Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

Thursday, 31 March 2022

Complementary and OTC Medicines Branch Therapeutic
Goods Administration
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Consultation: Proposed update to evidence guidelines for listed medicines

The Australasian Society of Clinical and Experimental Pharmacologist and Toxicologists (ASCEPT) is the leading professional body in Australasia for clinical pharmacology policy and practice and its members' expertise encompasses experimental and clinical pharmacology and toxicology, including drug development, toxicology, clinical trials and regulatory issues, pharmacovigilance and quality use of medicines.

ASCEPT thanks the Complementary and OTC Medicines Branch of the Therapeutic Goods Administration for the opportunity to comment on the proposed update to evidence guidelines for listed medicines.

ASCEPT commends the TGA for updating the terminology regarding the hierarchy of scientific evidence sources based on risk of bias, and improving clarity on how to assess the relevance and quality of evidence sources.

Use of robust scientific methodology to assess applications is imperative to protect Australian consumers. However, the guidelines continue to permit a product's indications to be based on a mix of evidence of traditional use, and scientific evidence. Permitting evidence of traditional use is fraught with risk, and ASCEPT strongly discourages evidence of traditional use in favour of, solely, scientific evidence.

Additional concerns with the guidelines that ASCEPT considers should be addressed in the update include:

a) there is no limit on the number of ingredients in a product;
b) there is no limit to the number of permitted indications that can be claimed for a product;
c) listing is based on evidentiary support from published information about individual ingredients, without any consideration of potential interactions in combination products;
d) there is no consideration of the effect of product formulation or presentation on bioavailability;
e) there is no reference to any special evidence requirements for use of products in children;

f) temporary weight loss remains a permitted indication with no clinically supported qualification.

Collated and reviewed by the ASCEPT Clinical Pharmacology Special Interest Group (SIG).



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On behalf of the ASCEPT Executive:

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