Record of the Immunisation Advisory Committee Ad-Hoc Meeting held on 10 October 2023

Immunisation Advisory Committee records are published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) Specialist Advisory Committees 2021.

Note that this document is not necessarily a complete record of the Immunisation Advisory Committee meeting; only the relevant portions of the meeting record relating to Immunisation Advisory Committee discussions about an application or Pharmac staff proposal that contain a recommendation are generally published.

The Immunisation Advisory Committee may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule.

Pharmac Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Committee meeting will be reviewed by PTAC at an upcoming meeting.

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

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1. Attendance

Present
Chair – Stephen Munn
Adibah Khan
David Murdoch
Elizabeth Wilson
Erasmus Smit
Lance Jennings
Michael Tatley
Nikki Turner
Osman Mansoor
Tony Walls

Apologies
Sean Hanna
Stuart Dalziel
Edwin (Gary) Reynolds

2. Summary of recommendations

2.1. No formal recommendation regarding the COVID-19 vaccine strain selection was sought at this meeting. However, the Committee considered there was a need for an updated COVID-19 vaccine strain in New Zealand for 2024.

2.2.

3. The role of Specialist Advisory Committees and records of meetings

3.1. This meeting record of the Immunisation Advisory Committee is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 2021 and Specialist Advisory Committees 2021.Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.

3.2. Conflicts of Interest are described and managed in accordance with section 6.4 of the SAC Terms of Reference.

3.3. The Immunisation Advisory Committee is a Specialist Advisory Committee of Pharmac. The Immunisation Advisory Committee and PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and

perspectives. The Immunisation Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for treatments for immunisation that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for immunisation that differ from the Immunisation Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by both the Immunisation Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for vaccines for immunisation.

4. Welcome and introduction

4.1. The meeting commenced with an opening karakia, mihimihi and whakawhanaungatanga.

4.2. The meeting welcomed two new members to the Committee, Prof David Murdoch and Dr Erasmus Smit.

5. COVID-19 vaccine composition in New Zealand

Background

5.1. The Committee noted that Pharmac sought clinical advice regarding the suitability of XBB.1.5 sublineage COVID-19 vaccine composition for use in New Zealand.

5.2. The Committee noted that COVID-19 XBB.1.5 vaccine has been recommended for use by the U.S Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee (FDA VRBPAC), by the World Health Organisation (WHO) and European Medicines Agency (EMA). The Committee noted that Northern Hemisphere countries were planning to roll out the XBB.1.5 vaccine programmes in the Northern Hemisphere Autumn 2023. The Committee noted that the Therapeutic Goods Administration (TGA) had not yet published its recommendations for the XBB.1.5 vaccine.

5.3. The Committee noted that its advice would inform Pharmac's COVID-19 vaccine procurement activities.

Discussion

5.4. The Committee noted the global circulation patterns of SARS-CoV-2 variants between 1 October 2022 and 16 April 2023 and considered that there continues to be substantial genetic and antigenic evolution of the virus. The Committee noted that XBB.1 descendant lineages, including XBB.1.5 and XBB.1.16 are dominant globally. The Committee noted that XBB descendant lineages, including XBB.1.5 and XBB.1.16 are highly immune evasive, with XBB.1.5 being one of the SARS-CoV-2 variants with the greatest magnitude of immune escape from neutralising antibodies to date.

5.5. The Committee noted that in the period from 21 August to 17 September 2023, EG.5 and its descendant lineages were the most reported globally at 51.8% of global reports. XBB.1.6 accounted for 10% and XBB.1.5 for 4.5% of global reports (WHO EG.5 Updated Risk Evaluation, 21 September 2023). The Committee considered that global antigen reporting data is becoming less complete, although New Zealand still has good data from wastewater monitoring.

5.6. The Committee noted ESR wastewater testing for August and September 2023 showed that the XBC lineage detections are dominant, followed by EG.5, then XBB 1.5 and XBB 1.6 (ESR monthly wastewater report). The Committee considered that the New Zealand sublineage landscape has tended to follow international trends with regard to circulating lineages. The Committee considered that many of the currently circulating sublineages are recombinant variants. XBB is a recombinant variant and EG is a lineage off XBB. The Committee considered that an XBB.1.5 vaccine would be expected to provide adequate protection for current circulating strains, including XBB recombinant sublineages.

5.7. The Committee noted that all estimates of protection against infection waned within months but remained high and sustained for hospital admission or severe disease. Individuals with hybrid immunity had the highest magnitude and durability of protection (Bobrovitz et al. Lancet Infect Dis 2023;23:556-67).

5.8. The Committee noted that the bivalent ancestral/BA.4.5 vaccine appears less effective against currently circulating Omicron strains in New Zealand.

5.9. The Committee noted that an XBB.1.5 vaccine would provide cross protection via neutralising antibodies for the BA 2.86 strain. The Committee considered that there is a limited number of studies comparing XBB.1.5 vaccine versus bivalent ancestral/BA.4.5 vaccine and therefore it was difficult to compare the effectiveness of vaccines against the current variants.

5.10. The Committee considered that the use of an XBB.1.5 vaccine in New Zealand would be appropriate unless circumstances arose, such as a change in disease burden from circulating viruses to a low/acceptable level, or a new lineage evolving that is antigenically very different from XBB.

5.11. The Committee noted that most hospitalisations in New Zealand currently are for XBB or EG.5 sublineages, consistent with waste-water surveillance. (ESR monthly waste-water report)

5.12. The Committee noted that international bodies such as the WHO's Technical Advisory Group of COVID-19 Vaccines (TAG-CO-VAC), the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) have recommended that new formulations of COVID-19 vaccines, used as a booster dose, should aim to induce antibody responses that neutralise XBB descendent lineages. One approach recommended by the WHO TAG-CO-VAC is the use of a monovalent XBB.1 descendent lineage vaccine, such as XBB.1.5 vaccine (WHO statement on the antigen composition of COVID-19 vaccines. 18 May 2023).

5.13. The Committee noted that in contrast, an Omicron-specific monovalent vaccine product as a standalone formulation for the primary series is not advised at this time as it is not yet known whether Omicron-specific vaccines will offer similar cross-reactive immunity and cross-protection from severe illness caused by other variants of concern in non-vaccinated individuals as the index virus-based vaccines have done (WHO statement on the antigen composition of COVID-19 vaccines. 18 May 2023). However, the Committee would be interested in reviewing New Zealand specific data as it becomes available.

5.14. The Committee noted that there is high seroprevalence in the global population as a result of widespread vaccination and/or infection. Immunological profiles against COVID-19 are heterogenous as individuals have been infected with different variants and/or vaccinated using different vaccine platforms. The Committee considered that

the New Zealand seroprevalence likely follows the international pattern. (WHO statement on the antigen composition of COVID-19 vaccines. 18 May 2023).

5.15. The Committee considered (at the time of the meeting) that there may be a need to have a vaccine available for primary courses and a different vaccine for booster doses, due to the lack of strong data. However, members considered there should only be one vaccine strain available for booster doses at any one time. The Committee further considered it reasonable, for implementation purposes, to only have one vaccine available for both primary and booster doses.

5.16. The Committee considered the future evolution of SARS-CoV-2 and the future efficacy of the XBB.1.5 vaccine against future circulating strains is unknown. Mutational rate/antigenic drift is unknown at this stage.

5.17. The Committee considered that New Zealand should move to using an XBB lineage vaccine as soon as it can due to the risk of future variants arising that could be more antigenically distant from the ancestral strain. The Committee considered that the current BA.4.5 vaccine remains effective against severe disease, therefore it would be appropriate to continue using remaining stock of BA.4.5 vaccine until an XBB.1.5 vaccine became available.

5.18. The Committee considered that it remained useful to have a protein subunit vaccine available as an alternative for people who do not tolerate an mRNA vaccine. The Committee considered it would be appropriate for a BA.4.5 protein subunit vaccine to remain available until an XBB formulation of this vaccine type was approved, even if an XBB formulation of mRNA vaccine gains Medsafe approval.