The Royal Australian & New Zealand College of Psychiatrists
Tū Te Akaaka Roa
New Zealand National Office

Your Health in Mind
Hauora hinengaro Manatuhia

15 October 2025

Medsafe
New Zealand Medicines and Medical Devices Safety Authority
PO Box 5013
Wellington 6140

By email to: medsafeadrquery@health.govt.nz

Tēnā koe

Re: Consultation - changes to the blood monitoring and prescribing requirements for clozapine

Tū Te Akaaka Roa, the Aotearoa New Zealand Branch of the Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide feedback on Medsafe's proposal to change the blood monitoring and prescription requirements for Clozapine.

The RANZCP is the principal organisation representing the medical specialty of psychiatry in Aotearoa New Zealand and Australia and is responsible for training, educating, and representing psychiatrists. The RANZCP has over 8900 members, including more than 6300 qualified psychiatrists, and is guided on policy matters by a range of expert committees, including Tū Te Akaaka Roa, the New Zealand National Committee of the RANZCP.

Recommendations

Tū Te Akaaka Roa supports the review of blood monitoring requirements for clozapine treatment, in line with international best-practice evidence. Clozapine is a vital medication which has been shown to be highly effective for treating schizophrenia, particularly in cases where other treatments were unsuccessful. Unfortunately, access remains poor due to the potentially dangerous side effects, lack of prescriber confidence, and strict monitoring requirements.

Blood Monitoring Requirements

Tū Te Akaaka Roa supports Medsafe's proposal to change current blood monitoring requirements, including the proposed changes to standard criteria and mandatory blood monitoring requirements. Based on best available evidence from national and international studies, we support the removal of a requirement for white blood cell count, focusing on absolute neutrophil count (ANC) only. Further, we recommend that mandatory blood monitoring end after two years of continuous clozapine treatment for tāngata whai ora who

- have had no previous confirmed clozapine-induced severe neutropenia/agranulocytosis, and
- are able to identify the signs and symptoms of infection and are likely to notify a healthcare professional accordingly to obtain a blood test.

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After mandatory blood monitoring has ended, we recommend that ANC is assessed as required, in response to signs and symptoms of infection. We recommend providing specific guidelines for prescribers to ensure blood monitoring is conducted appropriately.

While we prefer the term Duffy antigen receptor for chemokines (DARC) instead of benign ethnic neutropenia (BEN), we support the introduction of different thresholds in relation to this criterion. Specifically:

- A green' ANC threshold change to ≥1.5 x10^9/L for tāngata whai ora without BEN/DARC (standard monitoring) and ≥1.0 x10^9/L for those with BEN/DARC
- an 'amber' ANC threshold range change to 1.0 – <1.5 x10^9/L for standard monitoring and 0.5 – <1.0 x10^9/L for those with BEN/DARC
- a 'red' ANC threshold of <1.0 x10^9/L for standard monitoring and <0.5 x10^9/L for those with BEN/DARC

In cases of a confirmed 'red' blood test, we recommend an investigation of the cause is conducted before stopping treatment with clozapine. However, if ANC results are associated with clozapine use, treatment should be stopped. We recommend clinicians, together with tāngata whai ora and whānau, consider the severity of neutropenia, clinical presentation, ANC trends and history, haematologist advice, as well as treatment efficacy, alternative options, and risks associated with intractable psychotic relapse when deciding on whether to continue treatment with clozapine.

Current evidence suggest that clozapine can be safely restarted following cessation with the risk of serious outcomes from clozapine being no greater than for those on continuous clozapine treatment. Therefore, we support the proposal to keep the patient's usual monitoring requirements if clozapine treatment is restarted, unless treatment interruption was due to *clozapine-induced* severe neutropenia/agranulocytosis.

We support Point-of-Care testing to improve access and adherence to clozapine treatment and associated monitoring requirements.

Prescriber regulations

While Clozapine is a highly effective medication to treat schizophrenia, it does have the potential for causing potentially dangerous serious side effects across all the multiple body systems. Due to the unique and complicated risk profile, we strongly recommend involving specialist services and a requiring a high level of qualification for any health professional initiating and monitoring of clozapine treatment. Given the broad knowledge in mental and physical health required, we believe clozapine prescription should only be initiated by a psychiatrist or medical practitioners under supervision or in consultation with a psychiatrist.

We recommend clarifying the proposed criteria for medical practitioners initiating clozapine prescription to ensure clozapine initiation is in consultation/under supervision of a vocationally registered psychiatrist, which may be in a community mental health team.

We agree that clozapine prescription may be continued by a wider group of health professionals. However, qualification standards must be met, and non-medical practitioners (including nurse practitioners, nurse prescribers, and pharmacist prescribers) must consult

with, or practise under the supervision of a psychiatrist when continuing clozapine prescription.

Educational needs

Clear guidelines and education regarding clozapine treatment and associated side effects is crucial to improve access and safety of this medication. Unfortunately, provider often lack confidence due to fear of associated risks which limits the use of clozapine, despite its efficacy. We note that, while haematological issues can be serious, other risk factors such as myocarditis and constipation can also cause be as serious harm, including death. Therefore, we recommend comprehensive education for health professionals regarding the

- risks and benefits of clozapine treatment
- blood monitoring requirements
- recommended medical support following cessation of mandatory monitoring, including guidance regarding indicators for completing additional blood testing if signs of infection are presents
- require additional assessments
- dosing recommendations for specific populations (e.g., women or those tāngata whai ora with Asian heritage) which are not currently included in the data sheet
- recommended timeframes for dosing changes, in line with international evidence

Additionally, we recommend the development of clear guidance for tāngata whai ora taking this medication to ensure they are able to recognise the signs and symptoms of infection and seek medical advice as required.

Thank you for taking a collaborative approach for conducting this review and providing multiple opportunities for feedback; we look forward to working with Medsafe in the future. If you have any further questions regarding this letter, please contact the New Zealand National Office - Tu Te Akaaka Roa via nzoffice@ranzcp.org or on +64 (0)4 472 7247.

Ngā manaakitanga

Dr Hiran Thabrew

National Chair, Tū Te Akaaka Roa