letter from National Screening Service re HPV vaccination 16 October 2025 – GSK letter to NIAC re Arexvy SPC update 17 October 2025 – NHPO position paper 06 November 2025 – GSK email to NIAC re Shingrix SPC update 14 November 2025 – GSK email to NIAC re Priorix SPC and PIL update <p>Outgoing</p> <ol style="list-style-type: none"> 02 October 2025 – NIAC updated recommendations for RSV vaccination in older adults 06 October 2025 – Letter to Dr Derval Igoe re mpox 31 October 2025 - NIAC letter to GSK in reply to correspondence re RSV 	
10	<p>AOB</p> <p>Nil</p>	



Action Number	Actions Arising	Responsibility	Due By
1	Draft updated EHL mAb for RSV guidance and circulate	RSV working group	Q1 2026
2	Update wording on TB screening prior to BCG vaccination	Secretariat	Q1 2026
3	Circulate updated wording to TB task and finish group	Secretariat	Q1 2026
4	CDC links to be removed from chapters during updates	Secretariat	Ongoing