

Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health, Disability and Ageing
Via email: TGAMedicalDevices@health.gov.au

10 April 2026

Dear Sir/Madam,

Cannabis Council Australia input on the draft *Standards checklist for medicinal cannabis vaping devices*

I refer to your communique of 19 March 2026 seeking input on the draft ***Standards checklist for medicinal cannabis vaping devices*** from key stakeholders involved in the medicinal cannabis vaping device sector, and with other peak bodies involved in the supply and use of these products.

Cannabis Council Australia (CCA) is the national peak body for medicinal cannabis, representing licensed producers, prescribers, pharmacists and other health professionals. We became aware of this request for feedback via our Supporter network and would be grateful if you could add Cannabis Council Australia to your consultation contact list.

We note your advice that the checklist references standards a manufacturer can use to demonstrate they comply with the existing regulatory requirements and does not change the regulatory requirements.

We have consulted with Cannabis Council Australia Supporters and provide the following feedback:

Clarity of the checklist

The checklist clearly sets out existing regulatory requirements for medical device manufacturers. CCA notes that while the checklist provides clarity on demonstrating compliance with the Essential Principles for medicinal cannabis vaping devices, compliance with manufacturing and performance standards should not be interpreted as determining clinical suitability for an individual patient. Clinical judgement by the prescribing healthcare practitioner, informed by patient-specific factors, remains central to determining the most appropriate administration method and device.

In accordance with [CCA's submission](#) to the TGA's consultation on safety and quality of unapproved medicinal cannabis products, we consider that the standards for medicinal cannabis devices require review in alignment with broader medicinal cannabis reform measures.

Suggestions to improve the usability of the checklist

The checklist is designed for use by device manufacturers; however, it may not be in a suitable format to support discussions between patients and their healthcare practitioners regarding the use of unapproved vaping devices where clinically appropriate. CCA also notes that many patients are currently using medicinal cannabis vaping devices that have been prescribed and used safely over extended periods. Any clarification or interpretation of regulatory expectations arising from the publication of the checklist should consider continuity of care and the potential

clinical and patient-safety risks associated with unnecessary device substitution or disruption to established treatment regimens.

Further, consideration should be given to how such a checklist might support healthcare practitioners and sponsors when seeking inclusion of medicinal cannabis vaping devices and associated accessories (including spare parts) on the ARTG, or authorisation via existing pathways for access to unapproved devices for individual patients.

Given the checklist's reliance on international standards and comparable overseas regulatory frameworks, CCA considers there may be value in further clarifying how evidence generated for devices authorised or supplied in comparable international jurisdictions can be leveraged to support appropriate access for Australian patients, particularly where equivalent devices are not readily available domestically

Any unintended consequences that may arise from the TGA publishing the checklist

The checklist is intended to assist device manufacturers in demonstrating compliance, but further clarification on how it will be used by regulators could be beneficial. Clear communication about the checklist's purpose, status and role within regulatory oversight would support transparency, encourage confidence in the process, and reduce unnecessary uncertainty for sponsors and manufacturers. This is important to help avoid disruptions to or reduction of access for patients who rely on vaporisation as a clinically appropriate administration route.

While CCA acknowledges and appreciates the TGA's efforts to provide guidance to support regulatory compliance and patient safety, there is a risk that increasingly narrow or complex pathways for access to compliant medicinal cannabis vaping devices may result in unintended consequences for patients. In practice, patients may seek to access devices that are commonly available and prescribed in comparable international jurisdictions via alternative pathways, potentially outside the intended scope of regulatory oversight.

CCA would welcome further opportunity to engage with the TGA on the development of a clear, proportionate and patient-centred policy approach to medicinal cannabis vaping devices, including consideration of how safe and clinically appropriate devices can be accessed by Australian patients.

We thank you for the opportunity to provide feedback on this checklist. CCA would welcome the opportunity to engage further with the TGA as this work progresses, including through stakeholder discussions or additional consultation, to support a clear, proportionate and patient-centred approach to the regulation of medicinal cannabis vaping devices. Please contact Cannabis Council Australia at office@cannabiscouncil.org.au should you seek further information or clarification on the feedback provided.

Yours sincerely,



Lisa Penlington
Chief Executive Officer