

6.17 QUADRIVALENT INFLUENZA VACCINES

FluQuadri[®], Sanofi Pasteur

Fluarix[®] Tetra, GlaxoSmithKline Australia Pty Ltd

Afluria[®] Quad, Seqirus (Australia) Pty Ltd

Chief Medical Officer, Department of Health

1 Purpose of Application

- 1.1 The minor submission from the Chief Medical Officer (CMO) of the Department of Health requested that eligibility for National Immunisation Program (NIP) funded seasonal influenza vaccine for Aboriginal and/or Torres Strait Islander (Indigenous) people be expanded to include children and adolescents aged 5 to <15 years. The NIP currently provides free seasonal influenza vaccine each year to Indigenous people aged 6 months to <5 years and 15 years and over.

2 Requested listing

- 2.1 Table 1 outlines the brands of quadrivalent influenza vaccine that are currently listed on the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)* ('the Determination') and were provided through the NIP for the 2018 influenza season.

Table 1: Quadrivalent influenza vaccines currently listed on the NIP Schedule

Trade name	Sponsor	TGA registered indication	Age eligibility on NIP for Aboriginal and/or Torres Strait Islander peoples
FluQuadri	Sanofi pasteur	For active immunisation of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluQuadri is indicated for use in adults and children 3 years and older.	Aged at least 3 years but less than 5 years; and 15 years or older.
FluQuadri Junior		FluQuadri Junior is indicated for use in children aged 6 months to 35 months inclusive.	Aged at least 6 months but less than 3 years.
Fluarix Tetra	GlaxoSmithKline	For active immunisation of adults and children from 3 years of age for the prevention of influenza disease caused by the influenza virus types A and B contained in the vaccine.	Aged at least 3 years but less than 5 years; and 15 years or older.
Afluria Quad	Seqirus	For the prevention of influenza caused by Influenza Virus, Types A and B contained in the vaccine. The vaccine is indicated for use only in persons aged 5 years and over. ^A	Aged at least 18 years.

^A The TGA indication was amended from use only in persons aged 18 years and over, to persons aged 5 years and over, on 2 February 2018.

Note: Children aged <9 years who are influenza vaccine naïve require an additional dose in the first year of immunisation, four weeks after the initial vaccine.

- 2.2 If NIP eligibility for FluQuadri and Fluarix Tetra was expanded to Indigenous people aged 5 to <15 years, changes would be required to subsection 7(8) of the Determination.
- 2.3 A major submission from Seqirus requesting an extension to the current NIP listing of Afluria Quad to include children and adolescents aged 5 to <18 years who are currently eligible for other brands of free influenza vaccine through the NIP was also considered by the PBAC at its November 2018 meeting (*agenda item 6.04 refers*). Given the current NIP eligibility, the Seqirus submission specifically asked to extend the NIP listing to Indigenous people aged 15 to <18 years. The CMO requested that if Seqirus' submission is recommended that the PBAC consider expanding eligibility for Afluria Quad to include Indigenous people aged 5 to <18 years. Expansion of NIP eligibility for Afluria Quad would require changes to subsection 7(8)A of the Determination.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Background

- 3.1 In 2014, the Australian Technical Advisory Group on Immunisation (ATAGI) wrote to the PBAC seeking a recommendation to list seasonal influenza vaccines on the NIP for Indigenous people aged 6 months to <15 years, noting those aged 15 years and older were already eligible to receive a free dose each year.
- 3.2 The ATAGI requested seasonal influenza vaccination for Indigenous children aged 6 months to <5 years on the basis that the magnitude of increased risk of severe influenza among Indigenous children aged <5 years compared with non-Indigenous children was generally similar, by various severity measures, to that in children with underlying medical conditions for which annual influenza vaccination was already funded under the NIP. The ATAGI noted that the magnitude of increased risk was not as high for the 5 to <15 years cohort, compared with other age groups. However, ATAGI requested that immunisation of the broader age group (6 months to <15 years) be recommended on the basis of indirect benefits, such as providing herd immunity to other members of the community as well as better acceptance of the program by the community and enhanced program implementation.
- 3.3 The then Chief Medical Officer, Professor Chris Baggoley, was supportive of the request from the ATAGI to extend NIP funded seasonal influenza vaccine for Indigenous children aged 6 months to <5 years. However, Professor Baggoley noted that the 5 to <15 years cohort had the lowest rate of hospitalisations amongst all Indigenous age cohorts and that the risks and benefits of vaccinating this cohort were not directly comparable to the already funded medically-at-risk cohort. Professor Baggoley therefore expected that a cost effectiveness analysis of the 5 to <15 years cohort would be required to enable a PBAC recommendation.
- 3.4 In response to the 2014 submission, the PBAC recommended extending the availability of trivalent influenza vaccine under the NIP to include annual vaccination for all Indigenous children aged 6 months to <5 years (PSD, July 2014). The PBAC

considered that the cost-effectiveness of vaccination in this population was likely to be similar to the cost-effectiveness of vaccination in the already funded “medically at risk cohort” given the evidence provided by ATAGI and comparable vaccine effectiveness. The PBAC advised the Office of Health Protection (OHP) to encourage relevant companies to make a PBAC submission to demonstrate the cost effectiveness of vaccinating those aged 5 to <15 years against seasonal influenza.

- 3.5 The OHP advised that the relevant sponsors claimed that the small market and inadequate identification of Indigenous status in key morbidity and mortality data sets meant it would not be feasible to develop the submission requested by the PBAC in 2014.

For more detail on PBAC’s view, see section 5 PBAC outcome.

4 Consideration of the evidence

- 4.1 The CMO advised that the vaccine uptake rate amongst Indigenous children aged 6 months to <5 years in 2016 was only 11.6%. Public consultation and program evaluations have identified that the age gap in eligibility is an implementation challenge and may be discouraging uptake. The CMO advised that expanding the eligibility for seasonal influenza vaccines to all Indigenous people may assist to improve overall coverage of Indigenous families (both parents and children).
- 4.2 The CMO noted the increased burden of seasonal influenza amongst Indigenous people, compared with non-Indigenous people. The CMO stated that a key difference to the data presented in the 2014 submission was that the rate ratio of influenza related hospitalisations amongst 5 to 14 year old Indigenous Australians versus non-Indigenous Australians is now statistically significant (see Table 2).

Table 2: Rate ratio of ICD-coded hospitalisation for influenza (any diagnosis) of Indigenous Australians compared with other (non-Indigenous) Australians (all jurisdictions), 2010–2015, by age group

Age group	Rate ratio (95% CI)
0–5 months	2.7 (2.41–3.04)
6–23 months	2.5 (2.29–2.74)
2–4 years	1.5 (1.29–1.66)
5–14 years	1.4 (1.26–1.59)
15–29 years	2.1 (1.92–2.30)
30–49 years	3.2 (3.00–3.45)
50–64 years	4.3 (3.98–4.65)
≥65 years	2.0 (1.76–2.18)

Source: The Australian Institute of Health and Welfare (AIHW) National Hospital Morbidity Database analysed by the National Centre for Immunisation Research and Surveillance (NCIRS). An influenza hospitalisation was defined as an episode of hospitalisation recorded with ICD-10 codes J09, J10 or J11 as one of the diagnoses (principal or other) at separation (discharge).

- 4.3 The three sponsors with vaccines either listed or under consideration for use in this age group provided additional information with regards to safety and comparative effectiveness to support this submission. All three sponsors agreed to supply the vaccine for the requested cohort at their current contracted prices.

Vaccine cost/patient/year: \$ [REDACTED]

- 4.4 Vaccine cost of \$ [REDACTED] based on a single dose per child per year. This is equivalent to the nationally negotiated price for FluQuadri (≥3 years), Fluarix Tetra (≥3 years) and Afluria Quad (≥18 years).
- 4.5 For influenza vaccine naïve children aged 3 to <9 years, the cost would be \$ [REDACTED] in the first year based on the child receiving two vaccinations four weeks apart in the first year, followed by \$ [REDACTED] per child per year thereafter.

Estimated PBS usage & financial implications

- 4.6 Assuming the same uptake as in the 6 month to <5 years age group, of 11.6%, the minor submission estimated a net cost to the NIP of less than \$10 million in Year 6 of listing, and a total of less than \$10 million over the first six years of listing (see Table 3). As noted by the submission, costs would be marginally higher than these estimates as they do not account for children less than 9 years of age requiring two doses in the first year they receive a vaccine.

Table 3: Estimated utilisation and financial costs assuming uptake is unchanged

	Year 1 (2019)	Year 2 (2020)	Year 3 (2021)	Year 4 (2022)	Year 5 (2023)	Year 6 (2024)
Estimated number of Indigenous people aged 5-14 years	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Assumed uptake	11.6%	11.6%	11.6%	11.6%	11.6%	11.6%
Number of newly eligible children who would receive the vaccine	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Cost to the NIP using nationally negotiated price*	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

* As children <9 years require two doses in the first year they receive a vaccine, costs would be marginally higher.

- 4.7 The minor submission also presented utilisation and financial estimates if uptake were to increase to 20% for all age cohorts (including the new cohort). Under this scenario, the net cost to the NIP would be less than \$10 million in Year 6 of listing and a total of less than \$10 million over the first six years of listing.

For more detail on PBAC’s view, see section 5 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC recommended a change to the circumstances in which quadrivalent influenza vaccines currently listed on the NIP for people aged 5 to <15 years, (specifically, FluQuadri and Fluarix tetra) are designated vaccines for the purposes of the Act. The PBAC recommended that FluQuadri and Fluarix Tetra may be provided on the NIP to Aboriginal and/or Torres Strait Islander (Indigenous) people aged 3 years and older for the prevention of influenza.
- 5.2 The PBAC noted that the NIP currently provides free seasonal influenza vaccine each year to Indigenous people aged 6 months to <5 years and 15 years and older. The

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recommended change would provide access to seasonal influenza vaccine to all Indigenous people aged 6 months and older at no cost through the NIP.

- 5.3 The PBAC noted that another brand of quadrivalent influenza vaccine, Afluria Quad, is currently listed on the Determination for Indigenous people aged 18 years and older. At the same meeting, the PBAC recommended a change to the circumstances for Afluria Quad to allow use in people aged 5 years and older who are already eligible for other brands of influenza vaccine through the NIP. The PBAC considered that the recommendation for changes for Afluria Quad should also include Aboriginal and Torres Strait Islander people aged 5 to <15 years.
- 5.4 The PBAC recommended that the nationally negotiated price for the additional cohort for the three vaccines be the same as for the existing cohorts. The PBAC noted that all three sponsors agreed to supply the vaccine for the requested cohort at their current contracted prices.
- 5.5 The PBAC recalled that it recommended expanding eligibility for NIP funded influenza vaccine to Indigenous people aged 6 months to <5 years in 2014 on the basis of a submission from ATAGI and support from the CMO. OHP subsequently encouraged the relevant sponsors to make a PBAC submission requesting extension of eligibility for Indigenous people aged 5 years to <15 years; however, the sponsors advised this would not be feasible. The PBAC acknowledged the difficulty of developing such a submission given the small market and inadequate identification of Indigenous status in key morbidity and mortality data sets.
- 5.6 The PBAC noted the advice from the CMO that the age gap in eligibility for Indigenous people is an implementation challenge and may be discouraging current uptake. In this regard, the PBAC noted that uptake of influenza vaccine in Indigenous children aged 6 months to <5 years was only 11.6% in 2016. The PBAC anticipated that expanding eligibility for influenza vaccination to all Indigenous people aged 6 months and older would facilitate delivery of the vaccine to Indigenous people and reduce potential barriers to poor vaccine uptake across all age groups.
- 5.7 The PBAC noted that providing influenza vaccination to school-aged children may result in indirect benefits to non-immunised members of the community; this may be particularly important in the context of households comprising multiple generations.
- 5.8 The PBAC noted that if uptake in the additional age group is similar to the 6 months to <5 years ago group, the cost to the NIP would be less than \$10 million over the first six years of listing. However, the PBAC stated that the additional cost to the NIP would hopefully be larger than this estimate if removing the age gap results in higher uptake in the currently eligible age groups.
- 5.9 The PBAC noted that this submission is not eligible for an Independent Review because Independent Review is only relevant to submissions seeking PBS listing.

Outcome:

Recommended

6 Recommended listing

- 6.1 Amend the circumstances under which FluQuadri and Fluarix Tetra are available as designated vaccines such that they may be provided to an Aboriginal or Torres Strait Islander person who is aged at least 3 years.
- 6.2 Amend the circumstances under which Afluria Quad is available as a designated vaccine as specified for agenda item 6.04, Afluria Quad.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.