Australian Immunisation Handbook

Responses to Public Consultation Submissions

Changes to the recommended use of Herpes zoster vaccine to prevent herpes infection

Public consultation period: 8 July 2022 to 7 August 2022

Contents

1. Introduction

Public consultation for the revised Herpes zoster vaccine recommendations in the Australian Immunisation Handbook (the Handbook) was conducted over a 4 week period from 8 July 2022 to 7 August 2022, during which time the draft recommendations were available on the Citizen Space website. The Immunisation Branch invited a range of stakeholders, committees, working groups and interested people to provide submissions. A list of organisations formally invited to comment on the draft guidelines is provided in Appendix A.

This report outlines the public consultation comments received on the revised Herpes zoster vaccine recommendations. 17 submissions were received using the submission template provided on Citizen Space. Of these, 9 were on behalf of an organisation or jurisdiction and 8 were from individuals.

The Australian Technical Advisory Group on Immunisation (ATAGI) considered all responses from the public consultation in September 2022 and, where necessary, revised the recommendations in accordance with the submissions. Comments from the public consultation submissions and the ATAGI responses are summarised in the following section.

This report was submitted to the National Health and Medical Research Council (NHMRC) on 30 September 2022, reviewed at its meeting on 23 November 2022, and approved on 6 December 2022.

2. Summary of comments received through public consultation on updated Herpes zoster vaccination recommendations for inclusion in the Handbook

	Organisation	Comment	Proposed Action	Rationale
1a	Queensland Health	Even though screening tools in place, some immunocompromised people may receive Zostavax.	**Reviewed. No change in recommendation made.**	The *Australian Immunisation Handbook* zoster chapter will contain detailed information on the appropriate screening of people who are immunocompromised to prevent the administration of Zostavax. The update will also include the availability of alternative vaccines. Communication strategies on implementation will be managed by the Department of Health and Aged Care as per standard processes.
1b		Disparity for those that cannot afford to pay for Shingrix – consideration for this to be funded for immunocompromised. Potentially a state funding consideration. The funding should be made very clear, and the rationale for the general public and for providers. Even though this is stated, we tend to receive many enquiries as to the rationale for why certain vaccines are and are not funded, and for what cohorts.	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The Pharmaceutical Benefits Advisory Committee (PBAC) assesses the cost-effectiveness of vaccines to determine if they can be included in the National Immunisation Program (NIP). At this time, Shingrix has not been assessed as cost-effective by the PBAC.
2a	Individual	No additional comments to make.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
2b		Has there been any exploration into the provision of financial assistance with funding for Shingrix vaccines for low-income, medically assessed immunocompromised individuals?	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.
3a	Haematology Society of Australia and New Zealand	No.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
3b		Shingrix is recommended for immunocompromised patients; however, we note that it is not currently funded, and current out-of-pocket cost is approximately $300 per dose. This ATAGI recommendation will need to be followed by government support for this vaccination in a very substantial group of patients >50 years with immunocompromise and/or haematological malignancy.	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.
4a	Individual	I cannot be given the present vaccine as I am unable to be given live vaccine. I have had shingles 3 times, and this has left me with very significant neurological issues. Shingles (I have said earlier I have had 3 times, each full-blown) can be controlled for people like myself only with Shingrix.	**Reviewed. No change in recommendation made.**	The *Australian Immunisation Handbook* update will recommend the use of Shingrix instead of Zostavax in people who cannot receive live vaccines.

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4b		Shingrix should be on the Pharmaceutical Benefits Scheme (PBS) for people like me.	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.
5a	Australian Rheumatology Association (ARA)	The ARA agrees and welcomes the new ATAGI recommendations as outlined below: • People aged ≥18 years who are immunocompromised are recommended to receive zoster vaccine. • People who are immunocompromised are recommended to receive a 2-dose schedule of Shingrix®, 1-2 months apart, for the prevention of herpes zoster and associated complications. We believe that unintended consequences of this recommendation may include: • financial stress for people in whom Shingrix® is the recommended vaccine (private cost approx. $500–600 for 2 doses) as it is not listed on the NIP schedule or PBS • failure for immunocompromised patients to be vaccinated against zoster. If patients can't afford the recommended vaccine, they may not get vaccinated at all, thus increasing the risk of disease and further costs to the healthcare system • cost shifting from national health budgets to state health budgets as physicians may apply for individual patient approval/use (IPA) through the public hospital system. This in turn creates increased administrative burden to an already overstretched rheumatology workforce. It is estimated that it can take up to 25 minutes to complete the paperwork for an IPA; this is time that could be spent seeing patients. In terms of implementation, it is crucial for Shingrix® to be listed on the NIP to ensure that immunocompromised patients can access it without causing unintended consequences, as listed in the previous question. It is well known that people who are immunocompromised have an increased risk of morbidity and mortality from many vaccine-preventable diseases. Many rheumatology patients would be considered severely immunocompromised as a result of the medication(s) that they are prescribed to manage their disease. In particular, the reactivation of varicella-zoster virus is the most recognised infection complication with Janus kinase inhibitors, which places rheumatology patients taking this class of medicines at even greater risk.[1] The varicella zoster vaccine that is currently listed on the NIP is a live vaccine (Zostavax®). Live vaccines are contraindicated in patients who are severely immunocompromised; this includes patients who are taking highly immunosuppressive therapy, including biological or targeted synthetic disease-modifying anti-rheumatic drugs (DMARDs) or high-dose corticosteroids. This means that many rheumatology patients are unable to receive Zostavax® without interruption of therapy as it is usually not practicable	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.

	Organisation	Comment	Proposed Action	Rationale
		to have vaccination prior to commencing therapy, and interruption of therapy can result in a flare of their disease. This new recommendation by ATAGI acknowledges the issues with the live vaccine, Zostavax®; however, the out-of-pocket cost for a course of Shingrix® is approximately $500–600 (for 2 doses). This is often out of reach for patients who are already burdened by the extra costs and potentially reduced income associated with living with a chronic disease. We believe that the addition of the inactivated varicella zoster vaccine (Shingrix®) to the NIP and PBS is essential for rheumatology patients for these reasons. One of the quality-use-of-medicines principles is to ensure that the 'right' medicine is available for patients. The addition of Shingrix® to the NIP and PBS would enable better access to the most suitable vaccine (ie the inactivated varicella zoster vaccine) to prevent varicella zoster in this vulnerable patient group. Reference: 1. Clarke B et al. The safety of JAK-1 inhibitors. Rheumatology (Oxford) 2021;60(suppl 2):ii24-1130, doi: 10.1093/rheumatology/keaa895 (accessed 16 Nov 2021).		
5b		Unlike the COVID-19 vaccine, there is no evidence to inform the timing of Shingrix in relation to immunomodulatory medications, which may have an impact on the immunogenicity and effectiveness of the vaccine.	**Reviewed. No change in recommendation made.**	Unlike with Zostavax, there are no concerns around Shingrix causing disseminated disease in people receiving immunomodulatory medications. The chapter provides guidance on general considerations for timing of vaccination for immunocompromised people. There is also guidance on timing around specific conditions in the Handbook chapter 'Vaccination for people who are immunocompromised'.
6a	Victorian Department of Health Immunisation Unit	The recommendation of Shingrix vaccine for those with immunocompromise may result in less vaccine errors for people who are immunocompromised.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
6b		Low uptake due to prohibitive cost unless Shingrix is incorporated into the NIP. As Shingrix is not funded under the NIP, consumers will need to pay out-of-pocket costs. This will create inequities, as not everyone who is recommended to receive Shingrix may be able to pay for it. Clarification is required about inclusion of Shingrix in the NIP.	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.

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6c		Vaccine safety: The World Health Organization and Victoria's vaccine safety surveillance system (SAEFVIC) recommend close monitoring of adverse events following immunisation (AEFI) for all new vaccines. Therefore, should clinicians be encouraged to document and record all AEFI following the use of Shingrix to facilitate ongoing safety surveillance (not just significant events, which is the current recommendation)? (Compared with Zostavax, the rates of local and systemic adverse events following Shingrix vaccine may be higher, but the evidence is very uncertain.) Will the Commonwealth or jurisdictions lead responses to any emerging safety signals? The additional burden upon jurisdictions for detection and response to safety signals and serious AEFI is unknown.	**Reviewed. No change in recommendation made.**	The *Australian Immunisation Handbook* zoster chapter will contain detailed information on the expected adverse events. In addition to the guidance that will be provided in the Handbook, further communication strategies will be managed by the Department of Health and Aged Care. As the vaccine is not funded under the NIP and uptake is likely to be modest, it is not anticipated that there will be a large burden of AEFI reported.
6d		There is a potential risk of administration error due to the difference in the number of doses required in the 2 vaccine schedules.		The *Australian Immunisation Handbook* zoster chapter will contain information on the required number of doses for each zoster vaccine. In addition to the guidance that will be provided in the Handbook, further communication strategies will be managed by the Department of Health and Aged Care.
6e		Clinical guidance is required for co-administration of Shingrix with other vaccines.	**Reviewed. No change in recommendation made.**	The current ATAGI statement on the clinical use of zoster vaccines in adults provides guidance on the co-administration of zoster vaccines, including Shingrix. 'Co-administration of COVID-19 vaccine, other vaccines and zoster vaccines is acceptable if required. There is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. Separation of Shingrix from other vaccines may be preferable where possible'. This will be incorporated into the *Australian Immunisation Handbook* chapter update.
6f		Does research regarding efficacy support preference for a particular zoster vaccine?	**Reviewed. No change in recommendation made.**	Shingrix is the preferred vaccine over Zostavax. There are currently no studies that directly compare efficacy of Zostavax and Shingrix. Comparison of clinical trial data demonstrates higher vaccine efficacy of Shingrix against placebo than Zostavax against placebo for the outcomes of herpes zoster and post-herpetic neuralgia. The duration of protection is also longer for Shingrix than for Zostavax.

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6g		Several links in the *Australian Immunisation Handbook* and Commonwealth publications related to zoster vaccine will require amending, including chapters on zoster, vaccination for people who are immunocompromised and associated links.	**Reviewed. No change in recommendation made.**	Links will be updated appropriately.
6h		Administration systems: Amendments to the Australian Immunisation Register (AIR) must occur prior to the rollout of the proposed changes to support recording, facilitate surveillance and optimise jurisdictional reporting. General practitioner (GP) and community health services practice software will require backend updating to add Shingrix, to facilitate recording and reporting to AIR. Expected commencement date must consider expected supply of Shingrix vaccine. Both zoster vaccines share similar storage requirements. There will be separate cold chain breach reporting systems if Shingrix is not included in the NIP and available through private script only.	**Reviewed. No change in recommendation made.**	Implementation matters will be managed by the Australian, and state and territory health departments, and are outside the scope of this public consultation document.
6i		Will those who have received a Zostavax vaccine and then opt to receive a Shingrix vaccine be considered to have received dose 2 of a zoster vaccine?	**Reviewed. Change in recommendation made.**	No. A full course of Shingrix, consisting of 2 doses, is required regardless of whether a person has previously received Zostavax.
6j		Training and communication strategies: Clarification is required of the Commonwealth's lead role in the provision of resources, guidance for clinicians, guidance for jurisdictions, educational resources and communication strategy. Confirmation of expected commencement date is required to facilitate jurisdictional planning and editing of zoster vaccine resources, and stakeholder communication. Jurisdictional communication and educational strategies will be required to support the changes. Communication must assure those who have received Zostavax to date that they have not been supplied with an inferior vaccine.	**Reviewed. No change in recommendation made.**	Communication strategies will be managed by the Department of Health and Aged Care. Implementation matters will be managed by the Australian, and state and territory health departments, and are outside the scope of this public consultation document.
6k		Clarity and clinical guidance are required on 'mild immunocompromise'. Confirm the suitability of the 'Live shingles vaccine (Zostavax) screening for contraindications' tool to facilitate assessment.	**Reviewed. No change in recommendation made.**	The 'Live shingles vaccine (Zostavax) screening for contraindications' tool has been developed to facilitate identification of people who may be contraindicated for vaccination with Zostavax. Case-by-case assessment is then required by the patient's vaccine provider, immunisation specialist or treating specialist.

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6l		Clinical guidance is required to support the recommendation 'People who have previously received Zostavax can receive Shingrix if they wish to increase their protection against herpes zoster. A minimum interval of at least 12 months is recommended between receiving Zostavax and a subsequent dose of Shingrix'. Is this recommendation for a single dose, or the interval between a previous Zostavax and dose 1 of a 2-dose course of Shingrix? National Centre for Immunisation Research and Surveillance (NCIRS) fact sheet (May 2022), currently linked to the Handbook, recommends that 2 doses (of Shingrix) are required even if a patient has previously received Zostavax or suffered from shingles. This recommendation is contrary to the proposed ATAGI changes and requires clarification.	**Reviewed. Change in recommendation made.**	Additional wording added to the recommendation to clarify need for 2 doses of Shingrix in order for schedule completion.
7a	Arthritis Australia	Thank you for the opportunity to provide feedback on proposed changes to the recommended use of zoster vaccines for inclusion in the *Australian Immunisation Handbook*. Arthritis Australia strongly supports the inclusion of Shingrix® in the Handbook and the proposed changes: • The recommended age from which immunocompetent people can be vaccinated to change from ≥60 years to ≥50 years. • Immunocompromised people can receive Shingrix from age ≥18 years. People who are immunocompromised have an increased risk from many vaccine-preventable diseases, and this includes many rheumatology patients due to the medication(s) that they are prescribed to manage their disease. The reactivation of varicella-zoster virus is the most recognised infection complication with Janus kinase inhibitors, which places rheumatology patients taking this class of medicines at even greater risk. The varicella zoster vaccine that is currently listed on the NIP is Zostavax®, which, as a live vaccine, is not suitable for people taking highly immunosuppressive medicines, including biological or targeted synthetic DMARDs or high-dose corticosteroids. Many rheumatology patients are therefore unable to receive Zostavax® without interruption of therapy, which can result in a flare of their disease.	**Reviewed. No change in recommendation made.**	The *Australian Immunisation Handbook* update will recommend the use of Shingrix instead of Zostavax in people who cannot receive live vaccines.

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7b		A key implementation issue is the affordability of Shingrix®. Currently, the out-of-pocket cost for a course of Shingrix® is approximately $600 (2 doses at $300 each). Consumers with arthritis already often struggle to cope with high out-of-pocket costs of managing their condition, which can be exacerbated by the impact of their condition on their ability to work and earn an income. We believe that the addition of the inactivated varicella zoster vaccine (Shingrix®) to the NIP and PBS is essential for immunocompromised people with arthritis. This will ensure that they can access the safest vaccine without being financially disadvantaged. We understand that this consultation is not directly looking at the inclusion of vaccines in the NIP and PBS, but we would like our comments on this issue to be noted. We are aware that the PBAC considered this matter in November 2018 and felt that further information and modelling were required. Unfortunately, we understand that the sponsor has no plans to resubmit the application to the PBAC. This illustrates a major gap in the current system, which was highlighted in the report of the House of Representatives Standing Committee on Health, Aged Care and Sport inquiry into approval processes for new drugs and novel medical technologies in Australia.	**Reviewed. No change in recommendation made.**	Comment noted with thanks. This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.

	Organisation	Comment	Proposed Action	Rationale
8a	Individual	Re the new recommendation 'All adults aged ≥50 years are recommended to receive zoster vaccine'. It is perplexing why this new recommendation is so general, given the evidence cited within the draft 'Changes to the recommended use of zoster vaccines'. eg 'In immunocompromised adults aged ≥50 years, Zostavax is generally contraindicated and Shingrix should be used', page 8. 'Zostavax is contraindicated in people with significant immunocompromise, making Shingrix the only suitable vaccine for prevention of herpes zoster and associated complications in this population. Shingrix is the only zoster vaccine registered for use in immunocompromised people aged 18–49 years', page 9. 'However, since late 2021, Shingrix has been registered for use in people aged ≥18 years who are immunocompromised, and Shingrix is now the recommended vaccine for all levels of immunocompromise', page 9. Given the global pandemic and the increased impact of SARS-CoV-2 on the immune system overall, isn't the risk of contracting shingles even more of a concern now, in the immunocompromised 50+ cohort? While ATAGI is responsible for providing recommendations on the best clinical use of vaccines in Australia, I fail to understand why the new recommendation (All adults aged ≥50 years are recommended to receive zoster vaccine) is not broken down to allow for vaccine-specific recommendations for each of the immunocompetent and immunocompromised, given the evidence cited. It could be argued that advice for the over-50 cohort would be best separated into 2 distinct recommendations: for immunocompetent and immunocompromised adults over 50.	**Reviewed. Change in recommendation made.**	The wording of the recommendation now makes reference to immune status.

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8b		The fact that Shingrix is not funded under the NIP is arguably not only inequitable (significant out-of-pocket cost to individuals that could preclude it as an option) but also has the potential to be ultimately more costly to government and society as a whole, as a public health and workforce disruption issue – factors also arguably within ATAGI's remit. A vaccine/age/immune status–specific recommendation would leave no doubt that NIP funding of Shingrix to the over-50 immunocompromised cohort (along with the immunocompromised 18–49-year cohort) is an essential clinical, public health and economic measure that the PBAC should implement with some urgency. Regardless of the wording within this review, the NIP funding of Shingrix to any immunocompromised person (following individual medical review) needs urgent Australian Government attention. As an immunocompromised person who is in the privileged position to be able to afford Shingrix, I am grateful it was developed and registered by the Therapeutic Goods Administration (TGA). It is entirely inequitable and extremely poor public health policy for it to only be available to immunocompromised people who can afford it. ATAGI has a responsibility, I believe, to make strenuous representations to government to make it available via the NIP to the immunocompromised population. I would lend my support to any such representation efforts.	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.
9	Individual	The current free vaccine has less than half the efficacy of the newer Shingrix vaccine. Plus, Shingrix is safe to administer to immunocompromised patients. Shingrix will prevent a great deal of pain and suffering from herpes zoster infection. It will result in less serious complications including permanent ophthalmic damage, including blindness. Shingrix will result in less hospitalisations and will save on public health costs.	**Reviewed. No change in recommendation made.**	The recommendation for a preference of Shingrix over Zostavax is based on higher efficacy and duration of protection. This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.

	Organisation	Comment	Proposed Action	Rationale
10a	Individual	The unintended consequence of huge significance is you create a disincentive for anyone immunocompetent to take any vaccine. As Shingrix is so much more favourable on efficacy grounds, people will decline Zostavax but can't afford Shingrix. You may actually find fewer people are protected that really need that protection. Australians are much more vaccine-knowledgeable and literate now after the COVID-19 vaccine rollout and will avoid live vaccines of low efficacy that wane quickly with no booster available. I am a retired medical practitioner. I would like to give a personal perspective. I have previously had shingles, requiring oral antiviral treatment. I recently considered zoster immunisation. I could not justify taking a live vaccine when the vaccine substantially wanes in efficacy, and no booster is recommended. This means as I age and become more vulnerable to shingles, I will have even less protection. I would prefer to have the Shingrix vaccine, but find the cost prohibitive. Recently, I asked my aged parents to have vaccines also. They are aged in their 80s. They googled and did their own research. Please note that the elderly are more computer-literate now and will do own research, not just accept GP advice blindly. They said ATAGI recommends Shingrix as much higher efficacy. That it is funded in the United States. However, they will not each pay for it; that would be $1000 they don't have. So rather than take the inferior product, they have said they will wait for Shingrix to be listed on the NIP. In other words, try as I might, they don't want the live attenuated product because they want the best. Well, who doesn't want the best? That's human nature. So I urge the government to consider people wary of live vaccines due to past neurological vaccine complications, and the many elderly who decline vaccination waiting for 'the better one'. Consider how a person in their 50s cannot really take Zostavax knowing it wanes considerably and there is no booster when they are more vulnerable. Please list Shingrix on the NIP for anyone aged 50 years and older.	**Reviewed. No change in recommendation made.**	The purpose of the *Australian Immunisation Handbook* is to present the best available evidence for clinical decision-making, and, while it provides information on NIP-funded vaccines, it is independent of funding. The Handbook update will recommend zoster vaccination in all individuals aged over 50 years, with the permissive use of Zostavax in immunocompetent individuals in this age group as it remains a safe and efficacious vaccine. Zostavax is funded under the NIP for people aged 70 years and over, with a catch-up program for people aged 71–79 years until 31 October 2023. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.

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10b		You need to assess the true incidence of shingles in people repeatedly infected by SARS-CoV-2. You should not use pre-pandemic data; SARS-CoV-2 is associated with post-COVID reactivation of varicella. I also urge the government to consider the immune status of the population after rampant SARS-CoV-2 transmission, an infection with emerging evidence for T4 cell suppression and lymphopenia commonly occurring after severe disease. Any thinking medical person of even modest intellect might consider WHY viruses hitherto controlled in the western world are now becoming problematic, like monkeypox. Could it be SARS-CoV-2 is a mass immune disabling event? There is emerging evidence that SARS-CoV-2 increases risk for reactivation of other viruses, including varicella. This means broad immunisation against shingles becomes compelling, using the safest and most efficacious vaccine. I encourage ATAGI to make enquiries about whether there has been a lift in prescribing of antivirals for shingles in the past year, and to also enquire on hospital discharge diagnosis of shingles. Is the incidence in a pandemic world increasing? An incidence of 6 per 1000 in the 50–59 age group is not insignificant, but I suspect this incidence is a historic pre-pandemic one, and it is crucial that ATAGI make enquiries on the CURRENT incidence of herpes zoster.	**Reviewed. No change in recommendation made**	The relationship between herpes zoster and prior SARS-CoV-2 infection is an area of research. Data are currently insufficient to clearly establish a causal relationship between the 2 conditions. However, the epidemiology of vaccine-preventable diseases such as herpes zoster is routinely reviewed as part of updates to the *Australian Immunisation Handbook*. Disease burden and epidemiology are considered by the PBAC in its assessment of the cost-effectiveness of vaccines, to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.
11a	Individual	If all mildly immunocompromised people need to have serology before vaccination, this is likely to result in missed opportunities to vaccinate. Many people just won't bother to get the serology done but would have accepted the vaccine when offered by their GP. Rating: highly likely to occur. Need to clearly outline who should be offered serology – for example, are people with type 2 diabetes considered mildly immunocompromised?	**Reviewed. No change in recommendation made.**	The *Australian Immunisation Handbook* will provide guidelines for determining people who are significantly immunocompromised and for whom Zostavax is contraindicated. Individuals with lower levels, or an uncertain degree, of immunocompromise who are being considered for Zostavax should have serological testing to assess the risk of Zostavax. Providers should counsel patients about the importance of performing serology serology, as it is important for determining safety of Zostavax, and the risk of severe adverse events after vaccination.
11b		If people are offered the vaccine earlier, there is a chance their ATAGI record will not be checked when they turn 70 and they may be given a second zoster. Can practice systems be automated to remove the reminder for zoster at 70 if this is documented on the AIR as given at an earlier age?	**Reviewed. No change in recommendation made.**	AIR issues and practice system updates are implementation issues. Such matters will be managed by the Australian, and state and territory health departments, and are outside the scope of this public consultation document.
11c		I would imagine most 18–25-year-olds who are immunocompromised would have already received the chickenpox vaccine as infants. So not sure why this recommendation is started at this age. This just means that some people who have had varicella vaccine as children will now receive costly and unnecessary Shingrix.	**Reviewed. No change in recommendation made.**	Shingrix is not recommended for use in those who received a varicella vaccine when it was indicated.

	Organisation	Comment	Proposed Action	Rationale
11d		I do not understand the rationale for offering healthy people the vaccine at 50. As they age, they may become unhealthy and more likely to get shingles when in their 80s and with subsequent post-herpetic neuralgia. Is research planned or currently underway to determine the need for, and safety of, boosters?	**Reviewed. No change in recommendation made.**	The recommendations suggest consideration of the duration of protection when deciding on the timing of zoster vaccination. ATAGI will continue to monitor evidence on duration of protection of zoster vaccines and the need for and safety of boosters.
11e		While it is helpful to have a guideline on giving zoster vaccine after incorrect administration of varicella vaccine, what is the scenario if you do not know if the administration of varicella was incorrect? For example, a migrant over 14 is given 2 varicella vaccine doses as part of catch-up. You have no idea if this person already had chickenpox, and routine serology was not performed before vaccination. Can this person then have a shingles vaccine in later life? They have been given the varicella vaccine but, if they had already had chickenpox, they will still be at risk of shingles. Can this be clarified in the guidelines? I imagine the administration of the varicella vaccine to people who have already had chickenpox would be a common occurrence. I know we gave chickenpox vaccine to year 7s in the school program, and many would have already had chickenpox.	**Reviewed. No change in recommendation made.**	Shingrix can safely be given to those who have previously had a varicella vaccine or zoster vaccine, or experience varicella (chickenpox). However, zoster vaccination in people who have had varicella vaccine is not currently recommended. Studies of the safety and immunogenicity of zoster vaccines in people who have previously received varicella vaccine are limited, and data are insufficient to suggest a benefit from zoster vaccination.
11f		It is really difficult to offer someone a vaccine, explain the benefits and then say but you have to pay and it is expensive. While I understand the NIP will not fund this, could it be PBS listed at least for Health Care Card holders, and could health funds provide a larger rebate for vaccines?	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC. Although historically some vaccines were funded by the PBS, this funding model is no longer available since the introduction of the PBAC model.
12a	Australian College of Nursing (ACN)	ACN commends ATAGI for guidelines that are clear and easy to read. The guidelines for selecting which vaccine to administer to each adult are clear and well explained; however, there are some concerns, as detailed below. For ACN members, the persistent effects of shingles were a strong reason for encouraging vaccination. Members note that Shingrix appears to be more effective than Zostavax for a longer period and within the older population. Individuals should be well informed of the differences in the types of vaccine and their longer-term efficacy prior to determining which they should choose. The cost should not be a prohibiting factor in their decision – Shingrix should not be unaffordable to older community members.	**Reviewed. No change in recommendation made.**	This is a funding issue and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.

	Organisation	Comment	Proposed Action	Rationale
12b		A concern for many members was that the lowered age for receiving their zoster vaccine would mean that, in their more vulnerable years when shingles was likely to have more severe symptoms, they would not be able to receive a booster according to the guidelines. There was a clear recommendation that ATAGI revise the statement 'there is no current recommendation for boosters for either vaccine'. Developing guidelines for boosters to maintain good health and wellbeing into later age would be a fair and equitable addition to the guidelines.	**Reviewed. No change in recommendation made.**	The recommendations suggest consideration of the duration of protection when deciding on the timing of zoster vaccination.
12c		ACN members commended accessibility of the public health campaign and website (Know Shingles) to raise awareness of shingles in the community. When the changes to the zoster vaccine are approved, members suggested a reinvigorated health campaign to raise awareness of the benefits of being vaccinated. The campaign should highlight the risks of developing shingles, the longer-term symptoms and the length of time the symptoms last.	**Reviewed. No change in recommendation made.**	Comment is outside the scope of this public consultation document. Communication strategies will be managed by the Department of Health and Aged Care, as per standard processes.
12d		ACN members stressed the need for reliable feedback on any unforeseen reactions and/or incidence of anaphylaxis. Data on the number of Guillain Barré syndrome (GBS) cases appearing in those receiving the Shingrix vaccine should also be collected for Australia. This may impact the recommendations for who should receive which vaccine. Members noted that GBS may be the result of the zoster virus itself; this needs further research. Good data collection should be mandatory for reactions to all vaccines, with the ability to input data at any location where vaccines are administered.	**Reviewed. No change in recommendation made.**	Comment is outside the scope of this public consultation document. As for other vaccines, adverse events should be reported to the TGA (https://www.tga.gov.au/reporting-adverse-events). The TGA monitors adverse event reports for safety signals and will initiate investigations if any are found.
12e		Further research into the effectiveness of the vaccines and long-term protection provided by vaccines in immunocompromised people is also recommended.	**Reviewed. No change in recommendation made.**	Comment is outside the scope of this public consultation document. ATAGI will continue to monitor the evidence on vaccine effectiveness and durability of protection.
13a	GSK	*Australian Immunisation Handbook*, page 4: 'Herpes zoster occurs most commonly in people who: are of older age – particularly >50 years'. To align with the recommendation of herpes zoster immunisation in adults ≥50 years, we suggest changing > to ≥.	**Reviewed. Change in recommendation made.**	Recommendation wording updated to '≥50'.

	Organisation	Comment	Proposed Action	Rationale
13b		*Australian Immunisation Handbook*, pages 6, 8, 9: 'Effectiveness of Zostavax appears to wane more quickly, decreasing significantly by 5–10 years after vaccination'. Efficacy against herpes zoster at an average of 3.1 years after vaccination with Zostavax was 38% in adults aged 70 years and older (Zostavax product information), which aligns with the NIP-funded cohort. Further, Australian data show initial Zostavax efficacy of 63.5% (average 8 months post-vaccination) in adults aged 70–79 waning to below 50% efficacy (48.2%, average 18 months post-vaccination) (Lin et al 2021). The current wording may suggest that Zostavax provides high protection in the first 5 years, and further clarification on efficacy may help ensure a clear understanding of the level of protection that can be expected after vaccination with Zostavax, both initially and over time. References: Lin et al (2021): https://doi.org/10.1016/j.vaccine.2021.01.067 Zostavax product information: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-01547-3&d=20220804172310101	**Reviewed. No change in recommendation made.**	Waning of vaccine effectiveness is likely to be gradual, and is dependent on age, immune status and the starting vaccine effectiveness. Review of the current evidence supports this statement remaining unchanged.
13c		*Australian Immunisation Handbook*, pages 6, 8: 'Shingrix has demonstrated high vaccine efficacy for 7 years after vaccination'. We suggest changing wording to 'at least 7 years' to reflect the ongoing studies assessing efficacy up to 11–15 years after vaccination (https://clinicaltrials.gov/ct2/show/NCT05371080?term=NCT05371080).	**Reviewed. Change in recommendation made.**	Recommendation wording updated to 'Shingrix has demonstrated high vaccine efficacy for at least 7 years after vaccination. Ongoing studies are assessing the efficacy for up to 11–15 years after vaccination'.
13d		*Australian Immunisation Handbook*, pages 10, 11: 'People who have received varicella vaccine are not recommended to receive zoster vaccine', 'A person vaccinated with varicella vaccine in the past (that is, following the NIP schedule or clinical guidance because they were non-immune to varicella-zoster virus) is unlikely to have had wild-type chickenpox. This means that they are unlikely to require zoster vaccine as they get older'. There is uncertainty about the effect of varicella vaccine on herpes zoster incidence in key cohorts for vaccination (older adults, people with immunocompromising conditions). No other country has made this recommendation to avoid herpes zoster vaccination after varicella vaccination.	**Reviewed. No change in recommendation made.**	Shingrix can safely be given to those who have previously had a varicella vaccine or zoster vaccine, or experience varicella (chickenpox). However, zoster vaccination in people who have had varicella vaccine is not currently recommended. Studies of the safety and immunogenicity of zoster vaccines in people who have previously received varicella vaccine are limited, and data are insufficient to suggest a benefit from zoster vaccination.

	Organisation	Comment	Proposed Action	Rationale
13e		*Australian Immunisation Handbook* statement/text, page 10: 'Vaccine effectiveness studies on Shingrix using observational data have also shown good protection against herpes zoster. Participants in these studies were a general immunocompromised population aged ≥65 years, and people aged ≥50 years being treated for inflammatory bowel disease on immunosuppressant medications'. We suggest also including the 'general autoimmune disease population' included in the referenced Izurieta et al study (ATAGI reference 40) that demonstrated vaccine efficacy of 68.0% after 2 doses. Reference: Izurieta (2021): https://doi.org/10.1093/cid/ciab125	**Reviewed. No change in recommendation made.**	The Izurieta et al (2021) paper was reviewed as part of the GRADE assessment on the use of Shingrix in immunocompromised people aged 18 years and older. The vaccine effectiveness estimates for the population with autoimmune conditions were not included in this assessment because the authors' inclusion criteria for autoimmune conditions in their supplementary documents specified that participants were not required to be on immunosuppressive medications. The specific immunocompromised population and its corresponding vaccine effectiveness estimate was selected from this study.
13f		*Australian Immunisation Handbook*, page 6: 'People who are immunocompetent are recommended to receive a 2-dose schedule of Shingrix, 2 months apart, for the prevention of herpes zoster and associated complications'. The approved schedule for Shingrix immunisation is 2 doses 2–6 months apart. This flexibility in timing for the second dose is important to achieve high completion rates.	**Reviewed. Change in recommendation made.**	Recommendation wording updated to '2–6 months apart'.
13g		*Australian Immunisation Handbook*, page 8: 'People who are immunocompromised are recommended to receive a 2-dose schedule of Shingrix, 1–2 months apart, for the prevention of herpes zoster and associated complications'. To align with the ATAGI statement on zoster vaccines and the TGA-approved indication for Shingrix, consider updating the recommendation to include: • people who are shortly expected to be immunocompromised • a 2-dose schedule 2–6 months apart for the general immunocompromised population • a shorter interval of 1–2 months in individuals who are currently or shortly expected to be immunocompromised and who would benefit from a shorter vaccination schedule.	**Reviewed. Change in recommendation made.**	Wording updated to include people who are shortly expected to be immunocompromised.
13h		*Australian Immunisation Handbook*, pages 7, 9: 'People who have previously received Zostavax can receive Shingrix if they wish to increase their protection against herpes zoster'. Australian healthcare professionals rely on clear advice from ATAGI and the *Australian Immunisation Handbook*. There is no explanation of why they might want to increase their protection against herpes zoster after Zostavax vaccination. We suggest adding further reference to rapid waning of protection afforded by Zostavax, particularly in the NIP-funded (70–79-year-old) age group.	**Reviewed. Change in recommendation made.**	Wording updated to include rapid waning of Zostavax, to provide rationale for why an individual may want to increase their protection against herpes zoster.

	Organisation	Comment	Proposed Action	Rationale
13i		'Shingrix has been demonstrated to be immunogenic and safe in people who had received Zostavax a minimum of 5 years earlier'. Consider updating to 'within 1 year' and including efficacy to align with newly published evidence: • Lu et al (2021): https://doi.org/10.1016/j.ophtha.2021.04.017 (within 1 year) • Sun et al (2021): https://doi.org/10.1016/j.vaccine.2021.05.056 (within 1 year) • Izurieta et al (2021): https://doi.org/10.1093/cid/ciab125 (within 5 years) • Sun et al (2021): https://doi.org/10.1093/cid/ciab121 (within 5 years).	**Reviewed. No change in recommendation made.**	The permitted interval for use of Shingrix following Zostavax is 12 months, and the chapter provides guidance on the considerations for timing of zoster vaccination.
13j		Co-administration: Based on the co-administration advice presented in the ATAGI statement on the clinical use of zoster vaccines, consider including Prevenar 13 co-administration based on recently published phase III clinical trial data (Min et al 2022). The TGA is yet to evaluate this addition to the Shingrix product information. Reference: Min et al (2022): https://doi.org/10.1016/j.jinf.2021.12.033	**Reviewed. Change in recommendation made.**	Wording updated to include Prevenar 13 in co-administration advice.
13k		The *Australian Immunisation Handbook* recommendations are about vaccination in immunocompromised populations ≥18 years. The TGA-approved indication for Shingrix in adults aged ≥18 years is broader and covers individuals at increased risk, independent of their immune status. It could be helpful to provide clarity for healthcare providers on specific groups of individuals that ATAGI considers to be at increased risk through immunocompromise or other factors, as described by NCIRS and the New Zealand Manatū Hauora Ministry of Health, supported by Kawai & Yawn (2017), Marra et al (2020) and Izurieta (2021). References: New Zealand Manatū Hauora Ministry of Health: https://www.health.govt.nz/our-work/immunisation-handbook-2020/23-zoster-herpes-zoster-shingles#22-5 (Table 23.1) NCIRS frequently asked questions: https://www.ncirs.org.au/sites/default/files/2022-05/Zoster%20vaccines%20-%20Frequently%20asked%20questions_11_May_2022_Final.pdf Kawai & Yawn (2017): https://doi.org/10.1016/j.mayocp.2017.10.009 Marra et al (2020): https://doi.org/10.1093%2Fofid%2Fofaa005 Izurieta et al (2021): https://doi.org/10.1093/cid/ciab125	**Reviewed. No change in recommendation made.**	The *Australian Immunisation Handbook* update will recommend assessment on a case-by-case basis of the degree of immunocompromise using the 'Live shingles vaccine (Zostavax) screening for contraindications' tool and recommend that, if there is any uncertainty about the level of immunocompromise, Zostavax should not be administered and Shingrix should be used instead. There will also be a link to the chapter 'Vaccination for people who are immunocompromised', which provides guidance on assessing the extent of immunocompromise before vaccination (https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-people-who-are-immunocompromised#assessing-people-who-are-immunocompromised-before-vaccination).
13l		ATAGI text, page 10: 'haematopoietic stem cell transplantation'. We suggest specifying 'autologous' to differentiate from allogeneic stem cell transplant and align with the clinical trial data.	**Reviewed. Change in recommendation made.**	Wording of evidence for recommendation updated to specify autologous.
14a	Individual	No – the review is comprehensive.	**Reviewed. No change in recommendation made.**	Comment noted with thanks.

	Organisation	Comment	Proposed Action	Rationale
14b		No	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
14c		Thanks for updating the recommendations!	**Reviewed. No change in recommendation made.**	Comment noted with thanks.
15	Individual	Efficacy versus Shingrix vaccine to allow health consumers to make an informed choice about which vaccine will be best for them.	**Reviewed. No change in recommendation made.**	There are currently no studies that directly compare Zostavax and Shingrix. Comparison of clinical trial data demonstrates higher vaccine efficacy of Shingrix against placebo than Zostavax against placebo for the outcomes of herpes zoster and post-herpetic neuralgia. The duration of protection is also longer for Zostavax than for Shingrix.
16a	Seqirus	Seqirus welcomes the opportunity to contribute to the ATAGI consultation on proposed changes to the recommended use of zoster vaccines and notes the efforts to update recommendations in line with evolving evidence. We hope that our feedback enclosed is useful for the development of the updated final recommendations to be included in the *Australian Immunisation Handbook*. • New recommendation – adults: 'All adults aged ≥50 years are recommended to receive zoster vaccine'. Wording describing immunocompromise in the proposed update does not appear to be consistent throughout the updated recommendations. For example, 'Zostavax is not recommended for people who are or have recently been immunocompromised' may contradict later wording in the new recommendation for people that are immunocompromised: 'Zostavax is contraindicated in people with severe immunocompromise. However, Zostavax may be given to people with mild immunocompromise where Shingrix is not accessible, after careful assessment of the degree of immunocompromise …'. Seqirus suggests that clear reference to immunocompromise (severity/degree, duration) is made consistent throughout each recommendation in the zoster chapter of the Handbook.	**Reviewed. Change in recommendation made.**	Wording updated to be consistent with regard to level of immunocompromise.

	Organisation	Comment	Proposed Action	Rationale
16b		• New recommendation – people who immunocompromised: 'People aged ≥18 years who are immunocompromised are recommended to receive zoster vaccine'. New proposed wording in this recommendation includes the following: 'Zostavax is contraindicated in people with severe immunocompromise. However, Zostavax may be given to people with mild immunocompromise where Shingrix is not accessible, after careful assessment of the degree of immunocompromise …'. Zostavax remains an important option for consideration in appropriate patients, given its easier access due to funding on the NIP and its single-dose administration schedule. Seqirus suggest that this be reinforced in recommendations relating to its use in immunocompetent people, particularly those aged 70–79 years who may be able to access funded vaccine.	**Reviewed. No change in recommendation made.**	Recommendations already state that a single dose of Zostavax remains an effective alternative to Shingrix in people who are immunocompetent. It also describes the circumstances in which those who are mildly immunocompromised may consider Zostavax.
16c		To increase awareness of the potential risk of disseminated varicella-zoster virus infection with the vaccine-type strain in people with compromised immune function, in April 2021, Seqirus implemented a number of risk minimisation actions in collaboration with the TGA. These included updates to the Zostavax product information and consumer medicine information documents (including boxed warnings in both), distribution of a 'Dear healthcare professional' letter, a safety alert on the TGA website, and distribution of patient alert cards and warning stickers to be placed on refrigerators where the vaccine is stored. Seqirus continues to reinforce the appropriate use of Zostavax in immunocompetent persons. Recent communication from TGA's Advisory Committee on Vaccines – see Meeting Statement 27, 1 December 2021 – noted that the main area of difficulty is not a lack of awareness that Zostavax should not be given to immunocompromised persons, but the difficulty surrounding the assessment and definition of 'immunocompromise'. They suggest that simplification of clinical criteria and clinical guidance from ATAGI may assist in the decision to identify an immunocompromised person who should not be vaccinated, while acknowledging that there has been insufficient time for risk minimisation actions to have taken effect. While acknowledging the difficulty in defining immunocompromise, given the heterogenous factors influencing it, Seqirus believes it is important that the recommendations included in the *Australian Immunisation Handbook*, particularly those relating to 'mild immunocompromise', are expanded on further. GPs and other clinicians administering Zostavax may require further elucidation to help them understand their patient's degree of immunocompromise to enable appropriate prescribing. We note that the 'Live shingles vaccine (Zostavax) screening for contraindications' tool developed does not include or define the term 'mild immunocompromise' and suggest that this wording be included, in addition to criteria to define it (eg monotherapy with allowed immunosuppressants at doses below the defined safe dose threshold).	**Reviewed. No change in recommendation made.**	The 'Live shingles vaccine (Zostavax) screening for contraindications' tool has been developed to facilitate identification of people who may be contraindicated for vaccination with Zostavax. Case-by-case assessment is then required by the patient's vaccine provider, immunisation specialist or treating specialist.

	Organisation	Comment	Proposed Action	Rationale
16d		In addition, to facilitate access to the tool, we also recommend including a direct link to the 'Live shingles vaccine (Zostavax) screening for contraindications' tool in the new recommendation for people who are immunocompromised rather than having to access it via the 'Handbook tables' section of the *Australian Immunisation Handbook* website or via the 'Statement on the clinical use of zoster vaccines in adults in Australia'. Seqirus also suggests, if possible, that reference is made to the severity of immunocompromise consistently throughout each recommendation in the zoster chapter of the Handbook.	**Reviewed. No change in recommendation made.**	The *Australian Immunisation Handbook* update will be revised to include new links to appropriate resources and other relevant chapters in the Handbook.
16e		New recommendation: 'People who inadvertently received a varicella vaccine when a zoster vaccine was indicated are recommended to receive a subsequent zoster vaccine'. Seqirus recommends a statement in the explanation of the recommendation to highlight that potencies of varicella vaccines are significantly lower than those of zoster vaccines – for example, '… but the dose should not be considered valid given that potencies of varicella vaccines are significantly lower than those of zoster vaccines'.	**Reviewed. No change in recommendation made.**	The recommendation states that people who inadvertently receive a varicella vaccine when a zoster vaccine was indicated should receive a subsequent zoster vaccine and that the varicella vaccine is not considered valid protection against herpes zoster.
16f		New recommendation: 'Serological testing is recommended before administration of Zostavax in people with mild immunocompromise'. Seqirus refers again to our comments made above in relation to defining mild immunocompromise. We suggest that consideration be given to the recommendation of varicella-zoster virus serological testing, given that primary care clinicians likely lack experience in ordering and interpreting these tests. There is a possibility that this recommendation may lead to further confusion regarding the degree of immunocompromise. Therefore, should advice regarding the need for serological testing be made only by specialist physicians who have been directly consulted by GPs?	**Reviewed. Change in recommendation made.**	Wording updated to 'People with severe immunocompromise are contraindicated to receive Zostavax. Individuals with lower levels or an uncertain degree of immunocompromise who are being considered for Zostavax should have serological testing to assess the risk of Zostavax'.
17a	Royal Australian College of General Practitioners	Equity and accessibility: Research has demonstrated that barriers to vaccination are often practical, and include lack of access to medical services, lack of social support and competing pressures (Pearce et al 2015). At present, Zostavax is only funded under the NIP schedule for people aged 71–79 years. While expanding this to aged ≥50 years can decrease the rate of herpes zoster in the community, consideration must be given to the financial barriers. It is essential that vaccines are available in an equitable manner, and access is not dependent on the ability to pay for private vaccines or to access health care. References: Pearce A, Marshall H, Bedford H, Lynch J. Barriers to childhood immunisation: Findings from the Longitudinal Study of Australian Children. Vaccine. 2015;33(29):3377-3383.	**Reviewed. No change in recommendation made.**	This is a funding comment and outside the scope of this public consultation document. The PBAC assesses the cost-effectiveness of vaccines to determine if they can be included in the NIP. At this time, Shingrix has not been assessed as cost-effective by the PBAC.

	Organisation	Comment	Proposed Action	Rationale
17b		Knowledge gaps: New research has indicated that knowledge gaps exist among Australian GPs regarding live attenuated zoster vaccination of immunocompromised people (Dey at al, 2022). Changes in the recommendations must be supported by appropriate messaging and engagement with the health sector to ensure that clinicians are aware of these amendments. References: Dey A, Rashid H, Sharma K, Phillips A, Li-Kim-Moy J, Manocha R, Macartney K, Beard F. General ractitioner knowledge gaps regarding live attenuated zoster vaccination of immunocompromised individuals: An ongoing concern? 2022 July;51(7)	**Reviewed. No change in recommendation made.**	Communication strategies will be managed by the Department of Health and Aged Care.
17c		Monitoring vaccine safety, uptake and effectiveness: It is essential that all vaccinations are tracked and monitored; however, there are still some barriers with accessing the AIR. A recent report of pharmacists found that accessing and using the AIR site was problematic and not intuitive (NCIRS, 2021) Further, vaccines administered in hospitals or to healthcare workers are not routinely tracked at a national level. This information is essential to ensure that priority populations are receiving vaccines and doses can be tracked nationally. Addressing these challenges will require an end-to-end solution that includes significant outreach with pharmacists, GPs, healthcare and aged care workers, and others to close the gaps in the current system. This will ensure that every single vaccine dose is tracked and that all practitioners who administer vaccines regularly report to the AIR. References: NCIRS. A survey of pharmacist vaccination reporting to the Australian Immunisation Register. Final Report – Part C. June 2021.	**Reviewed. No change in recommendation made.**	Implementation matters will be managed by the Australian, and state and territory health departments, and are outside the scope of this public consultation document.
17d		Household contacts and pregnancy: Further details on when vaccine protection begins would benefit clinicians when advising patients who live with an immunocompromised person. Practical details, such as when it is safe to share a living space, will ensure that full coverage is provided. Additionally, a recommendation on the use of Shingrix in pregnancy would be beneficial to help guide clinicians.	**Reviewed. Change in recommendation made.**	Additional wording has been added to the chapter on the use of Shingrix in women of child-bearing age. In the absence of data on the use on Shingrix, guidance has been provided to align with other vaccinations that are not routinely recommended in pregrnancy.
17e		Cold chain management: There are instances when patients travel to receive a vaccine if their local doctor does not supply the vaccine. As the herpes zoster vaccine is required to be cold stored, those that travel long distances to pharmacies to buy the vaccine may not be able to maintain the correct temperature, which could result in less than optimal response to the vaccine. Consideration of how best to overcome this barrier is encouraged.	**Reviewed. No change in recommendation made.**	Implementation matters will be managed by the Australian, and state and territory health departments, and are outside the scope of this public consultation document.

3. Appendix A – Public Consultation Distribution List

An email was sent on 8 July 2022 to the following organisations and committees to provide advice on the public consultation:

- Advisory Committee on Vaccines
- Australian Association of Practice Management Secretariat
- Australian Health Protection Principal Committee
- Australian Technical Advisory Group on Immunisation
- Communicable Diseases Network Australia
- Consumers Health Forum of Australia
- General Practice Roundtable
- Jurisdictional Immunisation Coordinators
- Primary Health Networks
- Pharmaceutical Benefits Advisory Committee
- National Health and Medical Research Council
- Royal Australian College of Physicians