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Tegan Medsafe Pharmacovigilance Team Ministry of Health Wellington

By email: <u>medsafedrquery@health.govt.nz</u>

Tēnā koe Tegan

Ministry of Health-Medsafe consultation: Proposed Changes to blood monitoring and prescribing requirements – consultation changes for healthcare professionals.

The Royal New Zealand College of General Practitioners (the College) is the largest medical college in Aotearoa New Zealand with a membership of 6,018 specialist General Practitioners (GPs). Our General Practice Education Programme (GPEP) and Rural Hospital Medicine Training Programme (RHMTP) trains the specialist General Practitioner and Rural Hospital Doctor workforce. The Medical Council of New Zealand accredits the College to deliver a Vocationally Registered workforce through its Continuing Professional Development Programme, making up 40 percent of the specialist medical workforce. The College is committed to prioritising the reduction of health inequities experienced by Māori, honouring Te Tiriti o Waitangi, and the rights of Māori. To do this we prioritise initiatives that support our members to develop cultural safety capability throughout our Training, Member Professional Development and Quality¹ programmes.

Our members provide first point of contact medical care to patients and their whānau to manage 90 percent of all patient healthcare concerns in the community. Each year approximately 24 million<sup>2</sup> patient contacts are recorded by 1,085 general practice teams working across Aotearoa.

### Your questions:

Thank you for the opportunity to comment on your proposed changes to the management of clozapine. As we discussed, we do not feel that we are able to follow the proscribed template as the issues we wish to raise do not naturally fit into that format. Furthermore, as a major player in the management of anti-psychotic medicines we want to make sure that our views are easily understood.

# Duration of blood monitoring, monitoring of thresholds and management of low blood count results

The College has nothing to add to the expert opinions on frequency of testing and management of neutropenia. We support the recommendations outlined in the consultation paper. However, we hold strong opinions on is the "how to monitor" section, which included the complex algorithms proposed. While we acknowledge that this is not technically within the Medsafe remit, we believe these issues must be resolved before any changes to clozapine management are implemented.

The College would be happy to set up a working group between Medsafe, the Pharmaceutical Society, Royal New Zealand College of General Practitioners, Health New Zealand, Pharmac and the Royal Australasian College of Psychiatrists to reach a consensus on a practical way forward.

<sup>&</sup>lt;sup>1</sup> As at June 2025, 972 out of 1085 general practices met the RNZCGP Foundation Standard.

<sup>&</sup>lt;sup>2</sup> Ministry of Health, 2024 data.

From a general practice perspective, hard copy management tools are no longer in use; however, it is critical that an electronic tool be developed to record and monitor blood tests and results. This tool should accessible, functional and useful for all clinicians involved in managing clozapine prescribing. It should also be transportable as patients taking clozapine frequently change providers and locations.

These electronic tools are not difficult to develop and existing examples already in use include the management of isotretinoin and warfarin dosing.

### Proposed changes to clozapine prescribing restrictions

Firstly, we note that one of the consultation questions under this heading asks whether, "... you agree with the proposal for who can initiate clozapine treatment"; however, we were unable to find any reference to "initiation" in the consultation document. We seek clarification on this point.

With the multiplicity of clinician types who have prescribing access to clozapine, we do wonder how that will be managed and monitored in the absence of a Pharmac Special Authority (SA) process in place. Under normal circumstances we are opposed to unnecessary SAs; however, in this case it would be a useful audit and compliance tool.

We welcome the widening of access to clozapine, and research relating to isotretinoin prescribing shows that such changes can improve equity of access. We do however recommend that an additional prescribing group be formally identified in line with the changes instituted by the Medical Council of New Zealand (MCNZ).

The MCNZ recognises registered (Vocationally Registered) general practitioners as a specialist group and separates them from doctors who call themselves general practitioners but are in fact practising under a "general scope".

If this distinction is made, vocationally registered general practitioners would be given the right to initiate clozapine, while those on general scope would be required to work with or in consultation with a psychiatrist. The precedence for this is with initiating isotretinoin prescribing, and the SA limits who can do this.

## In summary

The added work that specialist GPs and their teams do in this context requires funding and resourcing. It is not covered by the current low capitation fee schedule and falls outside the scope of standard general medical care and undertaken on behalf of specialised secondary services.

If there is no, or limited access to a specialist GP due to patients not being enrolled or there are long wait times for appointments, it poses a significant risk of patient harm, such as when there are severe delays in diagnosing conditions, such as sepsis in people with serious psychotic disorders, who may lack insight or sufficient whānau support.

#### The College:

- Endorses the changes in testing frequency and the changes in monitoring neutropenia.
- Supports developing a robust electronic monitoring tool that should be developed as soon as possible.
- Considers that there should be a SA to improve audit and compliance.
- Proposes that vocationally registered general practitioners should be specifically identified and allowed greater freedom to initiate treatment.
- Suggests recognition of added work through funding and resourcing is a priority.

For any further clarification, please contact Maureen Gillon, Manager - Policy, Advocacy and Insights. <a href="mailto:maureen.gillon@rnzcgp.org.nz">maureen.gillon@rnzcgp.org.nz</a>.

Nāku noa, nā

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