3 October 2022

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Tēnā koe Jessica

Agenda of 69th Meeting of the Medicines Classification Committee (MCC)

Thank you for the opportunity to provide comment on the agenda items for the 69th meeting of the MCC.

The Royal New Zealand College of General Practitioners (the College) is the largest medical college in New Zealand. Our membership of 5,748 general practitioners comprises almost 40 percent of New Zealand's specialist medical workforce. The Division of Rural Hospital Medicine also sits within the College's academic remit of vocational training of doctors working in rural hospitals. Our members cover both urban and rural settings, and work in a variety of business structures. The College kāupapa is to set and maintain education and quality standards for general practice, and to support our members to provide competent and equitable patient care.

Our submission

The College has commented on the following agenda items

- 6.1b Glecaprevir and Pibrentasvir (Maviret) – proposed change to prescription classification statement (Manatū Hauora/Ministry of Health, Long Term Conditions)
- 6.1e National Immunisation Schedule - proposed change to prescription vaccine classification statements (Manatū Hauora/Ministry of Health)

Agenda item 6.1b Glecaprevir and Pibrentasvir (Maviret)

Agenda item 6.1 is an application to the MCC from Te Whatu Ora/Health New Zealand, seeking to widen access to glecaprevir and pibrentasvir (Maviret), a treatment for chronic hepatitis C infection, by allowing nurses with appropriate knowledge and experience to administer Maviret without a prescription.

Summary of RNZCGP position

The College supports the proposed reclassification of Maviret which will improve access for a particularly marginalised population. The reclassification will apply to only a small group of experienced nurses specialising in Hepatitis C with close links to secondary care gastroenterology services. The College notes that existing mechanisms enabling nurse prescribing, are not being utilised.

The College supports improving equity of access to Maviret

Chronic hepatitis C disproportionately affects marginalised populations, who access health services infrequently. Fifty to eighty percent of people who inject drugs (PWID) are infected with Hepatitis C compared to only on in every 100-200 individuals in the general population. The distribution of Hepatitis C by ethnicity in New Zealand is not known however Māori are overrepresented among patients with advanced liver cancer due to Hepatitis C and emerging data suggests that Māori have a higher prevalence Hepatitis C and are likely to have higher rates of long-term complications than non-Māori.[1] The College's Foundation Standard requires general practices to have a commitment to the principles of the Treaty of Waitangi (Indicator 3.1). Practices are required to identify and understand the health needs of Māori and partner with local Māori organisations, provider groups and whānau to deliver on these needs.[2]

The College supports taking services to places frequented by people with a high incidence of Hep C to remove access barriers and improve uptake of diagnostic tests and treatment. These include shelters for the homeless, the locations of services for drug users, and prisons. Allowing suitably trained nurses to prescribe Maviret is an important enabler of such outreach. Nurse led management is one of the recommendations of the National Hepatitis C Action Plan for Aotearoa New Zealand, which provides a framework for working towards the World Health Organization's (WHO's) goal to eliminate viral hepatitis by 2030.[3]

Nurse led treatment for hepatitis C must be integrated with both secondary and primary care

We consider that integration with general practice is a key requirement for outreach programmes. We note the requirement for nurses prescribing Maviret to have ready access to their secondary care team is mentioned in the application (p16). but integration with primary care is not mentioned. Engagement with general practice facilitates patient follow up after treatment with Maviret but also enables other comorbidities to be identified and manged. Members of marginalised population groups such as PWID often have multiple chronic conditions including metal health conditions. The comprehensive holistic care provided in general practice is essential for patients with comorbidities.

The submission acknowledges that patients may have health concerns other than Hepatitis C and suggests that nurses would be advised to always recommend that the patient sees a general practitioner regularly for their wider health needs (p16). We consider that in this patient population assistance to enrol with a general practitioner should be provided. Facilitating enrolment could potentially be an additional advantage of this reclassification. Enrolment with a general practice provides access to comprehensive health care and significantly decreases the financial costs of appointments

Current programmes to enable nurse prescribing are less appropriate for single medication prescribing.

The reclassification proposal is essentially a workaround resulting from a lack of uptake of the established pathways to enable nurse prescribing namely Nurse Prescribing in Specialist and Community Teams[4] and Registered Nurse Prescribing in Community Health.[5] These programmes equip registered nurses to prescribe a range of medications however the proposal states that nurses involved in hepatitis C management consider that the time involved is a deterrent to taking up the prescribing pathway. (P 4)

Agenda item 6.1e National Immunisation Schedule

Agenda item 6.1e is an application to the MCC from Manatū Hauora/Ministry of Health. It proposes to widen the classification for a number of vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer vaccines.

Summary of RNZCGP position

The College considers that improving the current process to enable authorised vaccinators to deliver a wider range of vaccinations should be explored, prior to consideration of reclassification. Moving from local to national authorisation of vaccinators and national approved vaccination programmes would remove the current geographic barriers for trained vaccinators wishing to administer the unfunded vaccines referred to in the application.

Should reclassification be considered necessary, a revised proposal which separately addresses childhood vaccines, unfunded adult vaccines and travel vaccines should be submitted. In this application the proprietary names of the vaccines under consideration should be included in the proposal. The College would likely support such a reclassification of adult vaccines, would likely support the role of pharmacists and other authorised vaccinators in providing childhood vaccines as part of an Outreach Immunisation Service (OIS), but would likely not support the reclassification of travel vaccines or BCG.

General practices play a key role in delivering vaccinations especially childhood vaccinations

General practices provide routine childhood vaccinations as part of providing comprehensive patient care. Whanau are contacted before immunisations are due (pre-call) via phone, letter, email or SMS. If vaccinations become overdue further contact is made on 2-3 occasions before a referral is made to the Outreach Immunisation Service (OIS). Immunisations are provided by practice nurses who are authorised vaccinators.

Indicator 7 of the Colleges Foundation Standards describes the expectations for general practices around Immunisations. These include an expectation that the practice will have a documented process for immunisation recalls and a team member (or members) responsible for overseeing the management of recalls. The practice is expected to have recent data on immunisations by age and ethnicity to identify need for improvement initiatives and benchmark progress.[6] Immunisation has a key role in addressing health inequities.[7]

The College considers that general practice should retain the key role of coordinating childhood vaccinations for their enrolled patient population.

Vaccination rates among unenrolled children are a particular concern. Dr Nikki Turner stated in her presentation to the 2022 RNZCGP conference that immunisation rates for eight-month-old enrolled babies, including Māori, were at 90 per cent or above but fell to just over 50 per cent for unenrolled eight-month-old Māori babies in February this year.[8] The College considers that Pharmacists and other authorised vaccinators have a valuable role in providing childhood vaccinations as part of outreach programmes, in particular for unenrolled children. Services to facilitating enrolment to enable the whanau to receive comprehensive health care must also be provided at the time of vaccination.

The College recommends moving from local to national authorisation and approved vaccination programmes.

Local approved immunisation programmes[9] allow authorised vaccinators to administer unfunded vaccinations. Influenza vaccination is one such programme. Under the National Immunisation Schedule (NIS) influenza vaccination is funded for people with certain health conditions or over certain age limits. However, influenza vaccination is provided to people who fund this themselves via a 'local approved immunisation programme.' Authorised vaccinators are approved by their local medical officer of health, and consequently are required to reapply for authorisation if they wish to work in a different area. Authorised vaccinators can administer a vaccine that is a prescription medicine 'otherwise than pursuant to a prescription" so long as it is part of an approved vaccination programme.
The College considers that both authorisation of vaccinators and unfunded vaccination programmes should be nationally rather than locally organised. The legal ability to do this exists already in that the Medicines Regulations 1984 state that authorisation can be from the Director-General or a Medical Officer of Health according to Clause 44A (1).[10]

> Any medical practitioner or other person who is authorised by the Director-General or a Medical Officer of Health in accordance with this regulation to administer, for the purposes of an approved immunisation programme, a vaccine that is a prescription medicine, may, in carrying out that immunisation programme, administer that prescription medicine otherwise than pursuant to a prescription.

The College considers that authorisation should be granted by the Director-General of Health, rather than the local Medical Officer removing the problem of geographical limitations on authorisation, and that influenza vaccination and other vaccinations such as MMR should be part of national rather than local programmes. We understand that influenza immunisation, moved from a local to a national programme for both funded and unfunded immunisations in 2022.[i] This will have resolved the problem identified on p 15 of the application namely that people without a qualifying health condition and under the age of 65 are unable to legally receive the flu vaccine from an authorised vaccinator without a prescription, unless there is a local vaccination program authorised by the medical officer of health.

Childhood immunisation provision should be part of a holistic service

Routine childhood immunisations provide a valuable opportunity to identify whanau requiring interventions. Providing childhood vaccinations in general practice extends beyond gaining informed consent and administering the vaccine. This opportunity is used to enquire after whanau wellbeing, with particular emphasis on mental health, safety, and infant health. Concerns can be followed up with the involvement of appropriate members of the general practice team, including, when necessary, Health Improvement

[i] Personal communication 3/10/22 Bernadette Heaphy, Immunisation Advisory Centre Programme Manager – Education

Practitioners. ‘Safety netting’ is also provided with whanau encouraged to be contact the practice should particular symptoms occur, or minor concerns persist or worsen.

Mental health issues are common in the perinatal period, with up to 18 percent of mothers and up to 10 percent of fathers developing depression, anxiety, or other mental health issues. These rates are higher among Māori and Pacific and Asian peoples. Evidence reveals that children with a parent with postnatal depression have poorer long-term health and developmental outcomes. Early identification and intervention as soon as issues begin to present is critical to achieving the best outcomes for mothers, babies and the wider whānau.[11]

Feedback from Māori Māmā shows that whānau want more than just immunisation services, they want a holistic service[12] This is consistent with the immunisation standards which state that organisations who offer immunisation services should not do so in isolation from other services Appendix 3 A3.4 (p 600).[3] General practices hold comprehensive and current lists of patients' medicines and adverse reactions. This information helps determine whether the vaccine is safe to administer. General practice offers a holistic service in a way that community pharmacy cannot.

Initial experiences of immunisation must be positive as this will influence future uptake

The immunisation status of a child at two years is influenced by the mother’s experience of her child’s early vaccinations with negative experiences decreasing the update of future vaccinations.[13]

Travel vaccinations and BCG should not be reclassified

The College considers that travel vaccinations should not be reclassified as there is currently no training available to vaccinators to support the consultation that is necessary when selecting appropriate travel vaccines and obtaining informed consent.

BCG Vaccinations currently require additional authorisation to administer BCG vaccination in the light of specific requirements of this vaccine. BCG is the only vaccine given intradermally, and it is supplied in a multidose vial.

Introduction of the Aotearoa Immunisation Register (AIR) is necessary before changes are made

The existence of multiple providers of childhood immunisation will introduce uncertainty around whether the child has already been vaccinated elsewhere and around who has responsibility for pre-call, re-call, and referral to outreach services, if required, and this uncertainty may have a detrimental effect on follow up of unvaccinated children. In future all vaccinations will be entered on the new Aotearoa Immunisation Register (AIR) unless the parents decline this. The College recommends that reclassification does not take effect until the AIR is operational.

Vaccines should be listed by proprietary names

The College recommends that the list of vaccines for reclassification reflects the vaccine formulations used in New Zealand. The current application does not include the proprietary names of the vaccines as per the guidance in the document ‘How to change the legal classification of a medicine in New Zealand’.[14] With the exception of Tdap, all vaccines are listed by the name of the disease, bacteria, or virus that they provide protection against. It is not clear why Tdap is treated differently to other vaccines.

The College considers that each vaccine formulation, should be considered individually for reclassification rather than a more generic reclassification naming a vaccine for a particular disease as vaccines protecting against the same disease can have different safety profiles.

Conclusion

Thank you for the opportunity to provide comment on the agenda items. The College supports the reclassification of Maviret. We support the widening of the vaccinator workforce but recommend that other avenues be explored to do this. If reclassification is determined to be the best option, then we recommend that a further application more accurately specifying the vaccines used in New Zealand is made. In this case we would likely support a reclassification of adult vaccines, would likely support the role of pharmacists and other authorised vaccinators in providing childhood vaccines as part of an Outreach Immunisation Service (OIS), but would not support the reclassification of travel vaccines or BCG.

If you require further clarification, please contact Maureen Gillon, Manager Policy, Advocacy, Insights - maureen.gillon@rnzcgp.org.nz

Nāku noa, nā

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