Submission

Draft Listed Medicines Evidence Guidelines

Thank you for inviting the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG; the College) to make a submission to the Therapeutic Goods Administration (TGA) on the Draft Listed Medicines Evidence Guidelines (Draft Guidelines).

RANZCOG is the lead standards body in women's health in Australia and New Zealand, with responsibility for postgraduate education, accreditation, recertification and the continuing professional development of practitioners in women's health, including both specialist obstetricians and gynaecologists, and GP obstetricians.

Background

The *Therapeutic Goods Act 1989* requires that, at the time of listing a medicine in the Australian Register of Therapeutic Goods (ARTG), sponsors must certify that they hold evidence to support any indications and claims made about their medicine.[i] The Evidence guidelines specify the type of evidence required to support indications made for listed medicines (excluding sunscreens) and help sponsors understand their regulatory obligations in relation to holding that evidence.[ii]

Specific Feedback

RANZCOG Women's Health Committee is of the view that the document adequately achieves its aims of clarifying how the TGA interprets and analyses the evidence to assess the efficacy of a listed medicines. The Draft Guidelines provide a meticulous guide for potential sponsors in relation to collating and presenting their data to support the claim, in a clear and organised manner. In particular, the document:

- Provides a clear description with examples of how to conduct a systematic literature search of medical databases;
- Outlines the acceptable standards of different levels of evidence for both specific and non-specific indications;
- Delineates the distinction between traditional and scientific evidence.

In RANZCOG's view, the case studies provided in Appendix 2[iii], outlining the common errors and acceptable submissions, are instructive and provides clear guidance for prospective sponsors.

The College proposes the following amendments and variations to the Draft Guidelines:

- P.18 - Each abbreviation for example, i.e.:"eg" is followed by a full stop, comma and a full stop, that requires to be rectified. For instance, p. 18 of the Draft Guidelines.

- P.19 – It is proposed to delete the repeated sentence as below, which appears three times consecutively:
  "Figure 3 shows the difference between And and OR Boolean operators"

- P.45 – The flowchart is illegible due to overlapping information texts.

- P.51 – The Draft Guidelines contain the following sentence that requires deletion: *"(refer to and Error! Reference source not found.5 on the categorisation of scientific indications)."*

- P.77 - Under the heading 'non-systematic search of international monographs and reference texts' the search term Vitamin B6 is to be amended as Vitamin B12.

Yours sincerely

Dr Benjamin Bopp
President

References

[i] Department of Health. Evidence Guidelines: Guidelines on the evidence required to support indications for listed complementary medicines. 2019. Available at: Evidence guidelines | Therapeutic Goods Administration (TGA)

[ii] Ibid i.

[iii] Draft Listed Medicines Evidence Guidelines. 2022. p 62.