Technical Alert

Version 1.1 Assessed Listed Medicines Evidence Guidelines

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The TGA have published an updated 'Assessed Listed Medicines Evidence Guidelines' on the TGA website, Version 1.1 (August 2018), available here.

Version 1 of the guidelines were published in March. In response to requests from CMA and other stakeholders, the TGA have refined sections of the document to improve clarity, utility, as well as consistency with existing guidance related to evidence for listed medicines. The draft Version 1.1 guidelines were provided for targeted consultation prior to publication.

We encourage member feedback if there are further questions or suggested improvements to these guidelines, at technical@cmaustralia.org.au, for attention by the Committee Secretariat.

Summary of changes

Major changes to the document are as follows:

1. **Level of evidence for low level claims for LA products (section 5.4.1).**
   - The requirements for general (non-specific) scientific or traditional indications now reflect the requirements for listed medicines.
   - The requirements previously described for general (non-specific) indications now apply to specific indications.
   - For general traditional indications, Category C is no longer listed as a source of evidence, as it is unlikely that Category C sources would contain information on tradition of use.
   - In table 6, pharmacopoeias have been removed from Category C as a source of evidence, as most pharmacopoeias do not contain information on therapeutic indications, posology, or safety of a medicine, since their purpose is to detail the quality aspects.
2. **Cross-references to Listed complementary medicines guidelines.**
   Cross-references to using the Listed complementary medicines evidence guidelines as a source of guidance for low level indications have been removed to make the guideline more user-friendly and to avoid confusion between the two pathways.
3. **Additional information and clarification on Method 2B for providing efficacy (sections 5.5.1, 5.1.2, 5.5.2 and 5.5.3).**
   Additional information has been provided about Method 2B, biopharmaceutic studies and biowaivers. This information expands on the type of products/situations where biowaivers may be applicable. The information also clarifies that in some situations where biopharmaceutic studies are not required, clinical or other studies may be required to support efficacy.

Regarding the requirement to demonstrate bioequivalence between innovator and generic products that contain differing excipient matrices, the sponsor is expected to provide sufficient evidence to justify any differences to the comparator product and how bioavailability/ bioequivalence in not affected.

Other amendments are as follows:

- Clarifying how the TGA will assess submissions with Comparable Overseas Regulator (COR) reports (section 5.4.1).
- Updating the status of the efficacy claimer (section 7.3.4).
- Amending the pre-submission meeting minutes process to be consistent with the information on the TGA website (section 9.1.3).
- Replacing the reference to 'Listed medicines application and submission user guide' with 'Guidance for completing the application form for an assessed listed medicine' (section 9.2.1).
- Correcting information regarding the appeal of preliminary assessment decisions and the timeframe for lapsing applications (sections 9.3.2 and 9.3.3).
- Clarifying how the TGA will conduct post-market compliance of assessed listed medicines (section 9.7.3).

Document Version History.

Version 1.1 contains the following summary of changes:

V1.1	Modified evidence for low level indications, consistent with listed medicines evidence requirements. Removed cross-references to guidelines to avoid confusion. Additional information on biopharmaceutic studies and biowaivers. Clarified use of CORs. Included cross-reference to 'Guidance for completing the application form for an assessed listed medicine'. Amended pre-submission meeting process. Corrected appeal of preliminary assessment decisions and timeframe for lapsing applications. Other minor amendments.	Complementary and OTC Medicines Branch, TGA	August 2018

GMP Forum Presentations

Presentations from the Inaugural Industry Forum on Good Manufacturing Practice (GMP) that occurred on 26 June 2018 have now been published on the TGA website here.

Transcripts of the presentations will also be published over the coming weeks.

Presentations (linked):

- Inaugural Industry Forum on Good Manufacturing Practice
- Overview of TGA's involvement in the International Regulatory Environment
- GMP Fees and Charges
- GMP Clearance
- GMP Clearance - Common mistakes made
- Driving a GMP / Quality Culture to provide supporting evidence of better business outcomes
- Updating the Manufacturing Principles
- PIC/S Guide to GMP PE009-13
- PIC/S Guide to GMP PE009-13 Annex 15
- PIC/S Guide to GMP PE009-13 Chapters 4 and 6
- PIC/S Guide to GMP PE009-13 Chapter 7
- PIC/S Guide to GMP PE009-13 Annex 2
- Risk Based Approach to Inspection Frequency
- Emerging Trends & Developments, Common Inspection Deficiencies and Other Concerns
- SME Assist
- Therapeutic Goods Regulation and the GMP Inspection Process (an inspectors perspective)
- Understanding your supply chain - GMP Agreements for GMP Clearance
- Recall of Therapeutic Goods - Overview

ENDS

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