Technical Alert

TGA Consultation: Guidelines for the Quality of Listed Probiotic Medicines

The TGA has announced a public consultation on the Proposed New Guidelines for the Quality of Listed Probiotic Medicines. The consultation is open from today, 24 July 2023, until **Sunday 10 September 2023**.

For CMA, the consultation document represents "Version 3" of the draft guideline; CMA has provided significant feedback on draft versions 1 and 2 in prior years through CMA's involvement in targeted industry consultation by our participation in the TGA-industry ComTech regulatory forum[1]. TGA consultation also occurred with groups such as the Advisory Committee on Complementary Medicines (ACCM), the Australian Society of Microbiology, the EDQM and the USP.

CMA has had concerns about the content of prior drafts and, while work has been done by CMA to try to address these to promote a strong and appropriately regulated industry, we urge members to review the guidelines to determine if any aspects cause a significant concern for your business, and provide a submission to the TGA. Submissions may be marked public or private. International partners may also comment on the TGA's consultation as it is open to the public.

The stated purpose of the Guidelines is to help sponsors and manufacturers meet the regulatory requirements to ensure the quality of their probiotic medicine is acceptable under the *Therapeutic Goods Act 1989* (the Act); and to assist with sponsor and manufacturer compliance by naming and explaining the most relevant applicable legislation related to ensuring the quality of probiotic medicines.

- The Guidelines will apply to probiotic medicines with an AUST L or L(A) number that are listed on the ARTG.
- The Guidelines do not apply to medicines with therapeutic activity attributed to distinct ingredients that are inactivated, non-viable microorganisms and/or their components (known as postbiotics or paraprobiotics). If a postbiotic is a distinct active ingredient *within* a probiotic medicine, then these Guidelines apply to the probiotic ingredients.

Stakeholder feedback is sought on the clarity and presentation of information in these guidelines and feedback received will be used to improve the way complex information is communicated, as well as the overall readability. The consultation survey questions are reproduced at the end of this alert.

Proposed Transition period for labelling requirements

The TGO 92 (Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines) will be sunsetting on 1 October 2026 which will require that is reviewed and publicly consulted on.

The TGA provide that the clarification of the labelling requirements (section 4.7 of the Guidelines) may appear new to some sponsors. The TGA is considering a transition period until **1 October 2026** for the labelling requirements in section 4.7 to align with the sunsetting of TGO 92. The TGA have stated that the labelling requirements in section 4.7 will be updated if necessary to align with TGO 92's replacement. However, CMA will be seeking a longer transition considering that changes to TGO 92 will not be known until the new TGO is published in 2026.

Sponsors that do not comply with the current requirements can apply for consent to import, supply, or export a medicine under section 14 of the *Therapeutic Goods Act 1989*.

[1] **ComTech** is a twice-yearly meeting of the TGA Complementary & OTC Medicines Branch (currently headed by Cheryl McRae) to discuss business with two representatives each of the associations: CMA; ACCORD; CHPA (Consumer Health Products Australia); ATGC (Association of Therapeutic Goods Consultants); GBMA (Generic Biosimilars Medicines Association).

Feedback to CMA

CMA invites comments and feedback from interested members on the draft Guidelines for the Quality of Listed Probiotic Medicines for consideration as part of CMA's industry response to the consultation. Please send your comments to Lucy.Lang@cmaustralia.org.au or technical@cmaustralia.org.au. Feedback on this consultation to CMA is preferred by **Tuesday 5 September 2023**.

Feedback to the TGA

Submissions to the consultation by individuals or companies may also be made directly to the TGA via the online survey on the Consultation Hub by the **10 September 2023**.

Resources

- TGA Consultation page: Proposed New Guidelines for the Quality of Listed Probiotic Medicines
- Consultation document [PDF]: Guidelines for the Quality of Listed Probiotic Medicines
- Proposed New Guidelines for the Quality of Listed Probiotic Medicines Online survey

TGA Public Consultation – Online Survey Questions

Section 3: Quality control

Section 3 of the Guidelines is intended to explain why it is important to control the quality parameters of probiotic medicines.

Q: Is the information provided in section 3 clear and easy to follow?

Q: Is Figure 1 helpful and clear?

Section 4: Demonstrating compliance with legislative requirements

Section 4 of the Guidelines is intended to explain how sponsors can demonstrate compliance with the legislative provisions outlined in Section 5 of the Guidelines. Figure 2 provides an overarching summary of the taxonomic level at which the active ingredient in a probiotic medicine should be identified, quantified and labelled in order to meet the legislative requirements.

Q: Is the information provided in section 4 clear and easy to follow?

Q: Is Table 1 helpful and clear?

Q: Is Table 2 helpful and clear?

Q: Is Figure 2 helpful and clear?

Q: Is Table 3 helpful and clear?

Q: Is Table 4 helpful and clear?

Q: Is Table 5 helpful and clear?

Q: Is Table 6 helpful and clear?

Section 5: Applicable legislation

Section 5 of the Guidelines is intended to outline all the legislative provisions that a sponsor must comply with to control the quality of their listed probiotic medicine.

Q: Is the detail provided in section 5 needed in the Guidelines?

Q: Is the information provided in section 5 clear?

Q: Is Table 7 helpful and clear?

Q: Is Table 8 helpful and clear?

Q: Is Table 9 helpful and clear?

Q: Is Table 10 helpful and clear?

Q: Is Table 11 helpful and clear?

Transition period

The Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (TGO 92) will be sunsetting on 1 October 2026 and will be reviewed and consulted on prior to sunsetting.

The clarification of the labelling requirements (section 4.7 of the Guidelines) may appear new to some sponsors. The TGA is considering a transition period until 1 October 2026 for the labelling requirements in section 4.7 to align with the sunsetting of TGO 92. The labelling requirements in section 4.7 will be updated if necessary to align with TGO 92's replacement.

Sponsors that do not comply with the current requirements can apply for consent to import, supply, or export a medicine under section 14 of the *Therapeutic Goods Act 1989*.

Q: Do you support a transition period?

Q: What labelling requirements in section 4.7 are difficult to comply with?

Q: Do you have an alternative option or other feedback you would like to put forward?

General feedback

Q: Do you have any suggestions for improving the overall readability?

Q: Do you have any other comments about the guidelines?