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From the President

25 January 2017

[redacted]

Via email: [redacted]

Dear [redacted]

Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)

The Royal Australasian College of Physicians (RACP) thanks you for the invitation to provide feedback on the Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis) (TGO 93).

The RACP has consulted with its Medicinal Cannabis Reference Group and the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT) to develop this response.

We would like to reiterate the fundamental concerns we have previously raised regarding the lack of a robust evidence base and clinical testing for medicinal cannabis. Patients deserve reliable, safe, and consistent products, and as with all medicines, high quality research needs to be supported before use, to determine product safety and suitability.

Our response on the detail of the TGO should not be seen as tacit support of access to medicinal cannabis outside of clinical trials and the regulatory regimes applied to other medicines, rather it represents an attempt to mitigate the potential harms.

The following recommended changes to the TGO 93 and draft Guidance are proposed:

- Section 4:
  - To include the excipients to be used as the vehicles and dilutents for the cannabinoid products;
  - To include cannabis extracts such as oils from the plant when defining the term ‘cannabis plant’;
  - It is not clear why the phrase ‘purported to be present’ is used in the last point of section 4 in the Guidance – the active ingredient is either specified or disclosed in an application and is therefore actually present.

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- Section 6:
    - The RACP recommends that TGO 93 should apply across the board, including to personal imports of medicinal cannabis products as described in item 1 of Schedule 5 to the Regulations, to avoid creating loopholes.
    - TGO 93 should apply to items 4, 8, 10, 11 and 12 of Schedule 5A to the Regulations without exception - we do not envisage a need for medicinal cannabis to be available in an emergency situation.

- Section 7:
    - To reference standards for heavy metals in drugs to cover incidental constituents and impurities that may be present in cannabinoid substances as contaminants, by-products of production, or arising during processing or storage of a substance, and also comply with default standard limit tests for heavy metals, for example: lead, cadmium, mercury and arsenic. Cannabis plants are also known to quite readily absorb heavy metals in the soil that can potentially contaminate samples.

- Section 10:
    - The type of mass spectrometry liquid chromatography equipment to be used should be specified. Traditional HPLC is not sensitive enough to detect all the components of a product being tested. Therefore, HPLC-MSMS should be used because of its ability to detect unknown components in cannabis samples.

- Section 12:
    - The Guidance on paragraph 2(c) to include ‘rectal suppository or topical formulation’ as a dosage form.

Should you require any further information about this matter, please contact [redacted], Policy Officer, on [redacted] or [redacted].

Yours sincerely

[redacted]

Dr Catherine Yelland PSM