

## Notice of Proposed Changes to the Medicinal Cannabis Minimum Quality Standard

I, Dr Diana Sarfati, Director-General of Health, give notice under Schedule 2 of the Legislation Act 2019 for the purposes of proposed changes to regulations made under section 37A of the Misuse of Drugs Act 1975, which prescribe the minimum quality standard for medicinal cannabis.

It is proposed that the minimum quality standard incorporates by reference:

- the *European Pharmacopoeia (version 11.0 including supplement 11.3)*
- the following material from *United States Pharmacopoeia-National Formulary (2023 issue 1)*:
  - <233> *Elemental Impurities - procedures (test methods only)*
  - <467> *Residual Solvents (test methods only)*
  - <561> *Articles of Botanical Origin (test methods only)*
  - <660> *Containers - Glass*
  - <661> *Plastic Packaging Systems and their Material of Construction*
  - <661.1> *Plastic Material of Construction*
  - <661.2> *Plastic Packaging Systems for Pharmaceutical Use*
  - <731> *Loss on Drying (test methods only)*
  - <922> *Water Activity*
  - *Excipient monographs*
- the following material from the *British Pharmacopoeia (2023)*:
  - *Appendix XI J. Ash*
  - *Excipient monographs*
- *European Medicines Agency Guideline on Plastic Immediate Packaging Materials.*

The proposed changes to the Medicinal Cannabis Minimum Quality Standard and the material incorporated by reference can be inspected free of charge during normal working hours (9.00am–4.00pm, Monday to Friday) at the Ministry of Health, 133 Molesworth Street, Thorndon, Wellington. To arrange an appointment between Monday 21 August and Friday 8 September 2023, please email [medicinalcannabis@health.govt.nz](mailto:medicinalcannabis@health.govt.nz).

The *European Medicines Agency Guideline on Plastic Immediate Packaging Materials* is available at [http://www.ema.europa.eu/en/documents/scientific-guideline/guideline-plastic-immediate-packaging-materials\\_en.pdf](http://www.ema.europa.eu/en/documents/scientific-guideline/guideline-plastic-immediate-packaging-materials_en.pdf).

Due to copyright restrictions, we are not able to display a copy online or send you an electronic copy of the *European Pharmacopoeia*, the *United States Pharmacopoeia-National Formulary*, or the *British Pharmacopoeia*.

The *European Pharmacopoeia (version 11.0 including supplement 11.3)* can be purchased at: <http://pheur.edqm.eu/home>

The *United States Pharmacopoeia-National Formulary (2023 Issue 1)* can be purchased at: <http://www.usp.org/>.

The *British Pharmacopoeia 2023* can be purchased at: <http://www.pharmacopoeia.com/>.

If you have any comment on the proposal to incorporate the specified material by reference, please email [medicinalcannabis@health.govt.nz](mailto:medicinalcannabis@health.govt.nz) by Friday 8 September 2023.

Dated this 18th day of August 2023.

DR DIANA SARFATI, Director-General of Health.