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 the addition of herpes zoster (shingles) vaccination to the adult vaccination programme

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About the Health Information and Quality Authority (HIQA)

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 the Minister for Children, Equality, Disability, Integration and Youth, 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 — T**he 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 in regard to the optimum 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.

HIQA undertook an assessment of adding herpes zoster (shingles) vaccination to the national immunisation programme for adults at the request of the Department of Health, following a recommendation from the National Immunisation Advisory Committee (NIAC). The aim of the HTA was to establish the clinical effectiveness, cost effectiveness and budget impact of adding shingles vaccination to the adult immunisation programme in Ireland. The draft HTA report was made available for public consultation over a six-week period in March and April 2024. This Summary 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 19 March 2024, and was available for public consultation until 30 April 2024. 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 email, post, or an online survey.

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 and LinkedIn). The findings of the draft HTA were publicised in the media. E-mail requests for feedback were sent to a targeted list of stakeholder organisations with relevant expertise and those who are likely to be affected by the proposed introduction of an adult shingles vaccination programme.

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. The submissions were stratified according to whether they were from members of the general public or stakeholder organisations. Feedback considered broad in nature was described narratively. Feedback relating to specific content in the draft report is presented in tabular format alongside direct responses to the feedback (Table 2 and Table 3). Where amendments were made to the report based on feedback, this is highlighted in the HIQA response.

3 Results

Overall, 97 unique and complete submissions were received during the public consultation period. As the incomplete responses contained no feedback, they have been excluded from the summary below. Submissions were received via the online survey, by email and by post to HIQA offices. A total of 82 submissions were received from individual members of the general public, eight were submitted on behalf of stakeholder organisations or institutions and seven were submitted by healthcare professionals responding in a personal capacity.

3.1 Summary of general feedback

A total of 82 responses were received from members of the general public; 60 of these were from people in Ireland and 22 respondents did not specify their country.

Most respondents expressed an opinion on the vaccine. The majority of respondents who expressed a favourable view of the vaccine had personal experience of herpes zoster (HZ) or had a close relative or friend who had experienced HZ, describing their personal experiences of the burden of HZ. These respondents expressed their belief that access to the vaccine would have prevented the symptoms and complications experienced. The burden of HZ was highlighted by 28 respondents and the burden of post-herpetic neuralgia (PHN) was specifically highlighted by 11. The verbatim of these responses is presented in Table 1. One respondent felt more detail underpinning the burden on PHN was warranted in the report. A total of 21 respondents mentioned their immunocompromised status and/or felt the vaccine should be given to those with immunocompromising conditions.

Eighteen respondents noted the prohibitive cost of paying for the vaccine privately and seven respondents commented that the vaccine should be subsidised to reduce the cost of paying for the vaccine privately. One respondent noted the ethical dilemma facing pharmacists when recommending the vaccine to individuals they feel would benefit from vaccination, but where they recognised the cost of the vaccine to be a barrier. Several respondents commented that other countries funded the HZ vaccine as part of their adult immunisation programmes.

Table 1 Verbatim of personal experiences with herpes zoster *

Number	Comment
Personal experiences	
1	"I personally suffered from facial shingles, it was very severe on my eye and forehead, leaving me with permanent neuropathy nerve damage on my forehead, despite getting appropriate antiviral medications and painkillers. I would get the vaccine as would my friends after I/ they saw what it did to me during that month of suffering and being bedridden. The price is truly excessive, and some form of subsidy should be considered, or else eligibility considerations such as 60+ etc."
2	"My friend had shingles 5 years ago and is still having pain in her head and eye. It is very debilitating, she is 58 years of age and I am 59 years old and I have had chicken pox as a child, so I am very nervous about getting it. The long term pain is what I am most afraid of. The vaccine at present is very expensive and it would be great if it was brought into the general vaccine programme for over 50s."
3	"I am over the age of 50 years and know of at least a handful of relatives and colleagues who have suffered badly with severe pain and long lasted effects from shingles. From what they have told me, I feel it would be most beneficial to this cohort of the population to be vaccinated against this debilitating condition."
4	"I have had shingles twice now and cannot afford to get vaccine. It should be free."
5	"I would like to see free vaccinations for shingles having suffered a very painful dose of shingles… I know too many people who also suffered from shingles ... please offer this vaccine free of charge to those who would like to have it. I never want to go through the pain of it again."
6	"As someone who had shingles 4 years ago, I am aware of how debilitating the infection can be and I believe a vaccine would be widely welcomed. I was lucky in that the outbreak I had did not leave me with long term nerve damage and pain. However, despite having had the disease, I do not have complete immunity. And since the disease can have more long term effects especially on more elderly people and those who are immunocompromised I believe that this vaccine should be made available either free of charge or at least at a subsidised cost."
7	"I had shingles for the 3rd time last March & I was very ill with them. It took me months to get back out & about. I'm 83 this year. I would love to get the vaccine but it is so expensive. I have been given the prescription but it is just so expensive. "
8	"I got shingles when I was 57, and ever since, have suffered from PHN. This has adversely impacted on my physical and emotional state of health. While I appreciate

	that obtaining shingles vaccine will not lessen my current PHN symptoms, I'm worried if I got shingles again, my PHN symptoms could worsen. As such, I would jump at the chance to avail of shingles vaccine if it were to be made free of charge to obtain from my GP. I'm sixty in a couple of months' time, so hopefully I will fall within the age bracket to avail of shingles free of charge, if a decision is made to offer it to the certain age cohort of the public."
9	"I currently have shingles which is extremely painful. I am 60 and feel the vaccine should be free."
10	"I witnessed my mother suffer with shingles in the later stages of terminal cancer. Any opportunity in my opinion to avoid this illness especially in the already ill or older generation is not money spent carelessly."
11	"Having suffered from shingles I believe adding the vaccination to the standard ones would be a good use of money as antivirals are so expensive"
12	"My mother suffered from post-herpetic pain for over a decade prior to her death. It reduced a vibrant, energetic, intelligent, strong woman to a shell and not only had severe health and welfare consequences for her but also for those around her. She had to give up work early, her social life was limited, she was hospitalised several times, she had constant GP visits, she had home help earlier in her life than maybe would otherwise have been the case. She was on a cocktail of medications, including extremely strong painkillers that further negatively affected her. The effectiveness of the vaccine may lessen overtime but my mother, and her family, would have jumped at the chance of more time without the severe pain she suffered. Anyone would. Her quality of life was ruined… I wouldn't wish what my mother endured on anyone."
13	"I am 74 years old and on immune suppressing medication to deal with arthritis. I also had my prostate removed because of stage 2 cancer, with a 30% chance of it recurring within the next 2 years. I am acquainted with two people of my own age who have had very severe cases of shingles recently. Vaccination should be freely available to people like ourselves who are not in a strong position to deal with the possible impact"
14	"Immunocompromised people are facing the huge risk of post herpetic neuralgia. They should be offered the vaccine. I suffer the chronic pain of this condition which is destroying my life despite all medical intervention."
15	"Having had family members gone through shingles, I strongly support a HSE funded program for shingles vaccination to prevent others having to go through the intense pain it causes to those affected"
16	"I think the Government should be prepared to provide the shingles injection to all people over 60. I had shingles when I was 68 and it was the most awful period of my life."
17	"I got shingles in early January this year and am still in pain every day. I'm now on pain patches which are very expensive and to my major disappointment an anti-depressant to try to kill nerve pain. I honestly believe the vaccine would have been so much cheaper if it was available to me before all of this happened. Prevention is better than cure!"

18	"The current cost for the 2-dose shingles vaccine is prohibitive for the average citizen and even though one might want to avail of it, at €480 this is just not possible. There really should be a national programme for shingles as I know how debilitating post-herpetic neuralgia can be. A family relative suffered for many years with pain after a bad dose of shingles at age 70. Even a subsidized vaccination programme would be good for those ages 50+. I dread the prospect of being impaired long-term if I was to contract the disease. "
19	"Shingles are very common and serious ailment for me and my wife. We are both immunocompromised. It is very expensive to get the vaccine, almost €900 for the two of us. We are over 74 years old and don't have the funds. It would be a great relief to get it from the HSE."
20	"My own experience with shingles is with regards to both of my parents, now sadly deceased, whose later years were completely and utterly blighted by nerve pain following shingles. Both my parents tried everything from medicines, creams, alternative therapies not to mention tens of visits to their GPs in search of help. Both ended up on multiple pain medications, antidepressants and sleeping tablets and in my father's case, a walking aid, as it seriously affected his mobility. I am 56 years old and have enquired about getting the Shingrix vaccine for myself, knowing what they both went through, I would totally take it if I thought I could avoid the agonies they both went through. I saw both my parents cry from the pain and frustration years after they were infected. My father died last year from lung cancer but he often said it was the nerve pain in his thigh from shingles that was worse."
21	"Shingles is a terrible virus! My mother got shingles over a year and a half ago, in her 80s and she has suffered in pain on a daily basis since then! She had it on her face and has had severe pain and discomfort all around her head over 12 months later with no let-up! It is incredible how this virus manages to take over someone's life for such a long time."
22	"I am a 74 year old male, I previously had shingles and suffered intense pain for 3 months. It is 10 years since I contracted the virus, but I still suffer from a constant pain. I have also had cancer I am terrified that I'll get shingles again."
23	"As a person of 60 years of age I have experienced shingles for the third time, I am currently in remission from cancer and this vaccine should be provided to people over 55 years of age and those who have a weakened immune system, free of charge."
24	"I agree that the cost burden to all wishing to avail of the vaccine privately is a huge impediment. At 69 years of age I have suffered from HZ three times so far. The cost of both doses of the vaccine comes close to €500, (€440 was the cheapest I found). Surely for people like me who are prone to contracting it, a free or heavily discounted vaccine would be a just and ethical decision?"
25	"I am disappointed at the conclusion of this report stating that it "would not be a good use of resources". New Zealand which has an excellent reputation for best practice vaccination policy has it in place for many years. Since 1 September 2023, the vaccine programme is being offered to specific cohorts by NHS. Germany and France also administer it. Having had shingles four years ago I found it a horrible experience.

	Please reconsider this recommendation. Maybe start with people over 70 years of age."
26	"Might you consider making the vaccine available for free to older cohorts for whom the effects of a shingles infection can be more serious and distressing, perhaps the over 65s, retired or the over 70s. Our family experience has been that our father's shingles infection in his mid-70s was very serious, affecting his eye and necessitating hospitalisation for a number of days. "
27	"If not cost-justified for everyone over age 50, perhaps offer free vaccination to older age-groups for whom the effects of a shingles infection can be more serious and distressing. I have recently heard of a number of people who contracted shingles in their late 60s and suffered greatly. They strongly recommend that I get the vaccine (even if I have to pay €450+). My own father had a shingles infection in his eye in his 70s and he ended up in the Eye and Ear hospital for a few days. "
28	"'Draft findings: The benefit of the vaccine decreases over time. The vaccine is safe. Reactions to the vaccine are mild and usually resolve within one to two days. Serious harm is rare. At the current vaccine price, adding shingles vaccination to the routine immunisation schedule for the general population aged 50 years and older would not be good use of resources for the HSE'. I understand that the vaccine provides protection as do all vaccinations, however, none is 100% and to provide some immunity against HZ in itself is beneficial, I have had HZ on two occasions in my fifties and I was extremely exhausted from the neuropathic pain as well as suffering the pain which was quite intense even though I recognised the shingles at a very early stage and got the required treatment. 'The shingles vaccine is effective for the general population aged 50 years and older and for immunocompromised adults aged 18 years and older. You cannot give shingles to another person, but contact with shingles can cause chickenpox in someone who never had it' This is really critical for our pregnant mothers as there are times that they come in contact with older parents with shingles and vaccination can prevent shingles occurring, even though the immunity from the vaccine wanes, it is only 70% at 10 years as per the document. 'Shingles causes a painful, blister-like rash. While this normally clears up within a month, some people may continue to experience pain for months, or even years'. I have two family members who have PHN and one needs to experience the pain to understand that they would have walked in the snow to get the vaccine should it have been available prior to their shingles. One of them is 15 years with PHN and the second person is 11 years. Older people deserve more protection and they have paid their taxes for 30-40 years. I note from the document that it is the HSE finances that are the critical blocker to the vaccination for shingles. They take all vaccines to protect themselves. Both of my relatives are dependent on family members for activities of daily living and if the vaccine was available these PHN cases may have been prevented. 'Older people and people with a medical condition or taking a medicine that can weaken their immune system have a higher risk of getting shingles'. Why not make it available when this is what is known?"

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

3.2 Comments on overall readability

Most people either skipped the question on overall clarity of the report, reported no feedback, or noted no issues. Ten people gave positive feedback on the report, finding the reporting clear and accessible. Five people found that report was too long for the general public, with one person suggesting that having multiple documents on the website was repetitive.

3.3 Specific comments/queries on report content

The feedback received on the report content and the response to this feedback is outlined in Table 2.

Table 2 Comments received on report content and responses

	Comment	Response
Number	**Burden of disease**	
1	My mother suffered from post-herpetic pain for over a decade prior to her death. It reduced a vibrant, energetic, intelligent, strong woman to a shell and not only had severe health and welfare consequences for her but also for those around her. She had to give up work early... when you talk about the financial costs of the vaccine, if my mother had lived pain free for longer, how much money would have been saved to the health system? How much tax would she have paid if she were able to work for longer? I wouldn't wish what my mother endured on anyone.	Chapter 3 (section 3.3) discussed the economic burden of HZ including the potential for productivity loss (absenteeism, presenteeism) associated with HZ. Published data on the long-term absences from the workplace and data relating to productivity losses for caregivers of those with HZ are limited. Identified data indicate productivity loss relating to HZ is mostly reported during the acute phase of HZ, with these data predominantly relating to those in paid employment. Given these data limitations, estimates of the productivity loss to society of paid work included in the economic model were limited to absenteeism due to HZ. Additional text has been added to Chapter 3 to describe the potential long-term burden of PHN.
2	After reading the draft assessment I feel full time carers over 50 should be offered the vaccination. Most carers are exhausted and don't have 500 euro for the vaccine. Most carers have no back up plan for the person they care for if they themselves get sick with shingles. I am aware this is a detrimental illness which can have long lasting effects Please considering a free shingles vaccine for all full time carers. I feel this report does not consider how unwell burnt out carers can become if they get shingles.	Chapter 6 (Ethical and social considerations) has been amended to include the following text: "Full time carers often do not have the option of a contingency measure if they themselves get ill, an episode of HZ can entail interrupted care for those they support."
3	The report does not identify fully the shattering and life changing condition of post herpetic neuralgia which must cost the HSE much much more than the price of the vaccine.	Additional text describing the long-term burden of PHN, and the full range of treatments received has been added to Chapter 3 (Epidemiology and burden of disease).

	Comment	Response
4	I got the Shingles in early January this year and am still in pain every day. I'm now on pain patches which are very expensive and to my major disappointment 10 mg of an anti-depressant to try to kill nerve pain. I honestly believe the vaccine would have been so much cheaper if it was available to me before all of this happened. Prevention is better than cure!	
5	My own experience with shingles is with regards to both of my parents, now sadly deceased, whose later years were completely and utterly blighted by nerve pain following shingles. Both tried everything from medicines, creams, alternative therapies not to mention tens of visits to their GPs in search of help. Both ended up on multiple pain medications, anti-depressants and sleeping tablets and in my father's case a walking aid as it seriously affected his mobility.	
	Epidemiology	
6	Shingles is very commonplace especially as one ages and quite painful and expensive to treat. On the other hand it is not included in the HSE's programmes and is not covered by health insurance. These reasons along with the current increase in chicken pox (a risk factor for shingles) justify the government running a free shingles program particularly for the vulnerable and over 60s.	The incidence of chicken pox (varicella) was considered in detail in our HTA. It highlighted that currently in the absence of varicella vaccination programme, seroprevalence of antibodies against varicella in those aged less than 15 years in Ireland has been estimated at 92.3%, reaching 95.3% in those aged less than 65 years. As a consequence, there is limited scope for an increase in incidence of chickenpox. Approximately one in three who experience chickenpox go on to develop HZ. Therefore, the extent to which the

	Comment	Response
		incidence of HZ could increase due to an increased prevalence of chickenpox is limited.
	Comparison with other countries	
7	I can't understand why this is not listed as a vaccine in Ireland, and in Australia, it is?	The types of information used to support funding decisions vary from country to country. Furthermore, if informed by economic evaluation, it is noted that those carried out in other countries are based on local healthcare utilisation, cost, and epidemiological data which can differ substantially from country to country. Evaluations are also dependent on the evidence of clinical effectiveness that is available at the time of analysis. Some international economic evaluations used for decision-making around shingles vaccination programmes were based on a previously available one-dose vaccine, which was cheaper than RZV. A key component in this evaluation was the cost of the vaccine. As there is only one manufacturer and the Irish population is relatively small, this can pose challenges for achieving a competitive price. The evaluation by HIQA has included the most recent long-term vaccine effectiveness data which would not have been available at the time of earlier international evaluations. These more recent data reflect real-world studies that provide additional information on the effectiveness of the vaccine in the general population, and over a longer period of time.
8	Shingles can be life threatening and if not, shingles are painful and long lasting. A highly effective vaccine is available, but only due to cost considerations not provided to the older population in Ireland. This population often does not have the means of paying Euro 500 and above for vaccination as they are on a small pension. Many countries provide the shingles vaccine free of charge to persons over 60 or 65, including the USA, Britain and Germany. The additional costs for the HSE is a poor excuse for not vaccinating the elderly who are most affected by shingles. How come that HIQA is so much better informed than the health authorities in Germany and the US who provide this vaccination for free for several years for the older population?	
9	My Sister lived in London and she has had the vaccine free of charge from the N.H.S. I find it hard to understand the different attitudes of the H.S.E and the N.H.S. to older citizens of their respective countries.	

	Comment	Response
	But I should know that an incompetent organization like the H.S.E. Management have little or no consideration for the people of this country.	
10	I am disappointed at the conclusion of this report stating that it "would not be a good use of resources". New Zealand which has an excellent reputation for best practice vaccination policy has it in place for many years. Since 1 September 2023, the vaccine programme is being offered to specific cohorts by NHS. Germany and France also administer it. Having had shingles four years ago I found it a horrible experience. Please reconsider this recommendation. Maybe start with people over 70 years of age.	
11	This is a very comprehensive review. The introduction of the vaccine into the national immunisation programme is clearly not supported on a pure cost effectiveness basis, given the current cost of the vaccine in Ireland. However, a small number of other countries have introduced a funded vaccination programme, including Luxembourg and New Zealand, both countries with a smaller population than Ireland. Since vaccine costs are undoubtedly subject to volume discounts, it would be useful to know the rationale for funding the vaccine against HZ in these countries (and perhaps in all countries where it has been done).	Cost effectiveness is one of a number of domains that is evaluated in a health technology assessment, and is not generally the sole consideration when deciding whether to fund an intervention. The reasons for a funding decision can be complex and may not be readily available.
12	Excessively long document with QUALS unbalancing ethics and social justice which itself is skimpy and repetitive. No explanation why Northern Ireland's cost benefit analyses is opposite to Southern Irelands. My question is this: What is the cost of NOT funding this vaccine, at least for the immunosuppressed: I believe denial of funding of this vaccine by the HSE to any immunosuppressed patient under their care who later dies or suffers shingles is negligent.	The circumstances and types of information used to support funding decisions vary from country to country. Evaluations to support decisions are carried out at a point in time, and our understanding of the longer-term effectiveness of interventions can change as additional data become available. Funding decisions can be based on a variety of considerations. In the case of the shingles vaccine, a decision could be made to provide the vaccine to one or more

	Comment	Response
		population subgroups and not to others. By outlining the clinical need and estimating the budget impact for different at-risk subgroups, the HTA supports the Minister for Health to potentially choose to fund the vaccine for specific populations. Chapter 3 provides detail of the increased risk of HZ and of complications associated with HZ in different subgroups of the population that are immunocompromised. Of note, Chapter 6, the budget impact analysis for those with HSCT (immunocompromised) has been updated to include potential cost offsets related to reduction in the need for HZ prophylaxis, in those who have been vaccinated against HZ.
	Economic evaluation	
13	The cost of long term health issues including hospital stays will I'm sure offset the cost of the limited and targeted immunisation.	The economic evaluation (Chapter 6) published by HIQA included potential cost offsets associated with a reduction in the incidence of HZ and PHN. This included the potential for reduction in hospitalisations and in primary care utilisation (GP visits, medication costs). These data were informed by Irish healthcare utilisation data.** Health technology assessment (HTA) is a multidisciplinary research process that collects and summarises information about a health technology. The information can cover a range of fields, including clinical effectiveness and safety, cost effectiveness and budget impact, organisational and social aspects, and ethical issues. The health budget in Ireland is finite. To invest in a new technology means that it may be necessary to stop or reduce funding for another technology or service. To make that choice, it is important
14	Why is cost effectiveness an issue for older immunocompromised citizens who have more than likely contributed taxes at very high rates? Was it a factor when free GP care etc. was extended to all other groups? Is cost effectiveness important in the running of the health service overall including administration? Why is this even a question when the vaccine is available free to immunocompetent people in England? Why is the vaccine so expensive in Ireland? Is anyone investigating that or methods to deliver it less expensively? Why are other groups given access to free contraception, period products and other endless lists, things that cannot benefit older	

	Comment	Response
	immunocompromised people? Money never seems to be an issue for other age groups.	that accurate and reliable evidence is presented to support decision-making. The goal of HTA is to provide that independent evidence. HIQA uses this HTA process when a request is received from the Department of Health or HSE. Not all products funded by the government undergo this process. See also response to comments 7 to 12.
15	Cost is prohibitive but worth it for elderly in particular, as although vaccine effects wane over time they have less lifespan at that stage and are less likely to be affected by this wearing off.	This is addressed in the economic model which considered vaccination strategies for the general population with vaccination at 50, 55, 60, 65, 70, 80 or 85 years. The model was informed by Irish data**, so the potential to benefit (based on initial vaccine effectiveness and waning immunity) considered the life expectancy of the age group being modelled In addition to estimates of cost effectiveness, a decision to fund recombinant adjuvanted vaccine (RZV) may be informed by a range of factors, including, for example, the burden of disease. In Chapter 3, detailed data were presented in relation to the burden of disease both in the general adult population aged 50 years and older (and stratified by 5-year age band) and in a range of identified subgroups at increased risk of HZ and its complications due to being immunocompromised. By outlining the clinical need and estimating the budget impact for different age groups and at-risk subgroups, the HTA supports the Minister for Health to potentially choose to fund the vaccine for specific populations.
16	I understand the cost assessment coupled with benefit assessment. As an immunosuppressed person who costs the state a lot in ongoing high tech medications, but also in ongoing healthcare associated with my increased risk of infections, I think it makes sense to fund the vaccine for immunosuppressed and those who are more elderly than 50 – perhaps over 65s or 70. This ensures that those most at risk, but also those most likely to cost the state money in treating the complications of shingles, are provided for.	
17	It would seem logical to add the shingles vaccine to those who are immuno risk, have previously had chickenpox, and are in receipt of state pension. For this segment of the population it is a very expensive vaccine. Given a 30% lifetime risk it would seem appropriate to reduce the greater population risk by vaccinating this segment without additional cost.	
18	The people most vulnerable are the over 50s. People who get shingles can suffer for a long time and it can recur in people who are	

	Comment	Response
	most vulnerable. How can you say that it is too expensive to vaccinate the elderly? These people have worked hard all their lives and given the best years of their lives to support this country. It's time now to protect them.	
19	Shingles has been on the rise since the COVID-19 pandemic; many, experience pain like no other and it costs them dearly. The price will be cost-effective so put it on the national immunisation list.	
20	The assessment feels the money spent on vaccinations would be better spent. If a lot of older people end up in hospital with this virus it will cost a lot more money and hospital resources. Vaccinations are very effective, all babies receive them. So should our senior citizens.	
21	My objection is that there even needs to be an expensive consultation. It has already been said that it might not be cost effective. Why have a consultation to say it's not cost effective and just save the money spent on it. How are immunocompromised people dealing with medical issues expected to be able to advocate for themselves?	The aim of this consultation exercise is to gain feedback from stakeholders with a broad range of experience that could potentially be affected by a herpes zoster vaccination programme. Input from all sectors of society is crucial in providing comprehensive, balanced and evidence-based information to aid decision making in our national health service.
	General queries/comments	
22	I had chicken pox as a child, nursed my parents through shingles. My immunity is severely compromised, am I likely to contract shingles? Shingles vaccination – would it help me avoid catching it?	This is addressed in the report in the description of technology and epidemiology and burden of disease chapters. There is clear and consistent evidence that the recombinant adjuvanted vaccine (RZV) vaccine is safe and effective at reducing HZ cases, but effectiveness diminishes over time. People considering getting the HZ vaccine should consult with a healthcare professional, such as their GP, to

	Comment	Response
		determine the best course of action given their individual circumstances.
23	The online site contains a number of articles which repeat some of the key messages. Perhaps one article with suitable sub sections would help clarify the risk benefit ratio for different elements of the population.	As part of trying to make HIQA's HTA more accessible, we summarise the findings for a variety of audiences. There is some duplication of text across summary sections of the report (for example, the Plain Language Summary, Executive Summary, Technical report) as these are directed to different audiences.
24	Given the high level of health misinformation on vaccination since COVID, more information is needed to the public to inform in lay terms what shingles is and what the vaccine prevents and protects from. People who have had bad experiences with shingles should be contacted and used in promotional materials.	Chapter 8, which covers organisational issues, outlines the information and awareness campaigns which would need to be considered by the HSE if HZ vaccination were added to the adult immunisation programme.
25	After reading the published news update of the Shingles Vaccine, do HIQA and relevant authorities deem the vaccines that GPs in Ireland hold as safe and tested to the highest levels?	In this particular assessment, we looked specifically at the safety and effectiveness of the shingles vaccine, and not at other vaccines administered by GPs in Ireland. Our assessment of safety was based on published evidence, which indicated that while local and systemic reactions are common, they are generally transient and mild to moderate in intensity. As with all authorised medicines, the safety and quality is monitored by the Health Products Regulatory Authority and by the European Medicines Agency through both proactive and reactive surveillance and pharmacovigilance programmes. Moreover, the National Immunisation Advisory Committee (NIAC) provides ongoing advice to the Department of Health on vaccines, immunisation and related health matters in the Irish context and advocates for best

	Comment	Response
		immunisation practice. NIAC also develops and disseminates the National Immunisation Guidelines for Ireland to support healthcare practitioners including GPs.
26	No one I spoke to had heard of the current Consultation process. It seems that somehow it has not hit the population as did the Measles vaccination programme and now the Bowel Cancer screening today. I am a retired healthcare professional, and I am greatly disappointed that the current HIQA Report and Consultation process is not widely or publically circulated or publicised. This hugely disadvantages older people whom it greatly effects and for whom shingles and its after-effects can have such devastating effects as you outlined. I am greatly concerned about the seemingly selected promotion or publishing of the report, the Consultation process which is for Public Consultation, and the seemingly lack of transparency for the general public, especially the over 65s group for whom it is most relevant. The following are my recommendations: 1. Extend the period of consultation to allow the public opportunity to input into it. 2. Ensure that it is promoted in the public domain e.g. the press; newspapers; radio. 3. The absence of a clear and open transparent public engagement process needs to be addressed.	The public consultation on HIQA's draft report ran for a six-week period. HIQA actively worked to promote this consultation through a press release, emails to key stakeholders, media interviews, a social media campaign, videos, and articles in newsletters. While we make a concerted effort to promote our public consultations, we cannot guarantee extensive media coverage. We welcome any feedback that can help improve our public consultations. We are exploring how we can better publicise and raise awareness of offline methods of participating in our consultations. We aim to implement improvements to our processes in future public consultations.

	Comment	Response
	4. Review the recommendations to specifically 65+ initially.	
27	I cannot understand as to why the report and findings concentrated on the 50+ when countries in the EU who have a Shingles vaccine programme are mostly for the 65+ group as well as the UK, Scotland, Nth Irl, Australia, Canada and New Zealand where the usual age group is 65+. As most of the 50 to 65 year people are mainly in the workforce and thus earning a salary, priority for them would be less of an issue whereas the over 65's are mostly on pensions and reduced incomes and the cost of the vaccines would be more prohibiting. If the recommendations were for the 65's initially, then the cost would be substantially reduced and taking everything into consideration could be as little as a third of the projected cost as outlined in the findings.	The report focuses on a general population aged over 50 and those aged 18 and over considered at increased risk of shingles as these are the populations the European medicines agency has determined the vaccine can be marketed for. We explored a range of ages at which vaccination could be provided, including for individuals at age 65 years. The report uses evidence from clinical trials and studies conducted all over the world; there were no geographical boundaries on the search for clinical efficacy, effectiveness and safety data.
28	I am deeply disappointed at HIQA's publication today of its draft health technology assessment on the addition of herpes zoster (shingles) vaccination to the adult vaccination programme. It fails to recommend Shingles vaccination as part of our adult vaccination programme for vulnerable people because of cost (HIQA quotes €151 per dose - 2 doses required in a course). This contrasts with the US, Canada, Australia, the UK and other European countries. Shingles can affect people of any age, but older people and younger people with reduced immunity are particularly affected.	See response to comments 7 to 12. The efficacy data referenced by this respondent is from randomised controlled trials only, it does not account for approximately 25% reduction in vaccine efficacy over 10 years and excludes real-world evidence which shows effectiveness in the region of 70%. Health technology assessment (HTA) is a multidisciplinary research process that collects and summarises information about a health technology. The information can cover a range of fields, including clinical effectiveness and safety, cost-effectiveness and budget impact, organisational and social aspects, and ethical issues. The health budget in Ireland is finite. To invest in a new technology means that it may be necessary to stop or reduce funding for another technology or service. To make that choice, it is important

	Comment	Response
	60% of Shingles occurs in over 60's and 30% of all people will experience at least one episode of Shingles in their lifetime. Severe Post Herpetic Neuralgia (persistent nerve pain) is common in 20% of cases. Another 20% can have nerves of their face and head involved which if it affects the nerves supplying the eyes can cause serious eye damage, including loss of or impaired vision of the eye involved. As a Geriatrician, I have dealt with large numbers of cases over my professional career, and I was looking forward to the advent of a safe, effective vaccine against Shingles which we now have in the form of a Recombinant Shingles (Zoster) Vaccine. When talking about Shingles vaccine it is very important to focus on the better tolerated more recently introduced Recombinant Zoster (Shingles) Vaccine which is administered in a course of two doses. The US Centre for Disease Control (CDC) recommends that adults 50 years and older get two doses of this Recombinant Shingles (Zoster) vaccine. The CDC quotes research that showed: • Two doses of Recombinant Shingles (Zoster) Vaccine provide strong protection against shingles and Post Herpetic Neuralgia (PHN), the most common complication of shingles. • In adults 50 to 69 years old with healthy immune systems, Recombinant Zoster (Shingles) Vaccine was 97% effective in	that accurate and reliable evidence is presented to support decision-making. The goal of HTA is to provide that independent evidence. HIQA uses this HTA process when a request is received from the Department of Health or HSE. Not all products reimbursed by the government undergo this process.

	Comment	Response
	preventing shingles; in adults 70 years and older, it was 91% effective. • In adults 50 years and older, Recombinant Zoster (Shingles) Vaccine was 91% effective in preventing Post-Herpetic Neuralgia (PHN). • In adults with weakened immune systems, Recombinant Zoster (Shingles) Vaccine was between 68% and 91% effective in preventing shingles, depending on their underlying immunocompromising condition. • In people over 70 years, immunity post Recombinant Zoster (Shingles) Vaccination remained high throughout 7 years following vaccination. HIQA says that their technology assessment is a draft document for public consultation. Hopefully, the Minister for Health, Department of Health and the HSE will follow the lead of the US and other countries in Europe and abroad who have recently placed Recombinant Shingles (Zoster) Vaccine on their recommended adult vaccination programmes. I earnestly request them to follow the advice of the US and other countries in recommending Recombinant Shingles (Zoster) Vaccine for all over 50's and for all over 18 who have an impaired immune system. It is crucial that Recombinant Zoster (Shingles) Vaccination becomes part of our Adult Vaccination Programme.	
29	Article 7.5 touches on the potential additional burden the administration of the vaccine may have on staff but I would argue	The economic evaluation (Chapter 6) published by HIQA included potential cost offsets associated with a reduction in the incidence of

	Comment	Response
	that the ongoing visits required to diagnose, treat and control the pain of patients with Herpes Zoster may have a more substantial burden on the already stretched time and resources of much of the GP staff.	HZ and PHN. This included the potential for reduction in hospitalisations and in primary care utilisation (GP visits, medication costs) associated with the diagnosis, treatment and ongoing management of patients experiencing complications associated with HZ. These data were informed by Irish healthcare utilisation data.**

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

Notes: ** Crosbie, B., Lucey, S., Tilson, L. et al. Acute herpes zoster and post herpetic neuralgia in primary care: a study of diagnosis, treatment and cost. Eur J Clin Microbiol Infect Dis 37, 627–631 (2018). https://doi.org/10.1007/s10096-017-3153-y

3.4 Feedback submitted by organisations and institutions

We received feedback from eight organisations or institutions as part of this public consultation. Feedback was received from Chronic Lymphocytic Leukemia (CLL) Ireland, National Immunisation Advisory Committee (NIAC), Irish Pharmacy Union (IPU), Merck Sharp and Dohme Ireland (MSD), National Cancer Control Programme (NCCP), Age Action, Lloyds Pharmacy and GlaxoSmithKline (Ireland) Ltd (GSK). The feedback from some organisations was extensive and has been summarised in this document. The full responses to the feedback are provided in this document. Feedback pertinent to this HTA is outlined in Table 3.

Table 3 Feedback submitted by organisations*

Number	Feedback	Response
	Age Action	
1	Requiring people to pay for vaccines creates further advantage for those on higher incomes over those on lower incomes, in a country where socio-economic health inequalities are already pronounced. Age Action has heard from practicing doctors that older persons with limited or modest incomes are less likely to seek out this vaccine. Social and economic health determinants lead to different groups of people being more or less healthy in later life, and having longer or shorter lifespans. Across Europe, including in Ireland, there is a life expectancy gap of several years between people on lower incomes versus those with higher incomes. There is also a gap in healthy life years between those on higher versus lower incomes. In Ireland in 2020, three quarters of persons aged 65+ with incomes in the top 20% reported their health to be good or very good (76.9%). This compares to just 62.9% of those with incomes in the bottom 20%. For every two older persons with incomes in the top 20% who reported a bad health status, three or more older persons in the bottom 20% did so (4.7% bad health versus 7.6%). Similarly, for every two older persons with incomes in the top 20% who reported fair health, three or more older persons in the bottom 20% did so (17.1% fair health versus 26.6%). A decision to maintain cost barriers to healthy ageing deepens inequality and contradicts the healthcare system's general move towards the Sláintecare model.	In Chapter 8 (ethical and social considerations), we have outlined the income-related inequity in access to the vaccine that currently exists.
2	Age Action strongly cautions against over reliance on the findings of the cost effectiveness study. This study relied on figures on the prevalence of shingles in Ireland that the report itself acknowledged do not capture	As the Irish incidence data were low in comparison with what was reported in epidemiological studies, we used international estimates for the cost-effectiveness modelling. As such, we

Number	Feedback	Response
	the full picture (in section 3.2). It would be indefensible to base a decision that impacts health outcomes and health inequalities on data that is known to be incomplete. It should raise serious concerns that the findings of this cost effectiveness analysis are so out of sync with the findings of analyses from the vast majority of other countries that have conducted them. The reason for this should be more fully interrogated. Before making a final decision, a recommendation should instead be made to conduct a point in time study to establish the true prevalence of shingles in Ireland.	were unlikely to have under-estimated the prevalence of shingles in Ireland. See response in Table 2, comments 7 to 12. Given the limited prevalence data for the Irish population, we would welcome any studies that could provide a more accurate estimate of the burden of disease in this country.
3	Age Action is seriously concerned about the growing social and political exclusion of the 6 in 10 persons aged 60+ who do not use the internet or who lack the skills to do so safely or to engage with any complex online processes. We know from our engagements with older persons that the matter of the shingles vaccine is of real importance to many people, and they would have greatly appreciated an opportunity to review this report and engage with the consultation process. There does not seem to be any possibility to engaging with this process offline, and if there are ways of doing so, they have not been clearly flagged to the public.	We welcome any feedback that can help improve our public consultations. We are exploring how we can better publicise and raise awareness of offline methods of participating in our consultations. Improvements to our processes, as discussed with Age Action, will be implemented in time for our next public consultation.
	CLL Ireland	
4	CLL (Chronic Lymphocytic Leukaemia) Ireland outlined that current medical advice for their patient community is that they should get the shingles vaccine. The feedback received outlined the immune challenges for people with CLL. The organisation also referenced a white paper providing further detail on the topic: https://www.clladvocates.net/whitepaper-cll-immune-challenges/	HIQA acknowledges the real burden faced by those with CLL particularly due their immunocompromised status. As the remit of the HTA is much broader than those with CLL (all haematological malignancies as well as a general population of adults aged 50 years and over), references specific to CLL were not included.

Number	Feedback	Response
		Cost effectiveness is one of a number of domains that is evaluated in a health technology assessment, and is not generally the sole consideration when deciding whether to fund an intervention. By outlining the clinical need and estimating the budget impact for different at-risk subgroups (including those with haematological malignancies), the HTA supports the Minister for Health to potentially choose to fund the vaccine for specific populations.
	Irish Pharmacy Union	
5	In Section 8.4 Respect for People of the draft HTA concerns are discussed in relation to patient privacy. Pharmacies in Ireland have in place a patient consultation area with the purpose of discussing in private any health matters or concerns patients may have. The Pharmaceutical Society of Ireland (PSI - the Pharmacy Regulator) has published Guidelines on Patient Consultation Areas in Retail Pharmacy Businesses regarding the requirements these areas should meet. Therefore, patients and pharmacists can discuss medical eligibility and consent information, as required, in a private matter. A hard copy or electronic form tends to be used to capture this information. An opportunity is provided for patients to supply further information or ask questions privately within the consultation area where the vaccine administration takes place. The pharmacist consultation also provides an opportunity for the patient to gain clarity on the potential complications from shingles and any concerns a patient may have regarding the safety or efficacy of vaccination. At all times respect for the patient and confidentiality is a key focus of the interaction.	Text amended in section 8.4 "Pharmacies in Ireland have in place a patient consultation area with the purpose of discussing in private any health matters or concerns patients may have. The Pharmaceutical Society of Ireland has published guidelines in relation to patient consultation areas in retail pharmacy settings – these areas are used for private consultations including vaccination administration. Therefore, patients and pharmacists can discuss medical eligibility and consent information, as required, in a private matter. An opportunity is provided for patients to supply further information or ask questions privately within the consultation area where the vaccine administration takes place. Although these are the guidelines, not all pharmacies may have these private consultation areas in place."

Number	Feedback	Response
6	Within section 7.5.3 Training of the draft HTA it is noted that there is a large proportion of community pharmacists who have already completed the core training required for the administration of any vaccine. Accredited training programmes for pharmacists are readily accessible. Should the shingles vaccine be added to the national vaccination programme, upskilling the pharmacist population to administer the vaccine would be straightforward and would ensure a considerable trained workforce is available.	Text added to section 7.5.3 "Accredited training programmes for pharmacists are readily accessible. Should the HZ vaccine be added to the national vaccination programme, upskilling the pharmacist population to administer the vaccine would be straightforward and would ensure a considerable trained workforce is available."
7	Community pharmacists currently record shingles vaccine administration on a Primary Care Reimbursement System (PCRS) Vaccine Claiming System and on the patient's medication record on the dispensary software system to satisfy legislative requirements. We would strongly recommend that shingles vaccinations are included in a national vaccination recording system such as HSE-COVAX to enable all healthcare professionals to have visibility of a patient's vaccination history.	Text added to section 7.4 "The existing COVAX and PharmaVax IT portals, which are currently used to manage other adult vaccinations, could potentially be adapted for this purpose. Irrespective of its funding status, recording vaccine administration in a national vaccination recording system such as the HSE-COVAX would enable all healthcare professionals to have visibility of a patient's vaccination history."
	Lloyds Pharmacy	
8	The current barrier in the community to patients availing of the Shingles vaccine is the cost. A significant interest exists from patients but once the cost is revealed to them, they decline to receive the vaccine. This creates an ethical dilemma for the pharmacist as there is a patient presenting who would benefit from the vaccine but is excluded due to cost.	The following line was added to the ethics chapter: "This also presents an ethical issue for GPs or pharmacists who may feel an individual would benefit from vaccination but they are reluctant to recommend it due to cost barriers."

Number	Feedback	Response
	A possible solution would be if the vaccine was reimbursable under DPS/GMS schemes. It would be reasonable for such reimbursement to require certain eligibility criteria.	
	MSD Ireland	
9	HIQA's draft health technology assessment (HTA) of shingles (herpes zoster) vaccination for adults reported that "at the current vaccine price, adding shingles vaccination to the routine immunisation schedule for the general population aged 50 years and older would not be a good use of HSE resources". In the absence of a national herpes zoster immunisation programme for adults, broadest possible varicella vaccination of the population offers twice the value to the national healthcare system by providing dual protection against both primary varicella and shingles with a single vaccine intervention. By preventing primary varicella infections, varicella vaccination reduces the pool of individuals who are susceptible to varicella zoster virus (VZV) reactivation, eventually leading to a decrease in the incidence and prevalence of herpes zoster. In parallel to the addition of two-dose varicella vaccination to the national childhood immunisation programme at 12 months and 4-5 years of age, a catch-up programme will play a critical role in reducing the long-term incidence of shingles, a painful and often debilitating condition caused by reactivation of the VZV. By vaccinating against varicella zoster virus, individuals are not only protected against varicella (chickenpox) but also against the risk of developing shingles later in life. Vaccination boosts immunity against VZV, thereby reducing the likelihood of viral reactivation and the subsequent onset of shingles.	Varicella vaccination was the subject a separate HIQA HTA (HTA of the expansion of the childhood immunisation schedule to include varicella (chickenpox) vaccination | HIQA) published in 2023. As outlined in the HTA of HZ vaccination, the majority of people who develop herpes zoster are aged 50 years and over. Therefore, even if a varicella vaccine was introduced for young children, it would have no impact in the short- to medium-term on the burden of herpes zoster in the population aged 50 and over.

Number	Feedback	Response
	This preventative measure not only alleviates individual suffering but also alleviates the burden on healthcare systems by reducing the incidence of shingles-related complications and the need for medical interventions. Ultimately, varicella vaccination represents a crucial tool in safeguarding public health and enhancing the quality of life for individuals by mitigating the occurrence and severity of shingles.	
	National Cancer Control Programme	
10	The discussion on the addition of herpes zoster (shingles) vaccine to the adult immunisation schedule is welcomed by the National Cancer Control Programme (NCCP), in particular by the NCCP Haemato-oncology Clinical Leads Group and the NCCP Medical Oncology Clinical Leads Group. We feel the availability of this vaccine for the immunocompromised cohort is of particular importance for the cancer patient population, especially those undergoing systemic anti-cancer therapy (SACT).	The assumptions used to develop the budget impact and analysis for HSCT and haematological malignancy groups were reviewed with NCCP clinical input and adjustments were made based on the feedback we received.
	NIAC	
11	NIAC notes that at a cost of €30 + VAT per vaccine dose, NIAC's recommended strategy would result in a cost of €52,667 per QALY gained, which approaches the current WTP threshold. The five-year incremental budget impact of NIAC's recommended strategy, with 50% coverage, was €53.31 million.	NIAC recommends the vaccination of all adults aged ≥65 years with RZV. The estimated incremental-cost effectiveness ratio (ICER) of €52,667 per QALY gained relates to vaccinating a single one-year age group, that is, adults aged 65 years only. This would be considered not cost effective at a willingness-to-pay (WTP) threshold of €45,000 per QALY gained. This estimate does not consider vaccination of all adults aged 65 years and older, the five-year budget impact for which, at the

Number	Feedback	Response
		vaccine list price and with 50% uptake, is estimated at €218 million. Additional wording has been added to the report to clarify these differences.
12	NIAC chose the precise cut-off of age 65 years to align with other current adult vaccination recommendations such as pneumococcal vaccines. NIAC believes this will facilitate implementation and uptake. Additionally, vaccinating at 65 years of age will optimise protection into older adulthood, and international modelling studies have found little difference in clinical impact in vaccinating at 60 or 65 years of age.	Added text to section 7.4 "Vaccinating individuals at age 65, coinciding with the administration of influenza and pneumococcal vaccines, might offer logistical advantages, potentially streamlining operations to support greater efficiency and increased uptake."
13	NIAC notes that the HTA reports that the cost effectiveness of the RZV vaccination strategies compared with no vaccination is highly dependent on the vaccine cost and the WTP threshold. The sensitivity analysis conducted for both the cost utility analysis and budget impact assessment highlight the considerable impact of the uncertainty associated with the vaccine cost.	Chapter 6: economic evaluation outlines that the cost-effectiveness results are driven by the prevalence of HZ in Ireland, vaccine efficacy, and vaccine cost. The WTP threshold is used in the HTA as a guide for interpretation of the cost-effectiveness analysis. There is no standard WTP threshold in Ireland. At the price submitted by the manufacturer, the current evidence suggests that HZ vaccination does not represent an efficient use of healthcare resources.
	GlaxoSmithKline (Ireland) Ltd (GSK)	
14	GSK, the manufacturer of the only HZ vaccine considered in the report, provided comprehensive feedback. The comments were structured by report chapter and ran to 45 pages. In their submission, GSK highlight concerns in relation to the following seven main issues:	We appreciate the level of detail in the feedback provided and have reviewed it carefully. Many of the points raised query analytical decisions in relation to data choices and how the data were incorporated into the evidence synthesis. It is important to emphasise that the report acknowledge instances where there is, substantial uncertainty in the data. Moreover, it

Number	Feedback	Response
	▪ conservative estimation of HZ incidence and associated disease burden; ▪ underestimation of vaccine effectiveness due to the use of lower quality effectiveness rather than high-quality efficacy data; ▪ a conservative perspective on long-term effectiveness, influenced in part by reference to a waning efficacy rate associated with a one-dose schedule; ▪ an inconsistent perspective on the risk of post-herpetic neuralgia (PHN) in breakthrough shingles in vaccine recipients (base case versus Scenario 1); ▪ lack of consideration of non-PHN complications in the model; ▪ insufficient consideration of PHN-related productivity losses and the HZ-related caregiver burden in the model; ▪ insufficient consideration of the broader ethical and social impact of equitable access to HZ immunisation for all at-risk adults (whether by age or immunocompetency status) in Ireland. The submission included further detail on these points along with additional commentary on associated aspects of the report.	must be emphasised that the findings of the economic evaluation were robust to this uncertainty. It should also be borne in mind that a HTA includes a range of domains to inform decision-making, and that decisions are based on consideration of all of those domains. More detailed responses are provided below in line with the headings of the different chapters of the report.
15	Description of the technology	An assessment is necessarily based on the information available at a point in time. In the context of national immunisation programmes, countries can and do revise their programmes on an ongoing basis. We have added clarification in the text to alert the reader to the timing of when international practice was reviewed.

Number	Feedback	Response
		It should be noted that NIAC does not take cost effectiveness into account when developing their immunisation recommendations.
16	Epidemiology and burden of disease	GSK highlighted concern over the terminology of "self-limiting disease" in relation to HZ. Given the possibility of recurrence, we have clarified the text to say that episodes of HZ are typically self-limiting rather than the disease. This is based on the fact that the vast majority of episodes do resolve within four weeks of onset. As outlined in section 3.5 of the report, the most common diagnosis is HZ without complications, and recurrence of HZ is infrequent.
17	Clinical effectiveness and safety	Feedback was provided on a number of aspects of the clinical effectiveness and safety chapter. *Long-term efficacy and waning immunity* The long-term efficacy of the vaccine was estimated based on published trial data, as outlined in the report. Those data were reported to 10 years, demonstrating a linear decrease in vaccine efficacy. A linear regression was used to estimate the rate of declining immunity that was incorporated into the economic model. We also analysed the data using a regression analysis that took into account the declining sample size over time, which suggested a slightly higher rate of waning immunity. For the purposes of reporting and the economic model we used the lower rate of waning immunity. The manufacturer has kindly provided confidential data that includes 11-year follow up. The data are not publicly available

Number	Feedback	Response
		and are not consistent with the previously published data from the same study, creating some concerns over the methodology. It should be noted that the rate of waning immunity obtained by a simple linear regression of the 11 follow-up data is within the 95% confidence bounds used in the economic model. In the report we make reference to observational data on waning immunity. GSK identified that the reported figure was based on a one-dose schedule rather than the recommended two-dose schedule. This has been corrected in the text. It should be noted that the observational data were not used in the economic evaluation and our interpretation of the magnitude of waning immunity was based on the published clinical trial data. *Vaccine effectiveness by age group* GSK stated that based on clinical trial evidence there is no evidence of changing vaccine efficacy by age. This is consistent with our reported findings that also included observational data to conclude that vaccine effectiveness does not change by age group. *Prevention of post-herpetic neuralgia (PHN)* As presented in the report, among individuals who experienced breakthrough HZ despite vaccination, the two randomised controlled trials did not show a reduction in the risk of PHN compared with the risk of over and above the reduction in herpes zoster. That is, the reduction in PHN matched that in

Number	Feedback	Response
		HZ. The observational data demonstrated a reduction in PHN over and above that seen in HZ. GSK have pointed out that due to the small number of HZ cases in the randomised controlled trials, they were underpowered to detect an additional effect on PHN. It can be noted that the effect estimate from the RCTs (RR 1.30, 95% CI: 0.50 to 3.36) did not embrace the effect estimate from the observational studies (RR 0.39, 95% CI: 0.30 to 0.50). It was therefore not possible to say that the difference in findings happened by chance or simply due to the clinical trials being underpowered to detect an effect. *Use of observational data of clinical effectiveness* GSK queried the inclusion of a study by Khan et al. in the meta-analysis of observational studies. The query arose because the study population was people diagnosed with inflammatory bowel disease (IBD), which can lead to an increased risk of HZ either because of the disease itself or because of some of the commonly used medicines used to treat it. Eligibility criteria for study participants included a diagnosis of IBD and a history of IBD medication use. The elevated risk associated with IBD is relatively low, and the study participants were considered closer to a general population than a high-risk group. As can be seen from the forest plot of the meta-analysis in the report, the Khan study is associated with a weight of 0.4%. Exclusion of the Khan study does not materially change the results of the meta-analysis. The incidence rate ratio is 0.2981 (95% CI: 0.2859 to 0.3108)

Number	Feedback	Response
		with Khan, and 0.2979 (95% CI: 0.2857 to 0.3107) without Khan. GSK queried the length of follow up in the observational studies. In the context of waning immunity, a study with longer follow up might expect to observe lower vaccine effectiveness. The average length of follow up in the vaccine arm was 7.3 months in Izurieta 2021, 8.4 months in Sun 2021a, 8.0 months in Sun 2021b, and 12.7 months in Khan 2022a. The majority of participants who received a vaccine were therefore followed for less than 12 months and there should be a negligible impact of waning immunity on the estimates of vaccine effectiveness. As already stated by both GSK and ourselves, there is no evidence of differing vaccine effectiveness or efficacy across age groups, and therefore the fact that observational studies did not all report for the same age groups should not bias the findings. It was stated in the report that "observational data may overestimate cases due to a reliance on systems reporting and inability to verify cases". This has been amended to say that it may over- or under-estimate cases. As can be seen with the sentinel practice data for Ireland, in the absence of laboratory confirmation there may be an under-estimate of cases as not all episodes of HZ may result in a consultation with a GP or other healthcare professional. However, reliance on case identification through prescriptions in administrative databases

Number	Feedback	Response
		may also be inaccurate where medicines may also be indicated for other conditions.
18	Rapid review of methodology for economic modelling studies of HZ vaccination	In their feedback, GSK noted the findings of two systematic reviews of economic evaluations of HZ vaccination. Of the two reviews cited, one of them is a critical review by GSK. The other is a systematic review which included 27 studies, of which 26 were for ZVL and only 1 study on RZV. Of the 18 studies included in our rapid review of methodology for economic modelling studies, 7 of these were GSK studies. When considering risk of bias in relation to economic evaluations, an important aspect is whether the analysis was carried out by the manufacturer. It was pointed out that published models have used either annual or monthly cycles for their Markov models. The choice of cycle length is often influenced by the nature of available data and the impact on model complexity. Much of the available data on duration of post-herpetic neuralgia is reported at specified months of follow up (i.e., at 3, 6 and 9 months) which naturally supports estimation of transition probabilities based on monthly cycles rather than annual.
19	Economic evaluation	*HZ incidence* For the economic model, in recognition of the fact that the available Irish HZ data were likely an underestimate of true incidence, international data were used to generate estimates for use in the model. While a trend for increasing incidence was noted in international data, this may well be influenced by

Number	Feedback	Response
		the growing number of studies from Asia, where incidence is higher than in Europe and North America. The data used for the economic model were limited to studies from Europe and North America as these were considered to most applicable to an Irish population. We looked at a variety of functional forms for characterising the relationship of incidence by age, using models such as generalised additive models, locally estimated scatterplot smoothing and polynomial regression. In all cases the year of data were included in the models to account for changes over time. A polynomial regression was ultimately used as it gave flexibility in taking uncertainty into account. The confidence bounds for incidence encompassed all of the functional forms and the majority of observed incidence values from European studies. *Waning immunity* The rate of waning immunity used in the model was derived from a linear regression of vaccine efficacy by year of follow up, as reported by Strezova et al. The observational study data (published by Zerbo et al.) was not in the analysis. *Duration of PHN* GSK queried how the duration of post-herpetic neuralgia was incorporated into the model, citing obtaining different results when attempting to recreate the calculation provided in Appendix C of the HIQA report. The table in the appendix provides the mean rather than median duration of PHN. The mean durations were not used as a model input but were

Number	Feedback	Response
		provided in the report to illustrate the modelled mean time from HZ onset to recovery for individuals who developed PHN. The distribution of duration of PHN is skewed and the model allowed for individuals to spend up to 60 months living with PHN with the associated impacts on health-related quality of life and treatment costs. Furthermore, the table in the appendix is the average durations across age bands rather than single year of age. In the model, individuals can develop HZ at any age and can move into the PHN state one month after onset of PHN. The parameters table in the appendix has also been updated to show the uncertainty associated with mean duration of PHN. *HZ-related complications* HZ-related complications impact on both costs and health-related quality of life. In terms of costs, there will potentially be medication, primary care utilisation and hospitalisation. Data on HZ-related costs came in part from an Irish study that considered the cost of care for HZ. It did not specifically limit costs to those for primary HZ infection at the exclusion of complications. Hospitalisation data was based on the broad ICD-10AM coding for herpes zoster that includes complications. As a consequence, the mean cost of hospitalisation incorporates costs arising from complications. *Productivity losses* With regard to the exclusion of additional productivity losses due to PHN in the societal perspective, a number of studies

Number	Feedback	Response
		reviewed in Chapter 5 of the HTA reported productivity losses associated with PHN. However, there was considerable variation in the number of work hours or days lost reported, as well as quality issues with reporting of data and lack of detail regarding the original data source. As this presented difficulties for application to the Irish setting, a scenario analysis was conducted that also included productivity losses associated with absence from paid work for those with PHN. The results of this scenario analysis did not change the overall interpretation of the findings of the economic evaluation. *Choice of effectiveness data* Part of the GSK feedback related to the use of observational data in preference to the randomised controlled trial evidence for the main analysis in the economic evaluation. Our preference is generally to use RCT evidence where available, with cognisance to the quantity, quality and applicability of data available. In this case the RCT evidence for the primary outcome of reduction in HZ was based on 29,311 person years of data, while the observational data included a much larger sample of 33 million person years. A more concerning issue was that in the RCT data, incidence was 32.4 per 1,000 person years compared with 16.0 in the observational data. The incidence in the RCTs was markedly higher than reported in epidemiological studies, raising questions about the applicability of the data. We also ran the economic model using the RCT data, and this is presented in the report as the first scenario analysis. As the RCT data did not show an additional effect of a reduction on post-herpetic neuralgia, it

Number	Feedback	Response
		was found to be less effective at improving quality of life than when observational data were used. *ACERs/ICERs* GSK queried the reporting of incremental rather than average cost-effectiveness ratios. We treated the vaccination strategies as mutually exclusive: individuals can be vaccinated once, and the question was "at what age does vaccination maximise the net monetary benefit?" In their submission, GSK described the vaccination strategies as independent strategies that could be implemented concurrently. That is, strategies to vaccinate at age 65 years and at age 70 years could be rolled out. In the context of a long-term immunisation policy, the older age group may be considered as a catch-up programme that would only continue until those turning 70 had already been offered vaccination as 65-year-olds. Such a programme should then be modelled as a catch-up and not as an ongoing strategy. In the event that vaccination at one or more ages had been demonstrated to be cost effective, then exploring the potential for catch-up programmes would have been explored. It can also be noted that both incremental and average cost-effectiveness ratios are provided in the results tables. *Risk of mortality* An elevated risk of mortality associated with HZ was included in the model in addition to all-cause mortality. The elevated risk was based on mortality in hospitalised cases. As hospitalised cases are likely to represent more severe cases

Number	Feedback	Response
		and those more vulnerable to serious complications, it may over-state the additional risk of mortality associated with HZ. *QALY losses* All original studies that elicited health-state utility values or disutilities associated with HZ and PHN using a generic preference-based measure were included in the estimation of utility values for HZ and PHN (and are referenced in section 6.2.9.6 of the report). A number of identified original studies were excluded from the estimation due to a lack of consistency in case ascertainment, the definition of PHN, the definition of pain severity and the instruments used to measure pain severity. This lack of consistency presents challenges in reliably estimating the burden of HZ and its complications at a population level. *Coverage rate* GSK noted that the modelled coverage or uptake rate (50%) was potentially conservative. It is important to note that the chosen coverage rate was based on the experience in the UK. As the addition of HZ to the adult immunisation programme would require minimal capital expenditure, the total cost is almost entirely dictated by the cost of procuring and administering the vaccine, and the cost offsets generated by reduced incidence of HZ and its complications. There is minimal onward infection associated with HZ – that is, very few cases of chickenpox are due to contact with a person with shingles. As such, the concept of herd immunity is not

Number	Feedback	Response
		pertinent and increased uptake will not improve the cost-effectiveness of HZ vaccination. Increased uptake will, however, lead to a substantially increased budget impact.
20	Organisational issues	GSK noted that for some populations, such as individuals who are immunocompromised, it may be possible to coincide visits for both vaccination doses with routine consultations. While this could potentially create some efficiencies for vaccination in a general practice setting, it must be borne in mind that it does not eliminate the associated cost or time needed to administer the vaccine.
21	Ethical and social considerations	As outlined in the report, vaccinating adults in the general population over the age of 50 years against HZ is associated with a substantial budget impact and was found to be not cost effective. As acknowledged by GSK, the healthcare budget is finite and needs to balance many competing priorities. Inclusion of HZ vaccination in the adult immunisation programme could require reallocation of resources, potentially impacting the existing healthcare system by diverting resources from other more cost-effective interventions or from the overall healthcare fund. 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 new investments are considered. So while provision of HZ vaccination could reduce inequities within the eligible population, the consequence may be to create substantial inequities for other populations in the healthcare system. As such, funding interventions that have been found to be not cost effective could create issues of

Number	Feedback	Response
		justice and equity with respect to a fair distribution of benefits and burdens.

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

3.5 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:

- Chapter 3 key points have been updated to include the burden of postherpetic neuralgia (PHN).
- Chapter 3 has been updated to clarify that it is an episode of herpes zoster (HZ) that is self-limiting, rather than the disease.
- Section 3.4.3.1 has been updated to include more detail of the burden of PHN.
- Section 3.4.3.1 has been updated to include details of the treatments used to manage PHN.
- Sections 4.5.1, 8.7.2 and Chapter 9 have been updated to correct the waning immunity estimate from an observational study that was used for context in this report.
- Section 7.5.1 has been updated to include text on the extra GP visits that are required for diagnosing, treating and managing PHN.
- Section 8.2.2 has been updated to include the benefit of vaccination for full-time carers.
- Section 8.5 has been updated to include the ethical issue faced by GPs and pharmacists when recommending the RZV to patients who face financial barriers.
- Appendix C has been updated with new uncertainty measures for PHN.

In addition to the changes made above, the Advice to the Minister, an Executive Summary and a plain language summary are presented in the final report. Every attempt has been made in the plain language summary, the Executive Summary and the Advice to the Minister to further emphasise issues of importance that were highlighted during the consultation process.

Appendix A – copy of submission feedback form

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Technology Assessment of the addition of Herpes Zoster (shingles) vaccination to the adult immunisation schedule

For public consultation

Consultation Feedback Form

Your feedback is very important to us. We welcome comments you would like to make.

When commenting on a specific section of a document, it would help if you can identify which element you are commenting on and the relevant page number.

The consultation remains open until 5pm on 30 April 2024

You may email a completed form to us at consultation@hiqa.ie. You may also complete and submit your feedback online at https://hiqa.qualtrics.com/jfe/form/SV_0fiwUVldKM2WWFM

About you

Name	
You or your organisation's country	
Today's Date	

General Information and Questions

You may provide us with feedback on the specific questions (see questions that follow), or alternatively you may provide us with general comments.

Part 1

Are you replying in a personal capacity or on behalf of an institution or organisation?

☐ Personal capacity

☐ On behalf of an institution *Please name*

☐ On behalf of an organisation *Please name*

Part 2

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

Please comment

Part 3

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

Please comment

Thank you for taking the time to give us your views.

After the closing date, we will assess all feedback and use it to finalise our documents. The final documents and the Statement of Outcomes (a summary of the responses) will be published on http://www.hiqa.ie.

If you wish to do so, you can request that your name and or organisation be kept confidential and excluded from the published summary of responses. Please note that we may use your details to contact you about your responses. We do not intend to send responses to each individual respondent.

Please return your form to us either by email

consultation@hiqa.ie

or complete it online at:
https://hiqa.qualtrics.com/jfe/form/SV_0fiwUVldKM2WWFM

If you have any questions you can contact the consultation team by emailing consultation@hiqa.ie.

Please return your form to us either by email or post before

5pm on 30 April 2024

Please note that the Authority is subject to the Freedom of Information Acts and the statutory Code of Practice regarding FOI.

For that reason, it would be helpful if you could explain to us if you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

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