Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report on the results of the public consultation on the health technology assessment of COVID-19 vaccination in Ireland: Statement of outcomes

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.

  Health technology assessment — Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

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1 Introduction

A health technology assessment (HTA) is intended to support evidence-based decision-making regarding the optimal use of resources in healthcare services. Measured investment and disinvestment decisions are essential to ensure that overall population health gain is maximised, particularly given finite healthcare budgets and increasing demands for services provided.

The aim of this HTA is to provide advice to the Minister for Health and Health Service Executive (HSE), to inform Coronavirus Disease 2019 (COVID-19) vaccination policy in Ireland. Specifically, and in the context of the updated COVID-19 vaccination recommendations published by the National Immunisation Advisory Committee (NIAC), the aim of this HTA is to provide advice in relation to the groups for whom COVID-19 vaccination is funded by the HSE for the 2027/2028 vaccination campaign onwards.

The draft HTA report was published for public consultation in June 2026. This Statement of Outcomes report summarises the feedback received during the public consultation period and outlines HIQA's responses to the issues raised, including any changes that were made to the report as a result.

2 Methods

The aim of the public consultation was to seek feedback to identify any issues with the draft HTA report, to consider that feedback and to amend the report, as necessary.

2.1 The consultation process

The draft HTA was published on the HIQA website on 29 June 2026 and was available for public consultation until 9 August 2026. The consultation webpage contained a link to the draft report, a link to the online survey (using the Qualtrics platform) for online submission of feedback, and a consultation feedback form that could be downloaded. To ensure wide accessibility, feedback could be submitted via an online survey, email, or by post.

A press release was issued to a wide range of media outlets at the beginning of the consultation period, and notifications of the public consultation were posted via social media sites (X, Facebook, Instagram, Bluesky, Threads and LinkedIn). To maximise awareness, social media notifications were posted on the day of publication, during the consultation period, and towards the end. The findings of the draft HTA were publicised in the media. Email requests for feedback were sent to a targeted list of 42 stakeholder organisations with relevant expertise and those who

are likely to be affected by changes to the groups for whom COVID-19 vaccination is funded in Ireland.

2.2 Feedback form

The template for submission comprised a general request for feedback to enable respondents to flexibly provide their submission for any aspects of the report. A copy of the submission template is provided in Appendix A.

2.3 Synthesis

Each submission was recorded (excluding personal information), read in its entirety and, where appropriate, broken down into individual components. In cases where a question was skipped by the respondent, it was assumed that there were no issues of concern specific to that question. Incomplete responses provided via the online survey platform (for example, due to someone opening the survey but not completing it) were excluded.

The submissions were stratified according to whether they were submitted on behalf of the general public or stakeholder organisations. Feedback considered broad in nature was described narratively. Verbatim responses of personal experiences with COVID-19 vaccination and commentaries from the general public are summarised in Table 1. Feedback from stakeholder organisations is presented in Table 2 alongside HIQA's responses to the feedback. Where amendments were made to the report based on feedback, this is highlighted in the HIQA response.

3 Results

Overall, 26 unique and complete submissions were received during the public consultation period through the online survey on Qualtrics (n=16) and email (n=10). Of these, 15 were submitted on behalf of the general public and 11 were submitted on behalf of stakeholder organisations. In addition, six incomplete responses were received via the online survey on Qualtrics and have been excluded from the summary below.

3.1 Summary of feedback

3.1.1 Members of the general public

There were 15 valid submissions on behalf of members of the general public received through Qualtrics or email. The feedback received was broadly summarised into two themes, namely:

- safety of COVID-19 vaccines
- burden of COVID-19.

Safety of COVID-19 vaccines

Three individuals expressed concerns regarding the safety of COVID-19 vaccination. The European Medicines Agency (EMA) and EU Member States continuously monitor the safety of COVID-19 vaccines to ensure the early detection of any possible risks. The EMA continuously checks new information on the safety of all vaccines available in Europe, through both proactive and reactive surveillance and pharmacovigilance programmes. Data sources include reports of suspected side effects from patients, parents and healthcare professionals; clinical studies; scientific literature and information shared by other regulators. The EMA carefully assesses suspected side effects to determine if they were caused by a vaccine or by something else, such as an illness. In instances where there is a reasonable possibility that a vaccine could have caused a suspected side effect, it is included in the vaccine's Summary of Product Characteristics (SmPC). This ensures that healthcare professionals and patients have up-to-date information to hand. Moreover, NIAC provides ongoing advice to the Department of Health on vaccines, immunisation and related health matters in the Irish context and advocates for best immunisation practice. NIAC also develops and disseminates the Immunisation Guidelines for Ireland to support healthcare practitioners including GPs.

As outlined in Chapter 4, evidence of the safety of antigenically updated COVID-19 vaccines in this HTA was sourced from a systematic review published in October 2025. This was supplemented by summaries of the safety profile and most frequent adverse reactions to authorised COVID-19 vaccines, extracted from SmPC documents of COVID-19 vaccines that are authorised in the EU. As concluded in this assessment, based on the available evidence to date, the safety profiles of the COVID-19 vaccines authorised in the EU are largely favourable. The most frequently reported adverse reactions (injection site pain, fatigue, headache and myalgia) were mostly mild to moderate in severity and resolved within a few days following vaccination. According to post-marketing safety surveillance of authorised COVID-19 vaccines, the frequency of myocarditis and pericarditis, where known, is very rare, occurring in fewer than 1 in 10,000 vaccinations, typically within 14 days of vaccination. However, it is also worth noting that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection itself is a risk factor for myocarditis and pericarditis. As reported in the HTA, data from the English National Immunisation Database of COVID-19 vaccination showed that the estimated extra myocarditis events in the month following vaccination was between 1 and 10 per million persons versus 40 events per million persons following SARS-CoV-2 infection. Guillain-Barré syndrome has previously been reported as a very rare side effect (less than 1 case in 10,000 people vaccinated) of the COVID-19 vaccines Jcovden® and Vaxzevria®, both of which have had their marketing authorisations withdrawn by the European Commission. Regarding the risk of stroke as an adverse event, studies included in

this HTA either found no association between COVID-19 vaccination and stroke, or they observed a reduced risk of stroke in vaccinated compared with unvaccinated individuals. These data support the advice that the authorised COVID-19 vaccines are safe and that while minor reactions are common, serious adverse events are rare.

Burden of COVID-19

Four individuals expressed concerns relating to the burden of COVID. Specifically, these individuals expressed concerns regarding the estimated burden of COVID reported in the HTA. There were also concerns that the economic evaluation did not assess the wider societal impact of COVID-19 (for example, reduced labour participation and productivity losses). Three of the four individuals indicated the need for increased investment in other non-pharmacological interventions (air ventilation and filtration); as these were outside the scope of this assessment, this feedback is not discussed further. Two of the four individuals indicated their preference for increased access to the protein subunit vaccine, Nuvaxovid®.

Estimated burden of COVID reported

One individual expressed concerns that the report underestimated the continuing burden of COVID-19 in Ireland, particularly in relation to the estimated burden of long COVID. Throughout the report, the lack of data in relation to the prevalence and burden associated with long COVID in Ireland and internationally is acknowledged. While several epidemiological studies of long COVID have been published, it is highlighted that the synthesis and interpretation of these studies is complicated and it is difficult to ascertain the true prevalence of the condition since study populations exhibit differing inclusion criteria, participant demographics and diagnostic criteria. Other challenges that are noted include the diversity of symptoms and range of organ systems that may be impacted, the severity of symptoms, and whether they are continuous or relapsing-remitting in nature. Moreover, it is highlighted that it is not known if the risk of long COVID has changed over time given virus evolution and changes in population-level immunity.

Chapter 3 outlines the approaches taken to estimate the incidence of long COVID in Ireland. Data from long COVID clinics were requested and showed that the number of new patients being referred to the long COVID clinics has decreased from 2023 to 2025 (which is broadly consistent with the trend observed for notified COVID-19 cases in Ireland). These data also showed that return patients comprised most patients being assessed at these clinics. While highlighting that new referrals to the long COVID clinics have decreased, the report notes that it is unclear if there is also a decrease in the incidence and prevalence of long COVID in Ireland given the general lack of data. Additional data considered in the report (see Chapter 3)

included the Follow-up After Disease Acquisition (FADA) Survey, which aimed to estimate the prevalence of long COVID, describe the symptoms, severity and duration of long COVID, investigate potential factors that may predispose or protect against long COVID, and describe the healthcare utilisation and preferences of those with ongoing or resolved long COVID. While the prevalence of long COVID reported in the survey was 16%, there are a number of limitations associated with this estimate. Firstly, the response rate on the survey was low (9.6%). Secondly, the published results of the survey were not limited to those who had received a clinical diagnosis of long COVID, but also included individuals who, having read a definition of long COVID, self-reported themselves as having long COVID. Thirdly, the survey only included individuals who had a confirmed SARS-CoV-2 infection prior to February 2022. This is important because from late November 2021, Omicron began to emerge as the dominant COVID-19 variant globally, causing less severe disease on average than the previous Delta variant. HIQA also reviewed data from the UK Office of National Statistics which estimated that the prevalence of long COVID symptoms 12 weeks or more after acute COVID-19 infection in a large sample of adults and children (from England and Scotland in February and March 2024) was 1.8%. In the absence of current Irish population-based prevalence estimates for long COVID, and given the limitations with the FADA study outlined above, the prevalence of long COVID in Ireland was estimated to be likely similar to the 1.8% observed in the UK, with use of this estimate endorsed by Irish expert opinion.

Wider societal impact of COVID-19

As stated in Chapters 3 and 5, the incidence of COVID-19 in Ireland is highly uncertain. In the absence of population-level data, notified case data were used to estimate the incidence of COVID-19 in Ireland. It is acknowledged that notified case data likely underestimate the total burden, particularly the burden in primary care since, in order to be identified as a case, an individual must present to a healthcare setting, be tested, and in the event of confirmed case, the data notified to the Health Protection Surveillance Centre (HPSC). While it is acknowledged that it is possible not all COVID-19 cases are laboratory confirmed and some discharges may not be coded, the notified hospital admission data are considered to be generally representative of the burden on the secondary healthcare system given widespread access to COVID-19 testing in hospital settings and current HSE guidelines in relation to the use of multiplex testing for those presenting with symptoms of acute respiratory tract infection. Chapter 5 acknowledges that by limiting the economic model to notified cases of COVID-19 only, the full disutility of COVID-19 is not captured in the analysis. However, as notified cases should represent the majority of cases that require medical care, it is considered that the model accounts for most of the impact of COVID-19 on healthcare resources and quality of life.

The economic assessment was conducted from the payer perspective which by definition does not incorporate productivity losses. Health benefits were expressed in terms of quality-adjusted life-years (QALYs). In the absence of data, QALY loss associated with COVID-19-related death and long COVID were estimated based on a lifetime time horizon. As pointed out in the limitations, economic modelling exercises are by their nature, limited by the choice of model, the underlying assumptions, and the availability of data, including both costs and utilities, to populate the model. In this case, data allowed for the incorporation of a number of medium-to-long-term outcomes associated with COVID-19 into the model, examples of which included long-COVID, discharge to short-term step-down or rehabilitation facilities and discharge to long-term care facilities.

While the economic guidelines allow for the societal perspective to be presented in addition to the payer perspective, when appropriate, it is noted that there is a lack of Irish data in relation to productivity losses associated with COVID-19.

Individuals' preferences

A number of respondents stated a preference for increased access to Nuvaxovid®. The purpose of this HTA is to provide advice to the Department of Health in relation to the groups for whom COVID-19 vaccination is funded by the HSE for the 2027/2028 vaccination campaign onwards. All authorised COVID-19 vaccines were considered in this HTA, including the protein subunit vaccine, Nuvaxovid®. The report notes NIAC's preferential recommendation for an antigenically updated messenger RNA (mRNA) vaccine, because of their extensive safety data and effectiveness against COVID-19. It is also noted that NIAC has advised that a protein subunit COVID-19 vaccine can be used as an alternative in those for whom an mRNA COVID-19 vaccine is unsuitable, with Nuvaxovid® (antigenically updated) the preferred alternative. In the review of the safety and effectiveness of COVID-19 vaccines (Chapter 4), it was noted that the majority of the included evidence relates to Omicron-adapted mRNA COVID-19 vaccines. While some studies included other vaccine types, such as the protein subunit COVID-19 vaccines, it was noted that only small numbers of participants received these vaccine types. Studies typically did not report findings disaggregated by vaccine type, so it is not possible to determine if effectiveness differs by vaccine type based on the evidence considered. Given this finding, the economic evaluation (Chapter 5), assumed vaccine equivalence for the purpose of modelling. Similarly, in the absence of specific prices for Ireland by brand, dose and formulation, a vaccine cost of €75 per dose was assumed, based on international data. The findings of the economic evaluation therefore are not specific to any one vaccine or vaccine type. Chapter 6 highlights that a programme comprising a range of vaccine products may increase choice and potentially improve resilience. However, it is noted that these benefits would need to be considered in

the context of the cost difference (if any) between products and the additional logistical burden associated with making a range of products available.

Decisions in relation to the vaccine(s) selected for use are based on NIAC guidance, Department of Health policy and funding and then the outcome of a HSE competitive tender process or Health Emergency Preparedness Response agreement for EU contracts.

Personal experiences and commentary

Verbatim personal experiences with COVID-19 vaccination and commentary on the HTA report are summarised in Table 1. In general, these statements were supportive of continued access to COVID-19 vaccination with some expressing concerns that they may no longer be eligible if the cohort is restricted. One individual stated that they would be willing to pay for vaccination should they no longer be eligible for funded vaccination through the HSE COVID-19 vaccination programme. One individual queried why COVID-19 vaccines are not available for private purchase and another suggested that the inclusion of COVID-19 vaccination uptake data (as reported in the National Immunisation Information System) may have been a useful addition but clarified that they were not recommending any changes be made to the report.

The report highlights (Chapter 2, Chapter 6) that COVID-19 vaccines are not currently available for private purchase in Ireland. However, it is noted such availability is at the discretion of the individual manufacturer. This detail has also been included in the Key Findings and Advice, which were drafted subsequent to the public consultation.

Table 1 Verbatim of personal experiences with COVID-19 vaccination and commentary*

Number	Comment
Personal experiences	
1	Continue with COVID vaccination for elderly, immunocompromised people and asthmatics. It's so hard to get doctor's appointments if ill so keeping people out of system is most important.
2	COVID-19 vaccination should be treated as a core preventive health measure, not an optional or exceptional programme. As someone immunocompromised, I have had to adapt to living in a society that no longer has a sense of collective responsibility.
3	I have two auto immune conditions. I am employed in third level education and I will always be exposed to a wide variety of airborne illnesses. Having the COVID booster twice a year and the annual influenza shot, increases my ability to go to work and maintain a healthy outcome each year.

4	Please maintain the current COVID booster regime for those people at risk, including myself.
5	I (for instance) would not fit into a pre-determined 'vulnerable' category, however I have a number of older family members who would greatly benefit from my opting to vaccinate - this should be available to me and my family circle for the safety of my extended family members.
6	My own experience with an elderly parent is that I need to keep an eye out for text notifications she receives, as otherwise she's unlikely to make an appointment, particularly for the spring campaign, in which her GP does not participate. Personally, as her primary carer, I feel that being given the option of a vaccine even though I am under 60 is something of an acknowledgement of what can be an isolating and lonely experience.
7	I am a 62-year-old female with a chronic respiratory condition who is also immunocompromised as a result of the medication used to treat said condition. I am currently among the cohort who is offered a COVID-19 vaccine twice yearly; I have always availed of the opportunity. If, as the draft seems to suggest, I am no longer eligible for free-of-charge COVID-19 vaccination, I would be more than happy to pay for a twice-yearly vaccine - I suggest that this option be included in any future policy.
Commentary	
8	Overall, an in-depth assessment that presents the relevant data and outlines those at high risk and the continuing impact of Covid-19 in terms of hospitalisations, ICU admissions etc. The cost implications are described. The only query is why the assessment does not explore why the vaccine is not/cannot be made available for private practice.
9	The draft assessment is clear in its definitions and descriptions. All sections are clear and informative.
10	One useful addition to this report would have been the inclusion of uptake data from the Immunisation Information System (IIS) COVID-19 vaccination dashboard. This data source would have provided weekly trend information over the last three winter and spring campaigns. The report correctly points out how target age cohorts have differed between campaigns based on NIAC recommendations, but 80+ year olds have been a consistent target group in each of them. For that reason, a graphic comparison of weekly uptake in this age cohort would have clearly shown a decline over the three previous winter and spring campaigns. In summary, according to the IIS dashboard as of 28/06/2026, at the end of each campaign, uptake among 80+ year olds was: Winter 2023-2024, Calendar Week 8, 86.5% (n=15,6624) Winter 2024-2054, Calendar Week 9, 74.9% (n=13,5665) Winter 2025-2026, Calendar Week 9, 65.9% (n=11,9249) Spring 2024, Campaign Week 11, 52.0% (n=94,174) Spring 2025, Campaign Week 12, 34.7% (n=62,833)

	Spring 2026, Campaign Week 11, 29.0% (n=52,452) Of note is one key difference between current HPSC reporting and that of the IIS dashboard. HPSC disaggregate based extracts provided by IIS calculate age based at the time of vaccination, but the IIS dashboard uses a person's current age. This is relevant when examining uptake by specific age groups and would account for differences observed in the numbers of doses administered and calculated percentage uptake values. In terms of presentation, IIS dashboard winter campaign can be presented by calendar week but its spring data should be presented instead by campaign week number given how each of these campaigns would have had different start and end dates.

*Responses have been slightly amended to correct for minor grammatical errors and or typos.

3.1.2 Stakeholder organisations

Eleven responses were received on behalf of the following stakeholder organisations:

- Accord Healthcare Ireland
- AVISTA
- Céile Care
- Health Service Executive
- Irish Heart Foundation
- Irish Nurses and Midwives Organisation
- Irish Pharmacy Union
- Moderna Tx, Inc.
- Nursing Homes Ireland
- Pfizer Healthcare Ireland
- Sanofi

The feedback from these stakeholder organisations and the actions taken to address this feedback where appropriate, are provided in Table 2.

Table 2 Feedback submitted by stakeholder organisations*

Number	Feedback	Response
Accord Healthcare Ireland		
1	Table 2.5 and Table A.2 should be amended to include the pre-filled syringe presentation to ensure consistency and accuracy throughout the report. This is particularly relevant given the report's discussion of the operational and logistical advantages associated with refrigerated, single-dose, pre-filled syringe products, including reduced vaccine wastage, simplified handling and administration efficiencies.	Table 2.5 has been edited to note the availability of a refrigerated only single dose pre-filled syringe product for Bimervax®. The text underneath Table 2.5 (Section 2.3.4) has been edited to include a description of the storage requirements for Bimervax® syringes and vials. Table A.2 has been edited to include "single dose pre-filled syringe of 40mcg/0.5ml (refrigerated only)" in the container type field and the special precautions for storage field now states the precautions relevant for both vials and pre-filled syringes.
2	The report discusses the advantages of refrigerated, single-dose, pre-filled syringe COVID-19 vaccines in the organisational considerations section, but does not reference that Bimervax® currently has such a presentation available. Explicitly acknowledging this would improve the completeness of the discussion and better align the description of available products with the report's assessment of operational efficiencies.	Section 6.1.5 has been updated to include Bimervax® as an example of a product that is available as a refrigerate only single-dose pre-filled syringe.
Avista		
3	The comprehensive report, which delineates characteristics and recommendations for specific age groups as previously proposed in NIAC, left some ambiguities for interpretation.	Thank you for your feedback. Evidence from early in the pandemic showed that those with intellectual disabilities had difficulty understanding or adhering to restrictive measures and that social

Number	Feedback	Response
	In disability services, the risk of an outbreak was significantly higher than in other populations due to challenges in adhering to recommendations and/or isolation.	distancing was challenging for those living in residential care or during close contact when receiving care. However, the literature base on this topic largely relates to 2020 and 2021 when restrictive measures were in place. The focus of this HTA is the current epidemiological situation. As such, no changes have been made to the report.
4	Furthermore, more severe illness could be observed within disability services, attributable to comorbidities and various underlying conditions, including neurological and endocrinological disorders (for example, people with Down Syndrome), which were not analysed in this report. It would be interesting to see how many people with underlying conditions were represented among people with disabilities. As in this population, for example, epilepsy is experienced by the majority of them.	The report highlights that while surveillance data on the burden of COVID-19 in Ireland are readily available for the age groups considered to be at risk of severe disease, there is a lack of data for other at-risk groups. The need for additional data to better identify those at highest risk of severe disease is highlighted in the report, as well as the importance of using national and international surveillance data to inform national COVID-19 vaccination policy.
5	I believe that including the population with intellectual disabilities as an additional group at risk or subgroup would help guide families in achieving vaccination compliance for their loved ones. But, I understand that the lack of evidence might restrict the report to general information, with a general health condition discussed.	The purpose of this HTA was to provide advice to the Department of Health and HSE relating to COVID-19 vaccination in Ireland, in the context of the NIAC recommendations (May 2025). While those with intellectual disabilities may be included within other risk groups, they are not identified as a separate at-risk group, nor are disaggregated surveillance data available for this cohort. As such, no changes have been made to the report.
6	Lower statistics for the younger age groups might result from not being tested and/or not being reported, due to overall cost and/or	The potential that the burden of COVID-19 in primary care may be underestimated is acknowledged in Chapter 3 where it is noted that

Number	Feedback	Response
	less severe illness. As per the detailed draft presented, the suggestion is that the older population was affected by medical intervention or required ED visits/hospitalisation. At the beginning of COVID-19, people were receiving free antigen/ polymerase chain reaction (PCR) tests and were expected to isolate with follow-up checks, etc., while at a later stage, only healthcare workers were encouraged to test and isolate. As much as the younger population will definitely be less affected, reporting would generally be underestimated.	testing in this setting in particular is likely limited to that required as part of sentinel surveillance and testing of subgroups at high risk of severe outcomes whereby knowledge of the specific pathogen would support clinical decision making (including for example, the need for antiviral therapy). While it is acknowledged that it is possible not all COVID-19 cases are laboratory confirmed and some discharges may not be coded, the notified hospital admission data are considered to be generally representative of the burden on the secondary healthcare system given widespread access to COVID-19 testing in hospital settings and current HSE guidelines in relation to the use of multiplex testing for those presenting with symptoms of acute respiratory tract infection. As such, no changes have been made to the report.
7	A discrepancy was identified between health regions regarding the inclusion criteria for the immunocompromised spring booster programme. This inconsistency is likely to affect reported vaccination uptake and the assessment of programme success. Clarification was sought from the health regions, and conflicting interpretations of the NIAC guidelines were identified, particularly regarding the definition of "older persons/ long-term care facilities," resulting in varying inclusion criteria being applied. Clear, evidence-based guidance is required to navigate vaccination frequency	The report highlights the need for clear communication regarding the HSE COVID-19 vaccination programme, particularly in relation to the groups recommended and eligible for vaccination. This point is stated in Chapter 6 and the Executive summary. As such, no changes have been made to the report. However, it is noted that this point has also been included in the Key findings and Advice, which were drafted subsequent to the public consultation process.

Number	Feedback	Response
	across age groups and, overall, to promote vaccine uptake and maintain a healthy population.	
8	More research and data are definitely needed, especially across the Long-term Care Facilities, Disability Services, or Community-based settings.	The report acknowledges the need for ongoing monitoring of the epidemiology of COVID-19, particularly in at risk groups. Additional text has been added to the Executive summary and Chapter 6 to emphasise this point. Moreover, it is included in the Key findings and Advice, which were drafted subsequent to the public consultation process. The Key findings and Advice, Executive summary and Chapter 6 now include the following text to make this clearer: "Given the continuing uncertainty regarding future disease patterns, variant emergence and long-term health impacts, it will be important to continue the use of national and international surveillance data as well as recommendations from NIAC to inform national COVID-19 vaccination policy."
Céile Care		
9	Overall, Céile Care welcomes the comprehensive and evidence-based approach adopted within the draft assessment and supports the conclusion that publicly funded COVID-19 vaccination should continue to be prioritised for those at highest risk of severe disease. The assessment appropriately recognises that although COVID-19 has transitioned from a pandemic to an endemic disease, it continues to pose a significant risk for older adults, particularly those living in residential care settings.	Thank you for your feedback. The unique characteristics of residents of LTCFs for older adults is acknowledged in the NIAC recommendations, which identify this cohort as a priority group for COVID-19 vaccination. While Irish incidence data specific to those living in LTCFs were lacking, the burden of COVID-19 among those in LTCFs was documented in Section 3.4.3. The following text has been added to Section 3.9 to further highlight that older adults residing in LTCFs may have increased susceptibility to infection and severe disease outcomes: "Older

Number	Feedback	Response
	We would, however, encourage HIQA to give further consideration to the unique characteristics of the nursing home population. Residents of long-term residential care facilities are not simply older adults; many are living with frailty, multiple long-term conditions, cognitive impairment and significant functional dependency. Even relatively mild respiratory infections can result in functional decline, increased care dependency, hospital admission or premature death. The assessment could therefore place greater emphasis on frailty and residential care status as important determinants of vulnerability, in addition to chronological age. Céile Care also recommends that the final assessment explicitly recognises the wider benefits of vaccination within nursing homes. Maintaining high vaccine uptake among eligible residents contributes not only to reducing severe illness but also to limiting outbreaks, avoiding unnecessary hospital admissions, reducing disruption to residents' quality of life and supporting continuity of care within residential services.	adults residing in LTCFs may have increased susceptibility to infection and severe disease outcomes due to a combination of risk factors such as advanced age, frailty, multimorbidity and close living quarters that can contribute to the spread of infection. Frailty at time of hospital admission is associated with adverse outcomes; the HSE's Specialist Geriatric Services Model of Care notes that 35% of 70-year-olds show functional loss at time of discharge compared with their pre-admission status, with this figure increasing to 65% for 90-year-olds. Hospital avoidance in this cohort is therefore noted to be beneficial, with the Model of Care emphasising the importance of interventions that enhance healthy ageing and prevent disease." In the review of clinical effectiveness and safety, data specific to those living in LTCFs were lacking. However, as highlighted in Section 4.4, high levels of protection against severe COVID-19 for this population were previously documented during the early years of the pandemic. As Irish incidence data are lacking, it was not feasible to evaluate the cost effectiveness of COVID-19 vaccination in this cohort. As policy decisions are informed by multiple domains and not just cost effectiveness, this does not preclude a decision to continue to provide COVID-19 vaccination for other subgroups at high risk of severe disease. To further emphasise the risk in this population, the following sentences in Section 6.1.6 were edited to include the italicised text:

Number	Feedback	Response
		"Restricting the groups for which COVID-19 vaccination is funded (based solely on age) may result in an increase in severe acute COVID-19 illness, particularly in populations known to be at increased risk of severe disease (such as, *those living in LTCFs and* those living with immunocompromise) *and those at increased risk of exposure (such as, health and care workers)*.
10	While the assessment appropriately considers clinical effectiveness and cost-effectiveness, greater acknowledgement could be given to the broader system impacts associated with preventing outbreaks in nursing homes. COVID-19 outbreaks continue to place significant pressure on staffing, infection prevention and control measures, resident wellbeing and service capacity. Preventing even relatively small numbers of severe infections within this vulnerable population can have important benefits for both residents and the wider health service.	The report acknowledges that preventing even relatively small numbers of severe infections in vulnerable populations is important and this point is captured in Section 4.4, where it is noted that while some estimates of vaccine effectiveness may appear to be modest, it is important that these effects are viewed in the context of the burden of COVID-19 within the subgroup of interest.
11	We also recommend that future policy continues to support vaccination of healthcare workers caring for vulnerable older people. While the primary purpose of staff vaccination is individual protection, maintaining a healthy workforce also contributes to service resilience, particularly during periods of increased respiratory virus circulation.	The report highlights the NIAC recommendations that access to COVID-19 vaccination should be available for health and care workers who choose to receive a vaccine. While not explicitly discussed in the report, the NIAC recommendations note that the effectiveness of COVID-19 vaccination against infection and onwards transmission is modest and short lived, and timing of SARS-CoV-2 peaks is unpredictable. NIAC therefore considered that there is currently insufficient

Number	Feedback	Response
		evidence to support a strong recommendation for yearly vaccination of all health and care workers. Section 6.1.5 highlights that that an increased burden of incidence of symptomatic or medically attended COVID-19 amongst health and care workers themselves, would augment the burden on the health service if staff are unable to work due to illness.
12	Finally, we recognise that decisions regarding vaccination should continue to be informed by evolving epidemiological evidence. We therefore support HIQA's proposal that vaccination policy should remain under regular review as new evidence emerges regarding disease burden, vaccine effectiveness and circulating variants.	As highlighted in responses above, the report acknowledges the need for ongoing monitoring of the epidemiology of COVID-19, particularly in at risk groups. The Executive summary and Chapter 6 now include the following text to make this clearer: "Given the continuing uncertainty regarding future disease patterns, variant emergence and long-term health impacts, it will be important to continue the use of national and international surveillance data as well as recommendations from NIAC to inform national COVID-19 vaccination policy." This point is also highlighted in the Key points and Advice, which were drafted subsequent to the public consultation process.
13	The report would benefit from a brief section outlining practical considerations for implementing vaccination programmes in residential care settings. This could include issues such as informed consent, accessibility, vaccine delivery within nursing homes and maintaining high uptake among eligible residents.	Given that COVID-19 vaccination programmes have already been successfully implemented in long-term care settings, a section outlining the practical considerations for implementation was not considered necessary for this HTA. As such, no changes have been made to the report.
14	Given the length and technical nature of the report, the inclusion of summary tables or infographics highlighting the principal findings	We appreciate that the full report is long and detailed. To facilitate accessibility, the draft report that was published for the public

Number	Feedback	Response
	and recommendations would improve accessibility for non-technical readers, including healthcare providers, policymakers and members of the public.	consultation included an Executive summary, Plain language summary and Key points for each chapter. Additionally, following the public consultation, a further summary of the Key findings and Advice is included.
15	Where possible, the report should consistently use the terms "long-term residential care", "nursing home" or "designated centre for older persons" throughout the document, rather than alternating terminology. Consistent language would improve readability and ensure clarity for stakeholders across the health and social care sector.	The terminology throughout the report has been reviewed to ensure consistent use of the term 'Long-term care facilities' or its abbreviation (LTCFs), where appropriate. Exceptions include instances where we describe HIPE data which includes data from a number of facilities that sit under the broad term LTCFs (for example, nursing homes) or where the term 'nursing home' is the one used in the specific data source or study cited.
Health Service Executive		
16	This is an important paper which provides an overview of the falling morbidity and mortality from COVID-19 over the past few years, along with the currently available COVID-19 vaccines licensed by the EMA. As limited data is available on the effectiveness of the vaccines separately by manufacturer, it was not possible to provide cost effectiveness by vaccine type, which may be a limitation when looking to procure COVID-19 vaccines in the future, as no preferential recommendation has been made.	As highlighted in Section 3.1.1. of this document, it was not possible to determine if effectiveness differs by vaccine type based on the evidence considered in the review of clinical effectiveness and safety of COVID-19 vaccines (Chapter 4). It is acknowledged however that the majority of the included evidence relates to Omicron-adapted mRNA COVID-19 vaccines. Given this finding, the economic evaluation (Chapter 5) assumed vaccine equivalence for the purpose of modelling. Similarly, in the absence of specific prices for Ireland by brand, dose and formulation, a vaccine cost of €75 per dose was assumed, based on international data. However, those involved with the procurement process will have access to the prices being offered by manufacturers, which should support

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	The paper will provide information for the Department of Health to consider the longer term policy in Ireland for providing COVID-19 vaccines as part of the national vaccine programmes. Given COVID-19 has not established a clear seasonal pattern yet, continued surveillance of COVID-19 variants in circulation in Ireland and beyond to inform national dynamic risk assessment alongside vaccine characteristics will be important to inform annual COVID-19 vaccine policy The COVID-19 vaccine programme policy and funding will need to be flexible to respond quickly if there is an increase in morbidity and/or mortality from COVID-19 in the future, whereby it would be considered a good use of healthcare resources to expand the eligible groups for vaccination to protect them. The Department of Health and HSE should also consider their duty of care to healthcare workers to protect them against COVID-19, which they are exposed to as part of their employment which will also protect health services and support patient care.	selection of a vaccine(s) that represents the best use of healthcare resources, when considering also potential differences in other costs (storage, handling, wastage) due to the product presentation and storage requirements. As noted in earlier responses, the importance of continued use of national and international surveillance data to inform national COVID-19 vaccination policy is highlighted in multiple sections of the report, and is also now included in the Key Points and Advice, which were drafted after the public consultation completed. As per earlier responses, text has been added to the report to highlight that health and care workers are a group at increased risk of exposure to infection. The potential for an increased burden on the health service if staff are unable to work due to illness arising from any increase in incidence of symptomatic or medically attended COVID-19 in these workers is highlighted in Section 6.1.5.
17	Consideration should also be given to the infrastructure required to support the ongoing lifecycle of evidence-informed decision-making, including evidence surveillance, horizon scanning, guideline development, and periodic review of national recommendations. Given the continuing uncertainty regarding future disease patterns, variant emergence and long-term health impacts, a structured governance framework for the timely	As highlighted in responses above, the report acknowledges the need for ongoing monitoring of the epidemiology of COVID-19, particularly in at risk groups. The Executive summary and Chapter 6 now include the following text to make this clearer: "Given the continuing uncertainty regarding future disease patterns, variant emergence and long-term health impacts, it will be important to continue the use of national and international surveillance data as

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	incorporation of new evidence into policy and clinical guidance will be important. This approach would support consistency, transparency and accountability in decision-making while ensuring that recommendations remain aligned with evolving national and international evidence	well as recommendations from NIAC to inform national COVID-19 vaccination policy." This point is also highlighted in the Key points and Advice, which were drafted subsequent to the public consultation process.
Irish Heart Foundation		
18	The Irish Heart Foundation recommends that people with cardiovascular disease (CVD) should be recommended twice-yearly COVID-19 vaccination regardless of age. The current draft recommends annual vaccinations for people with chronic heart disease and reserves twice-yearly vaccination primarily for those aged 80 years and over, residents of long-term care facilities, and people who are immunocompromised. While age is an important risk factor for severe COVID-19, the evidence shows that CVD is also an independent risk factor. People with CVD are consistently more likely to experience severe illness, hospitalisation and mortality following COVID-19 infection than people without CVD. Vaccination recommendations should therefore reflect clinical risk as well as age. Taken together, the evidence indicates that cardiovascular disease should be recognised as a high-risk category in its own right. While individual cardiovascular conditions carry different levels of risk,	The purpose of this HTA is to provide advice to the Department of Health and HSE relating to COVID-19 vaccination in Ireland in the context of updated NIAC recommendations for COVID-19 vaccination (May 2025). While the HTA documents the NIAC recommendations, and presents the findings of the assessment in the context of the population subgroups identified by NIAC and vaccination intervals recommended by NIAC, it was outside the scope of this HTA to revisit these recommendations. While not explicitly discussed in the report, it is noted that the aim of the NIAC COVID-19 vaccination recommendations is to offer year-round protection in those at increased risk of hospitalisation, ICU admission and death from COVID-19 infection. To achieve this aim, vaccination once per year is recommended for most at risk individuals, but for those in whom immunity wanes more quickly, twice yearly vaccination is required. This recommendation is consistent with that adopted by other national immunisation technical advisory groups.

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	they consistently result in poorer COVID-19 outcomes than the general population. Presenting chronic heart disease alongside a broad range of other conditions without acknowledging these differences may give the impression that all conditions carry a similar level of risk. The report would be clearer if it explained how condition-specific evidence was considered and whether differences in risk influenced the vaccination recommendations.	The report notes that the absolute risk of severe disease has continued to fall in all age groups since the end of the emergency phase of the pandemic. While there may be individuals and subgroups that have a higher risk of severe disease than the general population, the highest burden was consistently identified in the oldest old, with a disproportionate burden in those aged 80 years and older. The lack of data specific to other risk groups (residents of LTCFs for older adults, immunocompromised, those with medical conditions associated with a higher risk of severe disease) is noted. Moreover, it is noted that risk groups may overlap, so that an individual may be eligible for vaccination based on multiple criteria. As such, no changes have been made to the report.
19	The report notes that over 90% of patients admitted to intensive care with COVID-19 had at least one underlying medical condition. However, it does not identify which conditions were most commonly associated with severe disease. Including this information would provide a clearer picture of the conditions contributing most to serious COVID-19 outcomes. Irish data are available to address this. The HPSC Annual Report on COVID-19 intensive care unit (ICU) Admissions (2021) found that chronic cardiac disease was the most frequently reported underlying medical condition among people ages 15 years and over admitted to intensive care, affecting 35% of patients. This was higher than chronic respiratory disease (33%) and diabetes mellitus	Thank you for this suggestion. Data reported in this HTA were limited to 2023 onwards to facilitate the inclusion of data most relevant to the current epidemiological situation (that is, data specific to currently circulating variants in a population exhibiting high levels of immunity, recognising the differences in current testing practices compared to those implemented during the early years of the COVID-19 pandemic). As such, the HPSC data considered related to the period 2023 to 2025 (inclusive). The number of ICU admissions decreased year-on year during this period (from 161 to 72). As noted, data for all three years indicated that over 90% of notified ICU admissions each year were in those with one or more underlying medical condition (Chapter 3). Due to small ICU numbers, it was not possible to obtain these data

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	(26%). A national surveillance study using HPSC data on 19,789 confirmed COVID-19 cases in Ireland, published in The Lancet Regional Health Europe (2021), similarly found that chronic heart disease was independently associated with an increased risk of hospitalisation, intensive care admissions and mortality.	stratified by age and by underlying medical condition. The report notes that this observed COVID-19-related morbidity in those with underlying medical conditions is reflected in the international literature. As such, no updates were made to the report.
20	Multimorbidity is also an important consideration when assessing vaccination policy. TILDA's 2020 report on high-risk groups for COVID-19 found that an estimated 52% of adults aged over 50 have hypertension, while 55% live with cardiovascular disease, including hypertension, heart attack, angina or heart failure. The report also estimated that 638,000 adults aged over 50 were living with three or more chronic conditions. This is particularly relevant because many people living with CVD also have other long-term conditions such as hypertension, diabetes or obesity. As a result, cardiovascular disease frequently occurs as part of a broader pattern of multimorbidity that further increases the risk of severe COVID-19. This should be considered when defining and prioritising high-risk groups for vaccination. Evidence from the UK supports these findings. The British Heart Foundation has reported that people living with cardiovascular disease face around 3.9 times the risk of severe COVID-19 and 2.7 times the risk of death compared with people without cardiovascular disease. It also cites a UK study of more than 20,000 hospitalised COVID-19 patients in which chronic cardiac	The report acknowledges that multimorbidity is an important consideration in vaccination policy and that those with underlying medical conditions comprises a broad range of medical conditions whose risk of COVID-19 disease may differ. While it is outside the remit of this HTA to define high-risk groups that should be prioritised for vaccination, the burden of COVID-19 in those living with multimorbidity has been reported in Chapter 3 and Chapter 6. Additionally, the following text has been added to Section 4.4: "In addition, it was not possible to compare differences in risk by individual medical condition as this was outside of the scope of the HTA. Only one European case-control study reported results by type of chronic health condition (Table B.13). It is important to acknowledge that those with underlying medical conditions encompasses a broad range of different conditions whose risk of COVID-19 disease may differ."

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	disease was the most commonly recorded underlying medical condition. Together, the Irish and international evidence demonstrates that cardiovascular disease is one of the most common and clinically significant underlying conditions associated with severe COVID-19. The epidemiology section would therefore be strengthened by presenting more condition-specific data to illustrate the disproportionate burden experienced by people living with cardiovascular disease.	
21	The assessment of vaccination for people with underlying medical conditions, including chronic heart disease, only considered annual vaccination. Restricting the assessment to annual vaccination means the HTA does not evaluate whether a second vaccine dose each year could provide additional health benefits for people living with cardiovascular disease. As a result, the assessment may underestimate both the clinical benefits and the potential cost-effectiveness of a more frequent vaccination schedule for this high-risk group. The Irish Heart Foundation therefore recommends that both the clinical effectiveness review and the economic evaluation explicitly assess a twice-yearly COVID-19 vaccination strategy for people living with cardiovascular disease, regardless of age.	As described previously, the purpose of this HTA was to provide advice to the Department of Health and HSE relating to COVID-19 vaccination in Ireland, in the context of the NIAC recommendations (May 2025). NIAC currently recommends that those aged 6 months to 59 years with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death are recommended to receive a COVID-19 vaccine once per year, not twice-yearly. While the evidence in the clinical effectiveness review (Chapter 4) presented the data by subgroup of interest, it did not consider specific intervals for booster vaccination or the impact of repeated vaccinations. As such, the findings reported describe the protection provided by a single vaccine dose, albeit acknowledging that the majority of those vaccinated likely had some existing protection due to prior infection or vaccination. Estimates of effect were noted to be typically higher for outcomes related to severe disease

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		compared with medically attended or symptomatic infection outcomes. Protection against hospitalisation and mortality was observed up to five to six months post-vaccination among older adults, those living with immunocompromise, those living with underlying medical conditions, and those aged 18 to 59 years in the general population. However, there was evidence of waning protection, particularly over longer follow-up periods. Table B.13 in Appendix B includes the single case control study which reported COVID-19 vaccine effectiveness against hospitalisation for those with cardiovascular disease. Due to the lack of data to characterise the burden of disease in other risk-based subgroups, the cost-effectiveness analysis was limited to the age-based subgroups aged 60 years and older, using NIAC recommended vaccination frequencies. As such, no cost effectiveness evidence is presented specific to people living with cardiovascular disease, regardless of vaccination frequency. As such, no changes have been made to the report.
22	More broadly, future modelling should consider important high-risk medical conditions separately where evidence demonstrates substantially different levels of clinical risk. Grouping all chronic conditions together may obscure important differences in disease burden, vaccine benefit and cost-effectiveness between patient groups.	Thank you for your suggestion. This is outside the scope of this HTA and as such, no updates have been made to the report.

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23	The HTA acknowledges that its economic modelling was based primarily on age groups rather than individual medical conditions and notes that this should not prevent vaccination recommendations being made for other high-risk groups. This is an important limitation and should be given greater weight when interpreting the findings.	The Executive summary, Key points for Chapter 6 and Section 6.1.6, state that a decision to restrict access to funded COVID-19 vaccination to those at the highest risk of severe disease and or on the basis of cost effectiveness, could result in a potential increase in the incidence of notified cases, notified hospital admissions and mortality among non-eligible individuals. It is also explicitly stated that this is particularly the case if eligibility is based solely on age-based criteria, rather than also considering other groups known to be at increased risk of severe disease. The Executive summary, Key points for Chapter 6 and Section 6.1.6 also state that, due to lack of data, the assessment of cost effectiveness was limited to age-based cohorts and it was not feasible to evaluate the cost effectiveness of vaccinating other individuals at high risk of severe disease. It is noted that this does not preclude a decision on whether to continue to provide COVID-19 vaccination for such individuals, given that policy decisions are informed by multiple domains and not just cost effectiveness. As such, no changes have been made to the report.
24	Providing additional information on the composition of the Expert Advisory Group, including the expertise and stakeholder perspectives represented, would improve transparency and help readers understand the breadth of expertise that informed the assessment.	Thank you for your feedback. Information regarding the professional roles held by each Expert Advisory Group (EAG) member, including the stakeholder organisation they represent, are already detailed in the Acknowledgements section. As such, no changes have been made to the report.
Irish Nurses and Midwives Organisation		

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25	Protecting nurses and midwives from COVID-19 remains essential to maintaining a resilient health service. Given their continued exposure to infectious diseases across acute, community and long-term care settings, the Irish Nurses and Midwives Organisation (INMO) recommends that nurses and midwives are explicitly recognised as a priority cohort within the 2027/2028 vaccination programme. COVID-19 vaccination should remain free of charge and fully integrated into occupational health programmes, with timely workplace-based access during working hours to maximise uptake.	The report describes current NIAC recommendations on COVID-19 vaccination in Ireland, which include access to vaccination for health and care workers without additional risk factors for severe disease for whom vaccination is no longer specifically recommended, but who wish to receive the vaccine. The Executive summary, Key points for Chapter 6 and Section 6.1.6, highlight that a decision to restrict access to funded COVID-19 vaccination to those at the highest risk of severe disease and or on the basis of cost effectiveness include a potential increase in the incidence of notified cases, notified hospital admissions and mortality among non-eligible individuals. Health and care workers are recognised as a group at increased risk of exposure to infection. As such, the following text has been edited to include the following italicised text: "This is particularly the case if eligibility is based solely on age-based criteria, rather than also considering other groups known to be at increased risk of severe disease (such as those residing in long term care facilities for older adults or those living with immunocompromise), *and those at increased risk of exposure (such as, health and care workers)*."
26	Vaccination should form part of a broader strategy to reduce the impact of long COVID. While evidence continues to evolve, vaccination may reduce the risk of persistent symptoms following infection. However, it must be complemented by the formal recognition of long COVID as a work-related occupational illness, access to specialist assessment and rehabilitation, and appropriate workplace accommodations. The INMO also recommends the	Thank you for your feedback. As reported in the Executive summary, Key points of Chapter 4 and Section 4.4, there were limited data on the effectiveness of Omicron-adapted vaccines against post-acute sequelae associated with long COVID and the results from the single study that report on this are presented. It has also been noted in Section 4.4 and Section 6.1.3 that previous systematic reviews have reported a protective effect of vaccination

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	establishment of a dedicated Occupational Illness Scheme for healthcare workers living with Long COVID, developed in partnership with health sector unions and aligned with existing public service sick leave and absence frameworks	against long COVID, but it is acknowledged that the interpretation of long COVID studies is complicated since study populations exhibit differing inclusion criteria, participant demographics and diagnostic criteria. While a recommendation to establish a dedicated Occupational Illness Scheme for healthcare workers living with long COVID is outside the scope of this HTA, it is noted in Section 3.6.3 of the report that the model of care for long COVID is currently under review by the HSE. As such, no changes have been made to the report.
Irish Pharmacy Union		
27	The importance of ensuring the public can access robust information both in relation to the vaccine and the availability of vaccination services cannot be underestimated. As a result, the Irish Pharmacy Union (IPU) believes that patient access and public understanding of the disease and vaccination must remain at the centre of any future strategy. If eligibility for free vaccination is narrowed, clear and timely communication will be essential. Patients who remain eligible must be made aware of the benefits of vaccination, while those who may no longer qualify should receive clear information about this and alternative options. Ensuring that information is provided in an easy to understand and health literacy friendly format is paramount.	The need for clear communication regarding the HSE COVID-19 vaccination programme, particularly in relation to the groups recommended and eligible for vaccination is emphasised in the report. This point is stated in the Executive summary and Chapter 6 and as such, no updates have been made to the report. It is noted that this information has also been included in the Key findings and Advice, which were drafted subsequent to the public consultation process.

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28	The assessment also highlights the importance of cost effectiveness in determining future vaccination policy. We welcome the opportunity to move towards a single-dose pre-filled syringe that does not require ultra-low temperature storage, similar to that used within the Influenza vaccination programme. This would offer significant advantages compared with the current multi-dose vial presentation, including greater flexibility when providing a vaccination service, allow for opportunistic vaccination, reduce waste and potentially costs. The transport, storage and management of these vaccines would also be streamlined.	Thank you for this comment. The organisational efficiencies associated with refrigerate only, single dose pre-filled syringe formulations (packaged in a single unit pack size) are already discussed in Section 6.1.5. As such, no updates have been made to the report.
Moderna		
29	The health and economic consequences of SARS-CoV-2 infection extend beyond the acute COVID-19 outcomes currently represented within the economic evaluation. Consequently, economic assessments that primarily quantify vaccination benefits through reductions in acute COVID-19 events may underestimate the overall clinical and economic value of vaccination by not explicitly accounting for prevention of infection-mediated chronic disease onset, chronic disease progression, exacerbations of existing disease, and their associated downstream healthcare utilization. This limitation applies not only to the modelled population of adults aged ≥60 years, in whom these downstream consequences are not explicitly represented, but also to younger individuals aged ≥12 years at increased risk of severe COVID-19,	The economic assessment was conducted from the payer perspective which by definition does not include incorporation of productivity losses. As described in the limitations, economic modelling exercises are by their nature limited by the choice of model, underlying assumptions and availability of data, including both costs and utilities, to populate the model. Specifically, there is a lack of robust data in relation to the incidence of COVID-19-mediated chronic disease onset, chronic disease progression, exacerbations of existing disease and their associated downstream healthcare utilisation.

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	for whom these potential health and economic benefits are not evaluated because they fall outside the scope of the analysis.	In Chapter 5, it is acknowledged that by limiting the economic model to notified cases of COVID-19 only, the full disutility of COVID-19 is not captured in the analysis. As such, no updates have been made to the report.
30	The economic evaluation may underestimate the value of mRNA-1283 by not considering emerging evidence that COVID-19 vaccines may differ in their effectiveness against clinically important outcomes, particularly hospitalization, in older and medically vulnerable populations.	Thank you for the list of references and details provided in relation to the mRNA-1283 vaccine. Of note, the PICOS criteria (Table B.1) for the clinical effectiveness review did not include immunogenicity outcomes and moreover were limited to studies that provided direct comparison of an intervention and control group. Additionally, as is usual in HTA, studies eligible for inclusion were limited to those that provide published, peer-reviewed data. In the interest of efficiency (and as outlined in the protocol), a decision was taken to base the review on evidence from a high-quality, recently published systematic review of the clinical effectiveness and safety of COVID-19 vaccines, supplemented by additional searches where data for subgroups of interest were lacking. Restricting the review to a published systematic review had the net effect of excluding more recent effectiveness data, including for newer COVID-19 technologies authorised since 2025. This limitation is explicitly acknowledged in Chapter 4. It is acknowledged in Section 6.1.6 that the evidence identified in Chapter 3 on the burden of disease and Chapter 4 on the effectiveness and safety of COVID-19 vaccination were collected at

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		a specific point in time, and as such, the conclusions could change over time as the evidence base increases. The need for continued use of surveillance and outcome data to inform the COVID-19 vaccination policy are emphasised in the report As such, no updates have been made to the report.
31	The pharmacovigilance section should be updated to reflect the current EMA SmPC, which now includes Spikevax JN.1 and LP.8.1 formulations rather than XBB.1.5 as the latest antigenically updated vaccine. Furthermore, the statement that the SmPC does not include clinical data relating to the safety profile of JN.1 may be misleading. The current EMA SmPC adopts a platform-based safety assessment, incorporating clinical and post-marketing safety evidence across original and variant-updated Spikevax formulations, including BA.1, BA.4-5 and XBB.1.5, and concludes that there are no clinically meaningful differences in reactogenicity between formulations. The regulatory assessment therefore supports extrapolation of the established Spikevax safety profile to the current JN.1 formulation, rather than implying an absence of relevant safety evidence.	The SmPC for Spikevax was last updated on 6 August 2026, subsequent to the draft report being published for public consultation. In this version, Section 4.8 notes the undesirable effects associated with vaccination, stating that the reactogenicity profile of Spikevax XBB.1.5 was similar to that of earlier Spikevax vaccines. The following text has been added to Section 4.3.5: "Section 4.8 of the SmPC notes the increased risk of myocarditis after vaccination with the Spikevax® original strain vaccine, commenting that the increased risk is highest in younger males. Specifically, the results of two European pharmacoepidemiological studies reporting on excess risk are highlighted. One study found there were 1.32 (95% confidence interval (CI): 1.30 to 1.33) extra cases of myocarditis in 12- to 29-year-old males per 10,000 compared with unexposed persons seven days after a second dose of Spikevax® original vaccine. The second study found 1.88 (95% CI: 0.96 to 2.80) extra cases of myocarditis among 16- to 24-year-old males per 10,000 compared with unexposed persons 28 days after a second dose of Spikevax® original vaccine."

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		Additionally, we have removed the following sentence from this section: "The SmPC does not include mention of clinical data relating to the safety profile of JN.1 or KP.2 Spikevax vaccine formulations."
32	Moderna would like to reiterate that mCOMBRIAX is a combination vaccine providing protection against both COVID-19 and seasonal influenza in a single injection. Consequently, its value extends beyond that of a stand-alone COVID-19 vaccine and should therefore be considered within an HTA framework that captures the full public health and health system impact of combination vaccination. In addition to protection against COVID-19, the assessment should consider the potential impact of mCOMBRIAX on seasonal influenza outcomes as well as broader health system benefits.	Thank you for providing this information. This formulation was outside the scope of this HTA. As such, no updates have been made to the report.
33	Moderna respectfully requests clarification that mCOMBRIAX is a combination vaccine rather than a co-administration strategy.	mCOMBRIAX is described as a 'combined vaccine' or 'combination vaccine' in the Executive summary, Key points of Chapter 2, Section 2.3.3, Table 2.1, Section 2.6, Section 4.3.5 and Section 6.1.5. As such, no updates have been made to the report.
34	Moderna recommends that the discussion acknowledges the potential implications of the first licensed seasonal influenza and COVID-19 combination vaccine.	Further discussion of the potential implications of the first licensed seasonal influenza and COVID-19 combination vaccine is outside the scope of Chapter 2. The potential organisational efficiencies associated with use of a combined vaccine such as mCOMBRIAX have already been acknowledged in Section 6.1.5. As such, no updates have been made to the report.

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35	The current draft states: "This section of the SmPC makes no comment as to the severity of the reactions." The EMA mCOMBRIAX webpage states the following: "Although side effects were more common with mCOMBRIAX than with the comparator combinations, they were generally mild and short-lived."	Thank you. The following text has been removed: "This section of the SmPC makes no comment as to the severity of the reactions." This section now reads: "According to Section 2 of the EMA SmPC for the Quadrivalent Influenza and COVID-19 mRNA Combination Vaccine (mCombriax®), the vaccine composition includes SARS-CoV-2 Omicron XBB.1.5. According to Section 4.8 of the EMA SmPC, the most commonly reported adverse events included injection site pain, fatigue, myalgia, headache, arthralgia, chills, lymphadenopathy, nausea or vomiting, and pyrexia (Table B.49). These reactions had a median onset of two days post-vaccination and a median duration of three days."
36	Moderna respectfully requests clarification that the health economic evaluation presented in the current assessment is not directly applicable to mCOMBRIAX.	As already described in Section 5.2.6, the vaccine effectiveness parameter used in the economic model was informed by the evidence included in Chapter 4. Moreover, Section 4.4 explicitly states that the evidence reported in Chapter 4 does not include effectiveness data for newer COVID-19 technologies (such as, mCombriax® or mNexspike®). As such, no updates have been made to the report.
37	Moderna respectfully requests that the discussion of staff-related resources considers not only the use of a prefilled syringe but also the operational efficiencies associated with administering a combination vaccine.	Thank you for this suggestion. As per our response above, the organisational efficiencies associated with use of a combined vaccine such as mCOMBRIAX have already been acknowledged in Section 6.1.5. As such, no updates have been made to the report.
Nursing Homes Ireland		

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38	The information set out in the HTA is comprehensive and adequately provides a complete picture of COVID-19 and the myriad of factors that exist in relation to the ongoing provision of COVID-19 vaccination availability, administration and costs in Ireland. It is good to see that the full nursing home population is considered in the HTA and options are included in relation to all that reside in long term residential care as a distinct group. However, ageist perspectives are evident in parts particularly when the various costs of the vaccine are presented. Costs appear to take precedence over the proven positive impact on the health and wellbeing of older people who may benefit from ongoing administration of the vaccine twice a year.	Throughout the report it is acknowledged that policy decisions are informed by multiple domains and not just cost-effectiveness. It is also acknowledged within the report that although continued funding of a COVID-19 vaccination programme for a larger cohort improves equity of access, policy makers have a duty to ensure equitable allocation of resources. Decisions about healthcare distribution should ensure that resources are allocated or reallocated fairly and that the opportunity costs (the value of the next best alternative forgone) of investments are considered. Reconsideration of the groups for whom COVID-19 vaccination is funded is therefore appropriate at this time given the evidence of a decline in the burden of disease, and the potential for some of the current funding to be diverted to other programmes or interventions that could deliver a larger population health gain. Funding interventions that are not cost effective could create issues of justice and equity with respect to a fair distribution of benefits and burdens. To highlight this point, we have also included the following text in the Executive summary and Chapter 6: "This is particularly important in the context of a finite healthcare budget and increasing demands for services provided." This text was also included in the Key findings and Advice, which were drafted subsequent to the public consultation process.
39	The HTA is incredibly long and detailed and though it is well written, sectioned and accessible in that an easy read section is included, the full HTA it is very off putting to look at a document this long.	As per our response above, we appreciate that the full report is long and detailed. To facilitate accessibility, the draft report that was published for the public consultation included an Executive summary, Plain language summary and Key points for each

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		chapter. Additionally, the Key findings are further summarised in a new section drafted following the public consultation, which includes also HIQAs advice.
Pfizer		
40	Update the report to acknowledge Comirnaty's® new refrigerated single-dose glass pre-filled syringe presentation for individuals aged 12 years and older from 2027. In parallel, following EMA approval of paediatric dose harmonisation, the previous 3mcg formulation for children aged 6 months to <5 years has been harmonised to a 10mcg formulation for all individuals aged 6 months to 11 years. This harmonised paediatric formulation is expected to become available from September 2026 onwards and will be supplied in frozen/ultra-low temperature single-dose and/or multi-dose vial presentations.	The operational considerations discussed in Section 6.1.5 are based on the presentations of Comirnaty® currently available as part of the HSE COVID-19 Vaccination Programme. Table 2.1, Table 2.2, Appendix A.1 and Section 6.1.5 included information relating to the new Comirnaty® 30 mcg/dose pre-filled syringe presentation. Text has now been added to Section 6.1.5 to advise that Comirnaty® 30mcg/0.3mL will be available from 2027 onwards. Future organisational considerations will depend on the presentation type procured by the National Immunisation Office. Table 2.1, Table 2.3 and Appendix A.1 in the draft report include a description of the 10mcg formulation for all individuals aged 6 months to 11 years. Text has now been added to Section 6.1.5 to advise that the Comirnaty® harmonised paediatric formulation for all individuals aged 6 months to 11 years will be available from September 2026 onwards.
41	The evidence base of vaccine effectiveness is weighted heavily towards data evaluating mRNA COVID-19 vaccination. The approach by HIQA in using vaccine effectiveness derived primarily from mRNA vaccines and generalising across all vaccine types introduces significant uncertainty into the HTA and resulting cost-	Chapter 4 acknowledges that the majority of the included evidence relates to Omicron-adapted mRNA COVID-19 vaccines. As studies did not typically report findings disaggregated by vaccine type, it was not possible to determine if effectiveness differs by vaccine type based on the included evidence. These points are highlighted

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	effectiveness estimates. It is more robust and appropriate that cost-effectiveness findings are attributed to the health technology on which the evidence rests (Sections 5–6). Furthermore, the report should state in its conclusions and any resulting recommendations, that the demonstrated cost-effectiveness evidenced from mRNA vaccination and cannot be generalised to non-mRNA platforms, for which effectiveness presented in the HTA is limited.	in the executive summary and additionally in the Key findings and Advice which were drafted subsequent to the public consultation. The assumption of equivalence across vaccine types for the purposes of modelling has now been made more explicit in the report. Section 5.2.6 now includes the following text: 'Based on the evidence included in Chapter 4, it was not possible to determine if effectiveness against COVID-19 differs by vaccine type. As such, vaccine equivalence was assumed for the purpose of modelling'.
42	Add a statement to the conclusions acknowledging that recent European real-world data continues to show high effectiveness of BNT162b2 against COVID-19-related hospitalisation and death, and that the currently reported pooled base-case VE can understate the current actual VE.	As highlighted in responses above, Chapter 4 notes that the majority of participants in the included studies received mRNA vaccines. As such, the estimates are relevant to the mRNA vaccine, BNT162b2. Chapter 4 notes that estimates of effect were higher against severe disease (for example, hospitalisation and mortality), but that there was evidence of waning protection, particularly over longer follow-up periods. This waning protection is challenging given the noted lack of seasonality with COVID-19, and the potential that the period of maximal protection does not coincide with peaks in COVID-19 activity. The model parameter estimates used in the economic evaluation (Chapter 5) represent average annual vaccine effectiveness in the cohorts of interest, assuming currently recommended intervals (once or twice yearly), rather than the initial levels of protection that may be achieved.

Number	Feedback	Response
		As such, no change was made to the report. The need for continued use of surveillance and outcome data to inform the COVID-19 vaccination policy are emphasised in the report.
43	Updates to the methods and conclusions recognising that the absence of a subgroup cost effectiveness analysis reflects data and methodology limitations and is not due to the lack of vaccine effectiveness in these groups. Recommendations for these groups should be considered with caution, ensuring they are not adversely driven by the absence of cost-effectiveness modelling.	The HTA highlights that, due to a lack of data, it was not feasible to conduct a cost effectiveness analysis for some subgroups. It is now clarified within the report that the lack of data cited refers to a lack of Irish epidemiological data. Considering cohorts for which an assessment of cost effectiveness was not considered feasible, Chapter 4 highlights that protection against hospitalisation and mortality was observed up to five to six months post-vaccination in those living with immunocompromise, those living with underlying medical conditions, and those aged 18 to 59 years in the general population. It also notes that while no evidence was identified regarding the effectiveness of Omicron-adapted vaccines for those residing in LTCFs, high levels of protection against severe disease have been documented for this population during the early years of the pandemic. Similarly, it is highlighted that previous evidence of effectiveness supports COVID-19 vaccination during pregnancy to prevent severe disease and adverse maternal and child outcomes. Chapter 6 highlights that policy decisions are informed by multiple domains and not just cost effectiveness. As such, no changes were made to the report. However, these points are further noted in the Key findings and

Number	Feedback	Response
		Advice section, which was drafted subsequent to the public consultation process.
Sanofi		
44	The draft report further suggests that operational efficiencies could be achieved through future procurement of refrigerated, ready-to-use, single-dose products. Sanofi supports this conclusion. Vaccines supplied at standard refrigerator temperatures (2°C to 8°C) and presented in single-dose formats have the potential to reduce cold-chain burden, minimise preparation requirements, and lower wastage compared with multidose presentations. Nuvaxovid is supplied at standard refrigerator temperatures (2°C to 8°C) in single-dose presentations and therefore falls within the profile the report describes.	Section 6.1.5 which describes organisational considerations identifies Nuvaxovid® as an example of a product that is available in single-dose presentations. Additional text has been added to this section to identify that it is also an example of a refrigerate only product.
45	The model applies a uniform administration cost and does not include explicit assumptions relating to product-specific handling requirements or vaccine wastage, despite the report's discussion of these factors and their impact on programme delivery. We therefore suggest that HIQA acknowledge more clearly that operational costs, cold-chain requirements, preparation time, and wastage may differ between vaccine presentations and that these factors are not fully captured within the current cost-effectiveness model.	The cost of vaccine administration was based on the current negotiated payments to primary care contractors for COVID-19 vaccine administration, which does not differ by vaccine type or presentation. In the absence of publicly available list prices for the various authorised COVID-19 vaccines, the price was assumed based on international data. The following text has been added to Section 5.4.2, acknowledging that there may be different costs for pick and pack depending on the vaccine form: "The vaccination programme costs, including vaccine price, pick and pack, and cold storage and distribution, presented in Table 5.9, were informed by discussions with the

Number	Feedback	Response
		National Immunisation Office. As these costs may differ between different vaccine forms (such as multidose vials, single dose vials, single dose pre-filled syringes, and those requiring reconstitution and or thawing), the vaccination programme costs used in the model represent estimated average costs."
46	We also note that some relevant observational effectiveness evidence appears not to have been included within the literature reviewed for clinical effectiveness, including the large real-world study by Gwak et al. involving more than 100,000 recipients of Nuvaxovid (Gwak et al., Vaccine, 2024). Given the report's discussion regarding sample size limitations in the evidence base, consideration of this study may be informative.	The study Gwak et al. was not eligible for inclusion in the review of clinical effectiveness as the analysis related to vaccine recipients between February and December 2022. Studies were only eligible for inclusion in the review of clinical effectiveness if they included disaggregated data for 2023 onwards (to facilitate the inclusion of data relevant to the current situation, that is, data specific to currently circulating variants). As such, no updates have been made to the report.
47	Furthermore, the economic model applies a single pooled effectiveness estimate and a single reactogenicity input across all vaccine products. As a result, the model effectively evaluates the value of vaccination as a public health intervention rather than the value of any specific vaccine product. We suggest that the final report explicitly state that the cost-effectiveness findings apply to a generic EMA-authorised COVID-19 vaccine matching the modelled characteristics rather than to any individual vaccine platform.	As highlighted in the responses above, the assumption of equivalence across vaccine type for the purposes of modelling has now been made more explicit in the report. Section 5.2.6 now includes the following text: "Based on the evidence included in Chapter 4, it was not possible to determine if effectiveness against COVID-19 differs by vaccine type. As such, vaccine equivalence was assumed for the purpose of modelling."
48	In addition to traditional clinical outcomes, patient-reported outcomes may provide useful complementary information regarding	While the review of the safety and effectiveness of COVID-19 vaccination did not include patient-reported outcome data, health

Number	Feedback	Response
	the broader impact of vaccination. Studies such as SHIELD have reported reduced impact on work and daily activities among healthcare workers and first responders following vaccination, while more recent comparative patient-reported outcome research has demonstrated differences in the impact of post-vaccination reactogenicity on day-to-day functioning. Such evidence may be particularly relevant when considering programme acceptability and vaccine uptake.	benefits are expressed in terms of QALYs gained in the economic model. QALYs reflect the impact of an intervention on patients' quality and length of life, estimated using self-reported utilities or health-related quality of life. Section 5.2 provides detail on the included parameter values for quality of life estimates incorporated in the economic model (symptomatic infection, ED attendance, hospitalisation, mortality, post-acute rehabilitation care, long COVID) and the evidence underpinning these estimates. A QALY loss was also incorporated for vaccine recipients who experience Grade 3 solicited adverse reactions. No QALY loss was included for Grade 1 or 2 solicited adverse events given evidence from the safety review (Chapter 4) that these are typically mild and short-lived. The economic assessment was conducted from the payer perspective which by definition does not include incorporation of productivity losses. It is recognised that factors such as reactogenicity and adverse events may impact acceptability and uptake. Chapter 4 highlights that serious adverse events are rare and that local and systemic effects are common, these are typically mild and short-lived. Acceptability of post-vaccination reactogenicity is likely influenced by the individual's relative potential for benefit and harm. As outlined in the report, the NIAC recommendations prioritise those at highest risk of severe disease. Given their higher risk, the benefit harm balance will differ for these groups compared with, for example, those in the general population. Chapter 6 highlights the importance of targeted outreach to population groups that are

Number	Feedback	Response
		eligible for vaccination to support understanding of their ongoing risk of severe disease due to COVID-19 and the potential for this to be mitigated by remaining up-to-date with their vaccine recommendations. Health and care workers are not identified as a priority group for vaccination, rather NIAC recommends that the vaccine should be available for individuals who wish to avail of it. By presenting for vaccination, these individuals indicate the acceptability of vaccination.
49	The model relies on notified COVID-19 case data despite widespread reductions in testing compared with earlier phases of the pandemic. This may lead to underestimation of disease burden and therefore of the benefits associated with prevention. We note that HIQA applied a multiplier of four to notified case data in its recent health technology assessment of RSV immunisation to estimate the incidence of medically attended cases, and that the present draft draws on that same assessment for its estimate of GP visit frequency. In the RSV assessment, that frequency was applied per medically attended case following the multiplier adjustment, whereas in the present model the same values are applied per notified case without adjustment. A consistent approach, or a clearly labelled scenario analysis applying a range of multipliers to non-hospitalised notified cases, may assist in bounding this uncertainty.	Thank you for this feedback. As discussed in Section 5.4.2, limiting the model to notified cases of COVID-19 may underestimate the total burden. A multiplier was not considered appropriate in this HTA for several reasons. These included differences in disease presentation and the greater potential that those at highest risk of severe outcomes would be tested given the availability of a specific antiviral therapy for this indication (Paxlovid®). As such, notified cases should represent the majority of cases that require medical care and thereby most of the impact of COVID-19 on healthcare resources and quality of life. Also discussed in Section 5.4.2 are the limitations of using a static model. The static model, using notified COVID-19 case data, is the most appropriate model choice in this instance since a dynamic transmission model requires calibration, that is, identification of the model parameter values that align model outputs with empirical data. In the absence of observed data, calibration can result in erroneous parameter values leading to uncertainty around the validity of the model results. Given the incomplete data on

Number	Feedback	Response
		population-level incidence of COVID-19 in Ireland (beyond the notified case data), using a dynamic transmission model that is calibrated to estimated population level incidence of COVID-19 would potentially undermine the validity of the results of the economic evaluation.
50	Cost offsets were not estimated for Strategies 3 to 8, meaning six of the eight strategies under assessment are presented as gross cost with no averted healthcare costs netted off. By comparison, cost offsets for Strategy 1 amounted to 28% of total costs incurred. Readers comparing strategies across the report may therefore be comparing net and gross estimates without this being apparent.	The omission of cost offsets for the budget impact analysis for specific populations is highlighted in Sections 5.2.4 and 5.3.3. A note has been added to Figure 5.11 to highlight that data did not allow for the inclusion of costs averted for Strategies 3 to 8. A cost-effectiveness analysis was not conducted for these population groups, therefore, this has no impact on the incremental cost-effectiveness ratio.
51	The report recognises that a substantial proportion of the burden associated with long COVID relates to productivity losses and broader societal impacts. These effects are not included within the current payer-perspective analysis, notwithstanding their importance to patients, employers, and society.	The model was conducted from the payer perspective only, so productivity effects were not included. The cost-effectiveness evaluation was limited to two age-based strategies, which considered those aged 80 years and older and all those aged 60 years and older compared with no vaccination. Given levels of paid employment decrease with increasing age in those aged 60 years and older, it is considered unlikely that the findings from a societal perspective would differ substantially from those presented from the payer perspective.
52	The draft HTA highlights that cost-effectiveness estimates are highly sensitive to vaccine acquisition costs and that future	Thank you for this feedback.

Number	Feedback	Response
	procurement decisions will play an important role in determining value for money. Sanofi agrees that vaccine price will remain a critical determinant of economic value. As current European procurement arrangements evolve and future tendering opportunities emerge, competition between vaccine suppliers may support the delivery of cost-effective vaccination programmes in Ireland. Sanofi recommends that any future cost-effectiveness thresholds be considered in terms of the total cost per administered dose, including vaccine acquisition, storage, distribution, preparation, administration, and wastage, rather than acquisition cost alone.	As highlighted in earlier responses, in the absence of specific prices for Ireland by COVID-19 vaccine brand, dose and formulation, an average vaccine cost of €75 per dose was assumed in the economic evaluation, based on international data. Section 6.1.5 of the report notes the uncertainty regarding potential differences in the price per dose for vaccines procured as single dose versus multidose formulations and or for those supplied by the manufacturer frozen versus those supplied as refrigeration only. As such, the report highlights the importance of factoring in potential differences in storage and handling costs, wastage and staff time between the differing vaccine formats when comparing submitted prices as part of any competitive tender. However, those involved with the procurement process will have access to the prices being offered by manufacturers, which should support selection of a vaccine(s) that represents the best use of healthcare resources, when considering also potential differences in other costs (storage, handling, wastage) due to the product presentation and storage requirements. As such, no updates have been made to the report.

*Feedback has been slightly amended to correct for minor grammatical errors and or typos.

3.2 Changes to the report from the consultation process

The following changes were made to the draft report in response to comments and feedback received through the consultation process:

- Table 2.5, the text underneath Table 2.5 (Section 2.3.4) and Table A.2 (Appendices) have been edited to note the availability of Bimervax® as a refrigerated only single dose pre-filled syringe and its storage requirements.
- Section 6.1.5 has been edited to state that both protein subunit COVID-19 vaccines (currently authorised for use in the EU) are available as single dose refrigerate only pre-filled syringes.
- The Executive summary and Chapter 6 of the report have been edited to further highlight the importance of national COVID-19 vaccination policy being informed by national and international surveillance data as well as recommendations from NIAC.
- Text has been added to Section 3.9 to further highlight that older adults residing in long-term care facilities may have increased susceptibility to infection and severe disease outcomes.
- Text has been added to the Executive summary, Key points for Chapter 6 and Section 6.1.6 to note that restricting the groups for which COVID-19 vaccination is funded (based solely on age) may result in an increase in severe acute COVID-19 illness, in populations such as health and care workers, who are at increased risk of exposure.
- We have reviewed the terminology throughout the report to more consistently use the term "Long-term care facilities" where appropriate.
- Text has been added to Section 4.4 to explicitly state that those with underlying medical conditions comprise a broad range of medical conditions whose risk of COVID-19 disease may differ.
- Section 4.3.5 has been edited to reflect the current pharmacovigilance data as reported in the SmPC for Spikevax®, Comirnaty® and mCombriax®.
- Text has been added to the Executive summary and Chapter 6 to further highlight the importance of funding interventions being cost effective in the context of a finite healthcare budget and increasing demands for services provided.
- Text has now been added to Section 6.1.5 to advise that the Comirnaty® 30mcg/0.3mL refrigerated single-dose glass pre-filled syringe presentation will be available from 2027 onwards and the Comirnaty® harmonised paediatric formulation for all individuals aged 6 months to 11 years from September 2026 onwards.
- The assumption of equivalence across vaccine types for the purposes of modelling has been explicitly stated in Section 5.2.6 of the report.

- Text has been added to Section 5.4.2, acknowledging that there may be different costs for pick and pack depending on the vaccine form and as a result, the inputs used in the model represent average costs.
- A note has been added to Figure 5.11 to highlight that data did not allow for the inclusion of costs averted for Strategies 3 to 8.

In line with standard processes, subsequent to the public consultation, a section detailing the Key Findings and Advice to the Minister for Health and the HSE has been drafted, which takes consideration of the feedback received through this process.

Appendix A – copy of submission feedback form

Health technology assessment of COVID-19 vaccination in Ireland.

Public Consultation feedback form

The Health Information and Quality Authority (HIQA) is holding a six-week public consultation to give people an opportunity to provide feedback on the draft health technology assessment of COVID-19 vaccination in Ireland.

Your views are important to us. HIQA will carefully assess all feedback received and incorporate it into the report, where appropriate.

The final assessment and a statement of outcomes report (a summary of the consultation responses) will be published on HIQA's website once the HTA has been completed.

The closing date for the public consultation is 5 pm on Sunday, 9 August 2026.

How to provide feedback:

- If you are commenting in a personal capacity, there is no need to provide your name or any other personal information.
- If you are commenting on behalf of an organisation, please combine all feedback from your organisation into one submission form. We will request a name and contact number for a designated representative from your organisation in case we need to clarify your feedback.
- If your feedback contains any commercially sensitive or confidential information, please highlight this at the time of submission, so it can be excluded from the summary of feedback that will be published by HIQA.
- Please spell out any abbreviations that you use.

You can **email** the completed form to consultation@hiqa.ie

OR

Print the consultation feedback form and **post** the completed form to:

Health Information and Quality Authority
Public consultation on draft health technology assessment of COVID-19 vaccination in Ireland
Dublin Regional Office
George's Court,
George's Lane,
Smithfield,
Dublin 7,
D07 E98Y

Data protection and Freedom of Information

HIQA will only collect personal information, such as the names of individuals who provided feedback or any other personal details during this consultation, for the purposes of seeking clarification on your feedback, if necessary. No personal information will be included in the stakeholder consultation document that will be published by HIQA.

Any response you provide will be held securely and anonymised. Information provided in your response, for example, an anecdote or statement about an experience, may be included in the statement of outcomes that will be published by HIQA at the end of the HTA process. However, information will be provided in a manner which protects the privacy of respondents. All personal information will be deleted once no longer needed, in line with HIQA's record retention policy.

For further information on how HIQA uses personal information, please see our Privacy Notice available here. If you have any concerns regarding your personal information, please contact HIQA's Data Protection Officer at dpo@hiqa.ie.

Please note that HIQA is subject to the Freedom of Information (FOI) Act and the statutory Code of Practice in relation to FOI. We cannot give you an assurance that confidentiality can be maintained in all circumstances due to the requirements of the FOI Act.

☐ **I agree to take part in the public consultation**

1. About you

1.1 Are you providing feedback as:

☐ an individual

☐ on behalf of an organisation

1.2 If answer is 'on behalf of an organisation', please give the name of the organisation:

If applicable, for clarification purposes, please provide your name, your role in the above organisation and your contact details:

2. Your feedback on the draft health technology assessment

2.1 Please provide any general or specific feedback you have on the draft assessment. Where applicable, please specify the section to which you are referring.

2.2 Please outline any issues with the clarity or presentation of the draft report. In your response, where applicable, please specify the section to which you are referring.

Thank you for taking the time to share your feedback with us

Please ensure that you return your completed form to us either by email or post, to reach us by **5pm on Sunday, 9 August 2026**.

If you have any questions, please contact the evaluation team at consultation@hiqa.ie.

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