Document 1

LCS LISTED MEDICINE REVIEW CHECKLIST

TRIM Container				
ARTG Number (AUST L)				
Product Name				
Sponsor				
Reviewed by		**Date:**		
Peer reviewed by	*(If nessecary)*			
2nd reviewed by				
Tick the applicable information reviewed	Manufacturing	☐	Label	☐
	Advertising		☐	

1 Guidance for using the review checklist

1.1 Saving this document into TRIM

- Save a copy in TRIM within the relevant review container.

1.2 Recording your evaluation

The information recorded in this checklist will be an **official record** of the evaluation and thought process that occurred in this compliance review. This information will support the release of compliance review outcomes to the public (see s.22) and any regulatory decisions made in relation to the product under review. **This information may be under scrutiny by a range of audiences (FOI, s60 Delegate, Federal Court Judge, ANAO audit, etc.) at any time.** As such, **it is critical that the flow of logic, rationale behind conclusions, materials considered during evaluation must all be documented in this evaluation checklist and understandable by any reader of this document.**

The checklists below (label, manufacturing) **must contain** the information described in the table below. **Comment bubbles and/or tracked changes** may be used as a means of communication between the Evaluator and Reviewer during the evaluation process but **must not be present at the time of finalising the initial review checklist** (i.e., at the end of the Evaluation #1 stage). Once you start drafting a regulatory notice (if applicable), this checklist must be free of tracked changes and comments. If necessary, move information in comment bubbles into the columns.

Marked with	✓	N/A	C (#)
Circumstances where appropriate	Relevant regulatory requirement is satisfactorily complied with.	A legislative requirement is not applicable to the medicine.	Regulatory compliance issues (breaches of the legislation) are identified.
Deficiency box to be ticked?	No	No	Yes
Information to be included ('COMMENTS' column)	Information that describes how you determined that the medicine was compliant with the requirement. **Include enough information for any reader to understand how you came to that conclusion.** Links to evidence (that are recorded in TRIM) that helped you come to that determination s.37 [redacted]	Information that describes how you determined that the requirement is not applicable to the medicine under review. Include enough information for **any reader** to understand how you came to that conclusion.	Your comments about the compliance of the product including: • the relevant provisions of the legislation that have been breached (See TRIM s.22 [redacted] for an explanation of the provisions); • why you think they have been breached including links to evidence (recorded in TRIM if applicable e.g., captures of advertising material); and • why you're recommending the breach be pursued and in what form (e.g., Proposal to Cancel or Deficiencies notice). s.37 [redacted] **Ensure you include enough information for any reader to understand why you have decided that an aspect of the medicine is non-compliant, why you recommended the breach be pursued or not and in what form.** Information for the publication of outcomes including: • the classification of the deficiency/breach as one of 'safety-related', 'efficacy-related' or 'minor'. Refer to *How to interpret the compliance review results* section of the Database for definitions of 'Issues related to safety' and 'Issues related to efficacy'.

Note: For each regulatory requirement, some of the relevant legislation has been hyperlinked in the checklist. The hyperlinked legislation is not an exhaustive list. Always think about whether it is necessary for you to consider legislation, definitions, explanatory notes and/or guidance material other than those referenced below.

1.3 What to do when safety-related deficiency is identified

When a safety-related deficiency is identified, you will need to consider the level of risk the deficiency poses on consumers or anyone that may come into contact with the medicine. This is particularly crucial for non-compliant stock that are out on the market or are ready to be released to the market. If you are unsure, consult your supervisor to determine whether to request advice from the Adverse Events and Medicine Defects Section (AEMDS) in Pharmacovigilance & Special Access Branch (PSAB).

The advice may be used to inform the review pathway you should take after Evaluation #1 (e.g. the type of regulatory notice sent such as a Proposal to cancel or Deficiencies Notice), how to pursue the safety-related deficiency or whether additional information needs to be requested from the sponsor (e.g. number of non-compliant units of the medicine remaining with the sponsor, wholesalers/distributers, retailers and consumers). s.37

s.37

s.22

2 Assessment of medicine compliance and recommended enforcement strategy

PLEASE READ IN CONJUNCTION WITH s.22 :

The purpose of this section is to document the recommended enforcement strategy for non-compliance(s) identified during a compliance review, taking into consideration the type of non-compliance and sponsor compliance history. You should complete this section with reference to s.22 , which provides an overview of the principles to consider when developing an enforcement strategy.

How to complete this section

Before beginning your evaluation:

- A1-A3 **must** be completed.

After completing your evaluation:

- A4 and A8-A9 (A9 for reviewing officer only) **must** be completed.
- If you identified one or more safety-related deficiencies, you **must** complete A5.
- If you identified one or more compliance deficiencies, you **must** complete relevant aspects of A6.
- If you identified one or more compliance deficiencies that are safety, quality or efficacy related, you **must** complete relevant aspects of A7.

Please ensure all text you have entered is black before this table is completed.

s.37	Medicine under review Active ☒ Cancelled ☐ Medicine cancellation date (if relevant): Click or tap to enter a date. Last certification date (if relevant): Click or tap to enter a date. Sponsor under review Date of first listing: Click or tap to enter a date. Number of current listings: Non-compliance rate:

s.37

Number of past compliance reviews:

Type: Project:

Random:

Targeted:

A2. Signals/data/intel utilised to inform this review

Provide a summary of the initiating signal, data, intelligence, project, etc that lead to the initiation of this review.

If available, provide TRIM link(s) to relevant background documents such as ARTG scanning discussion notes, internal referral, project brief and scope, or investigation folder.

s.37

A4. Provide a summary of the compliance issues identified during this review

Summarise the identified compliance breach(es), including a plain language summary and the proposed breach of the legislation. **If no compliance breaches are identified, enter 'N/A' for this question and jump down to A7**.

The below table can be used to organise the information.

Question in checklist	Plain language description	Identified non-compliance (include relevant section of the legislation)
L8	The label for the medicine is missing the mandatory warning statement 'Contains crustacea', which is required by paragraph 8(1)(j) of TGO 92 and Schedule 1	Failure to comply with an applicable standard (which may constitute an offence under section 14(9AA) of the Act, and/or grounds for cancellation under paragraph 30(2)(e) of the Act).

A5. Are there safety-related issues for the identified compliance breach(es)?	Yes ☐ No ☐	s.37 [redacted]

A6. Are there any other relevant compliance signals held by the TGA for this medicine?

If yes, provide details and links if applicable. You will need to consider what is relevant to the compliance issue identified.

Yes ☐
No ☐

s.37 [redacted]

s.37 [redacted]

Summary of overall findings:

Include a summary of the findings for the medicine, including issues that may not be directly relevant to the compliance review and which are not documented above.

s.37



s.37 [redacted]

Multiple options may be applicable.

Cease review

☐

Conclusion notice

☐

Educational Email/Notice ☐

Obligations Notice

☐

Deficiencies Notice

☐

Proposal to Cancel

☐

Warning letter

☐

Condition of listing

☐

Suspension

☐

Cancellation

☐

Enforceable Undertaking

☐

Directions Notice

☐

A8. Recommended enforcement action(s)

Provide reasons for the recommended action(s). See s.22 for information about each type of enforcement action.

s.37 [redacted]

		Prevention Notice ☐ Infringement Notice ☐ Contact Recalls ☐ Other type of correspondence ☐ Specify the type:	
A9. Reviewing officer consideration	Agree with recommendation Disagree with recommendation	☐ ☐	s.37 Include any other matters or points you have considered if they are not already mentioned above.

3 Label/Presentation & Advertising

Requirement	Relevant legislation	Deficiency Identified	Comments
Required particulars on the label			
1. Name of goods consistent with ARTG entry. • Must be included on the 'main label' of the label and must be presented in a continuous, uninterrupted manner and not be broken up by additional information or background text. • Must appear as cohesive unit with the name of active ingredients unless excepted under subsection 9(3)(b) All text oriented in the same direction (except AUST L number can be oriented in any direction, TGO 92 Guidance)	• Paragraph 8(1)(a) of TGO 92 • Paragraph 9(1)(a) of TGO 92 • Subsection 9(2) of TGO 92 • s6 of TGO 92 for definition of 'name of the medicine' and 'main label' • Subsection 8(4) of TGO 92 • Subsections 9(3), 9(5), 9(6) and 9(8) of TGO 92 • Subsection 9(4) of TGO 92 (All text oriented in same direction) • Subsection 10(7) of TGO 92 • Paragraph 26A(2)(k) of the Act *(consider subsection 16(1A) of the Act for separate and distinct goods)*	☐	
2. Formulation consistent with ARTG.	• Paragraph 26A(2)(k) of the Act *(consider subsection 16(1A) of the Act for separate and distinct goods)*	☐	
3. Correct Australian approved names of all active ingredients. • Must be included on the 'main label' of the label unless subsection 9(5) or 9(6)(b) of TGO 92 applies. • The ingredient names on the ARTG may be different to the Sponsor's documents: pursue if the changes are not related to IHIN changes (the transition period to make the changes expires in 30 April 2023). • Inclusion of common names of vitamins is permitted in addition to the AAN in accordance with subsection 11(5)	• Paragraph 8(1)(b) of TGO 92 for label • Paragraph 9(1)(b) of TGO 92 for main label • Subsections 9(3), 9(5) and 9(6) of TGO 92 • Subsection 10(7) of TGO 92 • s6 of TGO 92 for definition of 'name of an active ingredient' • Subsection 11(5) of TGO 92 (Inclusion of common names of vitamins)	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
4. Quantity or proportion of all active ingredients in the goods – with correct expression and units. • Must be included on the 'main label' of the label unless subsection 9(5) or 9(6)(b) of TGO 92 applies. • Quantity requirements for enzymes and microorganism's subsection • Composite packs	• Subsection11(1) of TGO 92 • Paragraph 9(1)(c) of TGO 92 • Subsections 9(5), 9(6) of TGO 92 • Subsection 10(7) of TGO 92 • Subsection 11(2) of TGO 92 • Subsection 9(8) of TGO 92 for composite packs		
5. TGO 92 Schedule 1 Substances or Groups of Substances declared. *(Please check PI components too. PI components can be accessed via https://ingredients.production.tga.gov.au/#/)*	• Paragraph 8(1)(j) of TGO 92 • Schedule 1 of TGO 92	☐	
6. Correct name of dosage form (main label) as entered in the ARTG e.g., soft capsule, etc. (eBS Code Tables); s.37	• Paragraph 8(1)(d) of TGO 92 • Paragraph 9(1)(d) of TGO 92 • Paragraph 9(6)(a) of TGO 92 • Subsection 10(7) of TGO 92 for small containers • Subsection 10(8) of TGO 92 for individually wrapped dosage • Subsection 10(9) of TGO 92 for blister packs • s 6 of TGO 92 for the definition of name of dosage form	☐	
7. Quantity of the goods (main label).	• Paragraph 8(1)(e) of TGO 92 • Paragraph 9(1)(e) of TGO 92 • s6 of TGO 92 for definition of 'quantity of the medicine' • Subsections 9(3), 9(5) and 9(6) of TGO 92 • Subsection 10(7) of TGO 92 for small containers • Subsection 10(8) of TGO 92 for individually wrapped dosage forms • Subsection 10(9) of TGO 92 for blister packs	☐	
8. Required warning statements and representations present, correct, and complete. (eBS Code Tables) *(please check*	• Paragraph 8(1)(k) of TGO 92 • Paragraph 11(1)(d) of TGO 92	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
PI components too. PI components can be accessed via https://ingredients.production.tga.gov.au/#/)	• s6 of TGO 92 for definition of 'warning statements' • SUSMP (the Poisons Standard) • Schedule 2 Part 2 of the Regulations in relation to required representations • Schedule 4 – Current Regulations • Permissible Ingredients Determination – 26BB List for required warning statements linked to specific ingredients • Permissible Indications determination • Subsection 42DJ(2) of the Act in relation to required representations		
9. Required pregnancy specific warning statement if the medicine is for oral use and contains active ingredient(s) included in Category B or C.	• Prescribing medicines in pregnancy database | Therapeutic Goods Administration (TGA) medicines in pregnancy database' published on the TGA • Paragraph 8(1)(k)(ii) of TGO 92	☐	
10. Batch No. (with correct prefix). • Please note: sponsors may provide labels that are not part of a released batch and, therefore, do not have the batch number or expiry date (or the prefix) included on the label. • Ensure that space is provided for the Batch No. and Expiry date.	• Paragraph 8(1)(f) of TGO 92 • s6 of TGO 92 for definition of 'batch number' and 'batch number prefix' • Subsection 10(7) of TGO 92 for small containers • Subsection 10(8) of TGO 92 for individually wrapped goods • Subsection 10(9) of TGO 92 for blister packs	☐	
11. Expiry date (with correct prefix). • Please note: sponsors may provide labels that are not part of a released batch and, therefore, do not have the batch number or expiry date (or the prefix) included on the label. • Ensure that space is provided for the Batch No. and Expiry date. • Terms such as 'Best By' or words to this effect are not acceptable because they relate to foods. • For composite packs subsection 9(8)	• Paragraph 8(1)(g) of TGO 92 • s6 of TGO 92 for definition of 'expiry date' and 'expiry date prefix' • Subsection 10(11) of TGO 92 for composite packs • Subsection 10(7) of TGO 92 for small containers • Subsection 10(8) of TGO 92 for individually wrapped goods • Subsection 10(9) of TGO 92 for blister packs • Subsection 9(8) of TGO 92 for composite packs	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
12. Storage conditions.	• Paragraph 8(1)(h) of TGO 92 • Subsection 11(4) of TGO 92	☐	
13. Directions for use (method, dose, and frequency).	• Paragraph 8(1)(l) of TGO 92 • s6 of TGO 92 for definition of 'directions for use' • Paragraph 8(1)(m) of TGO 92 if the medicine requires some preparation before use • Subparagraph 8(1)(l)(ii) of TGO 92 if there is insufficient space on the label or primary pack and a package insert is provided	☐	
14. Name and contact details of sponsor/ distributor (only name or trademark required for blisters). • Note: Distributor details may not be on eBS but should include sufficient information to allow the Australian sponsor or distributer to be uniquely identified.	• Paragraph 8(1)(i) of TGO 92 • s6 of TGO 92 for definition of 'name and contact details', 'distributor' and 'sponsor' • Subsection 10(7) of TGO 92 for small containers • Subsection 10(8) of TGO 92 for individually wrapped goods • Subsection 10(9) of TGO 92 for blister packs	☐	
15. Indications/Statement of goods. • Are indications covered by the Permissible Indications Determination? • Intended purpose/indications/claims present and consistent with the ARTG record (condition of listing). • **This includes indications/statements on the website – refer Q35 under 'Presentation and Advertising'.**	• Paragraph 8(1)(n) of TGO 92 • Paragraph 28(5)(ab) of the Act	☐	
16. The approved route of administration if the medicine is contained in an **ampoule**.	• Subsection 8(1)(o) of TGO 92	☐	
17. AUST L (main label) – primary pack (or immediate container if no p/p).	• Subparagraph 7(2)(d)(i) of TGO 92 • Paragraphs 15(1)(b) and (c) of the Regulations	☐	
18. For topical preparations only – name of any antimicrobial agents.	• Subsection 10(2) of TGO 92	☐	
19. If the medicine is for **external use**, the statement "Caution: Not to be Swallowed" or	• Subsection 8(1)(i) of TGO 92	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
"For External Use Only" or words to this effect			
20. Medicine Kits and composite pack requirements • **If you identify a deficiency, tick the relevant box above e.g., AAN incorrect, tick L3, etc.**	• s6 of TGO 92 for the definition • Subsection 9(3) of TGO 92 • Subsection 9(8) of TGO 92 • Subsection 10(6) of TGO 92 • Subsection 10(11) of TGO 92	☐	
General labelling requirements for above required particulars			
21. Legible, durable, **clearly visible** (not obscured) and strongly contrasted. English language. • All information that is required by TGO 92 to be on the label must be in English. • Other languages are allowed provided they are not misleading or breach the legislation. • Information on a delivery device	• Paragraphs 7(2)(a), (b), (c) and (e) of TGO 92 • Subsection 8(4) of TGO 92 • Subsection 8(5) of TGO 92	☐	
22. Letter height of required particulars is ≥ 1.5 mm, AUST L ≥ 1mm. • Use the scaled magnifiers (with or without illumination) to measure letter height. • Scaled magnifiers are in the LCS APS6 area.	• Paragraphs 7(2)(d) of TGO 92 • s6 of TGO 92 for definition of 'text size' • Paragraphs 15(1)(b) and (c) of the Regulations	☐	
23. Information is in a colour or colours contrasting strongly with the background, except for: (i) the expiry date and expiry date prefix; and (ii) the batch number and batch number prefix when that information is embossed or debossed and not printed	• Paragraph 7(2)(e) of TGO 92	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
Ingredient requirements			
24. Any quantity restrictions complied with. e.g., Organic forms of Chromium, Vitamin A, KCl and Iron.	• Therapeutic Goods (Permissible Ingredients) Determination – 26BB List • SUSMP (the Poisons Standard) • Schedule 4, of the Regulations		
25. Appropriate metric units.	• Subsection 11(1) of TGO 92 • Subsection 11(2) of TGO 92	☐	
26. Expression of quantity/proportion – herbal ingredients.	• Paragraph 11(2)(i) of TGO 92	☐	
27. Expression of quantity/proportion – vitamin A.	• Subparagraph 11(2)(i)(iv) of TGO 92	☐	
28. Expression of quantity/proportion – minerals.	• Paragraph 11(2)(h) of TGO 92	☐	
29. Expression of quantity/proportion – biological organisms.	• Subparagraph 11(2)(i)(v) of TGO 92	☐	
30. Expression of quantity/proportion – homoeopathic products.	• s6 of TGO 92 for definition of 'homoeopathic medicine', 'homoeopathic potency' and 'homoeopathic preparation' • Subsection 10(3) of TGO 92 • Subsection 10(4) of TGO 92 • Subsection 11(3) of TGO 92	☐	
31. Expression of activity units of enzymes.	• Subparagraph 11(2)(i)(iii) of TGO 92 • Schedule 3 of TGO 92	☐	
32. Ingredients are not included in a Schedule to the Poisons Standard.	• Schedule 4, item 3(ca) of the Therapeutic Goods Regulations 1990	☐	
Presentation and Advertising			
33. Does the presentation of the medicine contain "Free from <ingredients>"?	• Subsection 8(1) of Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021(the Code)	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
Are they accurate and substantiated? *Note:* • *e.g., Maltodextrin may contain gluten.* • *Check extraction solvents for alcohols.*	• Subsection 3(5) of the Act		
34. "Unacceptable" presentation: a. Does the presentation include misleading claims based on lack of evidence? b. Is product presentation misleading or confusing as to content or proper use? c. Could the form of presentation lead to unsafe use? d. Does the presentation include novelty dosage forms (i.e., in the shape of animals, robots, cartoon characters, etc) that is likely to result in the goods being mistaken for or confused with confectionery or toys?	• Definition of 'presentation' subsection 3(1) of the Act • Subsection 3(5) of the Act • Regulation 3A of the Regulations • Subsection 8(1) of the Code • s9 of the Code	☐	
35. Does the website advertise indications that are: a. covered by those in the ARTG b. covered by those in the Determination i. Do they fall within the definition of a restricted rep? ii. Do they fall within the definition of a prohibited rep? • i.e., the indications on the website are not for the **treatment** of a disease, condition, ailment or defect specified in Part 8, section 28 of the Advertising Code? • *Note: the condition does not need to be 'serious'.*	• Paragraph (d), Item 3 of Schedule 4 of the Regulations • Therapeutic Goods (Permissible Indications) Determination – 26BF • Paragraph 28(5)(ab) of the Act	☐	
36. Accuracy: Is the advertisement accurate, balanced, and not misleading or likely to be misleading?	• s8 of the Code	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
37. Safe and proper use a) Does the advertisement present the therapeutic goods as completely safe or free from all harm or side effects? b) Does the advertisement state or imply the goods are effective in every case or a guaranteed cure? c) Does the advertisement portray the goods as flawless, never failing, or able to produce results as if by magic? d) Could the advertisement provoke undue alarm, fear or distress? e) Is the advertisement inconsistent with labelling information, directions for use, or other patient materials for the goods? f) Does the advertisement delay or discourage seeking medical care or following prescribed treatment? g) Does the advertisement exaggerate the efficacy or performance of the goods? *This breach is not related to the lack of evidence.*	• Definition of 'presentation' subsection 3(1) of the Act • Subsection 3(5) of the Act • Regulation 3A of the Regulations • s9 of the Code	☐	
38. Information included in the ARTG is correct.	• The certification under paragraph 26A(2)(k) of the Act	☐	
39. Is the advertisement consistent with public health campaigns? *(Details of current public health campaigns can be found https://www.health.gov.au/topics?page=0)*	• s10 of the Code	☐	
s.37	• s11 of the Code	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
s.37			
41. Practitioner only medicines a. Is this a practitioner only medicine? Is the medicine only available from a pharmacist / not available for purchase by the general public? b. Does it contain the relevant required statements – **'ASK YOUR PHARMACIST ABOUT THIS PRODUCT'**, and/or **'THIS PRODUCT IS NOT AVAILABLE FOR PURCHASE BY THE GENERAL PUBLIC'**	• S15 of the Code • s16 of the Code	☐	
42. Medicines for traditional use. Does the advertisement have a statement about the reliance on the traditional use prominently displayed or communicated?	• Subsection 23(1) of the Code	☐	
43. Medicines related to weight management. Does the advertisement of this medicine: a. Include statements or visual representations, that are prominently displayed or communicated the need for healthy energy-controlled diet and physical activity,	• Subsection 23(3) of the Code	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
b. Include references or depiction suggesting that the medicine will correct or reverse the effects of overeating, overconsumption of food or drink, c. contain visual representations, statistics or testimonials of individuals that are not consistent with the results that would be expected to be achieved on average by consumers of this medicine.			
44. Testimonials and endorsements. Are the testimonials and endorsements consistent with the label and directions for use for this medicine?	• s24 of the Code	☐	
45. Does the advertisement (label, website) include or imply an endorsement from: a. a government authority (i.e., TGA, FDA, etc), hospital or healthcare facility (excluding healthcare pharmacy)? b. an employee of above-mentioned organisations? c. a health practitioner, health professional medical researcher or a group of such persons? d. An organisation that represents the interests of healthcare consumers, practitioners, health professionals and medical researchers? e. An organisation that conducts or funds research into any disease, condition, ailment, or defect?	• Subsection 24(6) of the Code	☐	
46. Claims regarding vitamin or mineral supplementation are only permitted where the recommended daily dose of the product provides at least 25% of the RDI for that vitamin or mineral. • There shouldn't be reference to the presence of vitamins or minerals in the claim/indication unless they are present in the recommended daily	• Schedule 2, part 1, item 8 of Regulations • NHMRC Nutrient Reference Values	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
dose of at least 10% of the RDI, unless there is evidence to support a therapeutic effect below this level.			
47. Does the medicine comply with all applicable permitted indication requirements?	• Therapeutic Goods (Permissible Indications) Determination Paragraph (e), Item 3 of Schedule 4 of the Regulations	☐	

4 Manufacturing

Requirement	Relevant legislation	Deficiency Identified	Comments
Product Manufacturer(s)			
1. Manufacturers included in the specifications/formulation documents are nominated in the ARTG entry and steps of manufacture are consistent.	• Paragraphs 26A(2)(h) and (i) of the Act • Paragraphs 28(5)(f) and (g) of the Act	☐	
2. Australian manufacturers included in the ARTG hold licences for the type of product, dosage form and the manufacturing steps that are nominated in the ARTG for the medicine.	• Paragraph 26A(2)(e) of the Act • Paragraph 28(5B)(a) of the Act • Manufacturers information database (MIS) in eBS	☐	
3. Sponsor holds a valid clearance certificate for any overseas manufacturers for the type of product, dosage form and manufacturing steps that are nominated in the ARTG for the medicine.	• Subsection 26A(3) of the Act • Paragraph 28(5B)(b) of the Act • Manufacturers information database (MIS) in eBS	☐	
4.1 Finished Product Details and Testing Specifications *The finished product specification is the set of tests and limits applicable to the finished medicinal product to ensure that every batch is of satisfactory and consistent quality at release and throughout its shelf life.*			
4. Product name and/or product code(s) present and capable of uniquely identifying the product.	• Consistent throughout documentation. • Often not identical to name in ARTG entry. e.g., "Healthy life super omega-3 concentrated fish oil" in ARTG entry may be "fish oil concentrated" in documentation. s.37	☐	
5. Date specification approved, version number, name and signature of company official.	s.37	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
6. Dosage form (*stated and consistent with ARTG*).	• Paragraph 26A(2)(k) *(consider subsection 16(1A) of the Act for separate and distinct goods)*	☐	
7. Description of the physical appearance of the product. • Consistent with Certificate of Analysis?	s.37	☐	
8. Description of pack/container size(s) and closure system. • *Applicable for certain iron-containing and essential oil products.*	• TGO 95 – Child-resistant packaging requirements for medicines • SUSMP (the Poisons Standard)	☐	
9. Recommended storage conditions included on finished product specification document. • Must be consistent with the label and TGO 92 requirements, and appear acceptable, e.g., probiotics normally stored at 2 – 8°C.	• Paragraph 8(1)(h) of TGO 92 • Subsection 11(4) of TGO 92	☐	
10. Shelf-life included on finished product specification document (maximum five years in final container). • If the shelf-life is not present, it would suggest that stability data does not exist, or stability testing may not have been performed.	• s 6 of TGO 92 for definition of 'expiry date' s.37	☐	
Tests and limits for the finished dosage form are acceptable and consistent with relevant default standards, TGOs, and TGA guidelines. *Specific tests are listed below:* • Part 3-1 of the Act – Standards • Section 13(2) of the Act (TGOs take precedence over pharmacopoeias) • Subsection 26A(2)(d) of the Act • TGO 101 – *Standard for tablets and capsules* • *TGO 98 – Microbiological standards for medicines* • British Pharmacopoeia (BP) *Available online via the Information Resources Catalogue (library)*			

Requirement	Relevant legislation	Deficiency Identified	Comments
• European Pharmacopoeia (PH Eur) *Available online via the Information Resources Catalogue (library)* • United States Pharmacopoeia – National Formulary (USP-NF) *Available online via the Information Resources Catalogue (library)* • BP Volume III – Formulated Preparations: Specific Monographs • BP Volume III – Formulated Preparations: General Monographs: *Please see Attachment 1 for all dosage forms* • BP Volume IV – Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products • BP Volume IV – Materials for use in the Manufacture of Homoeopathic Preparations • BP Volume V – Appendices *Please see Attachment 2 for relevant tests and assays*			
11. For a finished product with an applicable monograph in a default standard – complies with relevant tests and limits (as outlined above).	• See TGO 101 for tablets or capsules with an individual BP monograph • Paragraph 26A(2)(d) of the Act • BP Volume III – Formulated Preparations: Specific Monographs • USP – NF monographs • PH-Eur monographs	☐	
12. Uniformity of weight for tablets, capsules.	• See TGO 101 for tablets and capsules with an individual BP monograph • See TGO 101 for tablets and capsules without an individual BP monograph • Paragraph 26A(2)(d) of the Act • BP Volume V – Appendix XII C. Consistency of Formulated Preparations. 1.Uniformity of Weight (Mass) • BP Volume III – Formulated Preparations: Specific Monographs. • BP Volume III - Formulated Preparations: General Monographs. Capsules • BP Volume III – Formulated Preparations: General Monographs. Tablets	☐	
13. Uniformity of weight (mass) of delivered doses from multidose containers. • This is applicable to oral dosage forms such as granules, powders or liquids which are supplied in multidose containers and include a measuring device e.g., droppers.	• Part 3-1 of the Act – Standards • Paragraph 26A(2)(d) of the Act • BP Volume V – Appendix XII C. Consistency of Formulated Preparations. 2. Uniformity of Weight (Mass) of Delivered Doses from Multidose Containers.	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
N.B. Not applicable/enforceable if manufacturer is using USP method to measure uniformity of weight.			
14. Disintegration of tablets, capsules.	• Part 3-1 of the Act – Standards • Paragraph 26A(2)(d) of the Act • See TGO 101 for tablets or capsules without an individual BP monograph • BP Volume III - Formulated Preparations: General Monographs. Capsules • BP Volume III – Formulated Preparations: General Monographs. Tablets • BP Volume V Appendix XII A. Disintegration.	☐	
15. Dissolution: • Tablets and capsules containing 100 mcg or more folic acid. • Modified-release tablets and capsules.	Folic acid: • See TGO 101 Paragraph 26A(2)(d) of the Act • USP-NF Chapter <2040> 'Disintegration and Dissolution of Dietary Supplements' Modified releases: • See TGO 101 BP Volume III - Formulated Preparations: General Monographs. Capsules • BP Volume III – Formulated Preparations: General Monographs. Tablets • BP Volume V Appendix XII B. Dissolution	☐	
16. Assay for the content of preservative. • Only applicable to liquid or semi-solid preparations especially with high water content.	• Not a mandatory test but good quality control. • Where a liquid or semi-solid preparation, especially with a high-water content, does not assay for content of preservative, it *may* in some circumstances be worth considering for routine microbiological testing. • Multidose medicines may have anti-microbial agents that may require	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
	preservative efficacy testing. Please see s 10 of TGO 100.		
17. Microbial attributes of a complementary medicine **oral dosage form** containing raw material of natural (animal, vegetal or mineral) origin.	• Subsection 11(2) of TGO 100 • Schedule 1 of TGO 100 • Schedule 2 of TGO 100 for herbal medicines to which boiling water is added before use (i.e., tea) • Paragraph 26A(2)(d) of the Act	☐	
18. Microbial attributes of a non-sterile medicine (other than above).	• Subsection 11(1) of TGO 100 • Paragraph 26A(2)(d) of the Act • BP Volume V– Appendix XVI D – Table 5.1.4.-1 • USP-NF Chapter <1111> Microbiological Examination of Nonsterile Products. Table 1 – Acceptance Criteria	☐	
19. Other testing as required (describe).	• BP Volume V – Appendices *Please see Attachment 2 for relevant tests and assays*	☐	
20. Stability data (if reviewed) supports the claimed shelf life and storage conditions.	• Technical guide on the interpretation of PIC/S guide • Stability testing of Listed complementary medicines	☐	
21. The finished product does not contain a prohibited substance e.g., aristolochic acid.	• Schedule 9 or 10 of SUSMP (the *Poisons Standard)*	☐	
4.2 Formulation document *This section is used to check the requirements in the Formulation documentation also known as 'active ingredient details'.*			
22. Details of full product formulation present and consistent with the ARTG entry. • Each active ingredient and equivalent quantities must be able to be identified as correct for the purposes of verification	• Paragraph 26A(2)(k) of the Act. *You may consider Separate and distinct goods – subsection 16(1A) of the Act*	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
against the product's label, ARTG and eligibility for listing requirements.			
23. All excipient ingredients, including any coating and capsule shell ingredients consistent with the ARTG entry. • Where the formulation includes a PI, confirm the PI number and, where relevant, that the quantity of PI is consistent with the ARTG entry.	• Paragraph 26A(2)(k) of the Act. *You may consider Separate and distinct goods - subsection 16(1A) of the Act*	☐	
24. Herbal ingredients including the botanical species, plant part and preparation type. For extracts: • the amount of extract; • strength of extract (extraction ratio); • equivalent amount of dried or fresh plant; • extraction solvents; and • diluting medium (carrier).	• TGA approved terminology for medicines/herbal ingredients	☐	
25. Quantification of active ingredients in the finished product. • Analysis in each batch or on rotation: - satisfactory limits are applied, any overages specified are compatible with statutory limits. - 'restricted' ingredient(s) assayed in each batch (*unless justified*). • Quantified by input (QBI).	• See TGO 101 for tablets or capsules with an individual BP monograph. • BP Volume III – Formulated Preparations: Specific Monographs. • See TGO 101 for tablets or capsules without an individual BP monograph. • See TGO 101 for Limits for content of each active ingredient or component in a listed good that is a tablet or capsule. • Subregulation 11(2) of the Regulations for restricted ingredients.	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
4.3 Certificate of Analysis *The Certificate of Analysis is a quality control document that confirms that the product meets its product specification. The test data should be accompanied by the acceptable test specifications, normally referenced, which the batch must comply with before release for supply.*			
26. Product name/product identification.	• Product name and/or product code(s) present and capable of uniquely identifying the product. • Consistent throughout documentation. • Often not identical to name in ARTG entry. • e.g. "Healthy life super omega-3 concentrated fish oil" in ARTG entry may be "fish oil concentrated" in documentation. • Include in manufacturer's spreadsheet if there is an issue.	☐	
27. Date and batch number present.	s.37	☐	
28. Name of manufacturer present and nominated on ARTG for **manufacture of dosage form** OR **release for supply** manufacturing steps. **If a deficiency is identified, tick the relevant box in the previous section(s)**	• Paragraphs 26A(2)(h) and (i) of the Act • Paragraphs 28(5)(f) and (g) of the Act • Paragraph 26A(2)(e) of the Act • Paragraph 28(5B)(a) of the Act • Manufacturers information database (MIS) in eBS • Subsection 26A(3) of the Act • Paragraph 28(5B)(b) of the Act	☐	
29. Description of the physical appearance of the product. • Consistent with Product Specifications. • Dosage form consistent with the ARTG entry.	s.37 • Paragraph 26A(2)(k) of the Act *(consider subsection 16(1A) of the Act for separate and distinct goods)*	☐	
30. Physical test – uniformity of weight (see TGO 101) – for tablets and capsules.	• See TGO 101 for tablets and capsules with an individual BP monograph • See TGO 101 for tablets and capsules without an individual BP monograph	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
If a deficiency is identified, tick the relevant box in the previous section(s)	• Paragraph 26A(2)(d) of the Act		
31. Physical test – Disintegration time (see TGO 101) – for tablets and capsules. **If a deficiency is identified, tick the relevant box in the previous section(s)**	• Part 3-1 of the Act – Standards • Paragraph 26A(2)(d) of the Act • See TGO 101 for tablets or capsules without an individual BP monograph	☐	
32. Dissolution test required for: • tablets and capsules containing 100 mcg or more folic acid. • modified release tablets and capsules. • NA where not applicable. **If a deficiency is identified, tick the relevant box in the previous section(s)**	Folic acid: • See TGO 101 Paragraph 26A(2)(d) of the Act • USP-NF Chapter <2040> 'Disintegration and Dissolution of Dietary Supplements' Modified releases: • See TGO 101 BP Volume III - Formulated Preparations: General Monographs. Capsules • BP Volume III – Formulated Preparations: General Monographs. Tablets • BP Volume V Appendix XII B. Dissolution	☐	
33. Quantitative analysis for active ingredients / ingredient components / preservatives (if applicable) ***OR*** QBI (do not pursue unless restricted ingredients close to limit – assess the need to pursue with supervisor). **If a deficiency is identified, tick the relevant box in the previous section(s)**	• See TGO 101 for tablets or capsules with an individual BP monograph. • BP Volume III – Formulated Preparations: Specific Monographs. • See TGO 101 for tablets or capsules without an individual BP monograph. • See TGO 101 for Limits for content of each active ingredient or component in a listed good that is a tablet or capsule. • Subregulation 11(2) of the Regulations for restricted ingredients	☐	
34. Microbial assays. • Regular assay may not be required for all complementary medicines. • However, particular attention should be paid to products that are liquid and semi-solid preparations.	• s 10 of TGO 100 – for multidose medicines • Subsection 11(2) of TGO 100	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
If a deficiency is identified, tick the relevant box in the previous section(s)			
35. Name and signature of appropriate official present.	s.37	☐	
36. Any other notable issues relating to manufacturer added to spreadsheet.	• TRIM ref: s.22	☐	
4.4 Starting Material Specifications *This section is only required to be completed when reviewing raw material specifications, which are not always requested.*			
37. Material suitably characterised prior to formulation: • Herbal ingredients include: – botanical species; – plant part; and – preparation type. • For extracts: – the amount of extract; – strength of extract (extraction ratio); – equivalent amount of dried plant; – extraction solvents; and – diluting medium (carrier). **If a deficiency is identified, tick the relevant box in the previous section(s)**	• eBS Listed Medicines Validation Rules for naming conventions	☐	
38. Raw material complies with relevant default standard, or compositional guideline or material otherwise satisfactorily identified. Raw material testing establishes an ingredient profile and demonstrates that it is the same ingredient that has been approved for use in Listed complementary medicines, thereby ensuring the quality and safety of the medicine.	• Part 3-1 of the Act – Standards • Paragraph 26A(2)(d) of the Act Compositional guidelines: • http://www.tga.gov.au/industry/cm-cg.htm • British Pharmacopoeia (BP) • European Pharmacopoeia (PH Eur) • United States Pharmacopoeia – National Formulary (USP-NF)	☐	

Requirement	Relevant legislation	Deficiency Identified	Comments
If a deficiency is identified, tick the relevant box in the previous section(s)			
39. Assay of components: • 'restricted' and mandatory components. – Oxedrine: maximum daily (max. 30 mg.) – Alkaloids – Vitamin A from Retinyl palmitate – Identification Test **B** for Ginkgo biloba extracts (USP32-NF27) – Aristolochic acids (**must confirm the absence or be below current detection limits**). • When components are claimed on the label. Examples: DHA & EPA in Fish Oils. **If a deficiency is identified, tick the relevant box in the previous section(s)**	• SUSMP (the *Poisons Standard)* or other restrictions applicable to Listed complementary medicines. • Therapeutic Goods (Permissible Ingredients) Determination – 26BB List	☐	

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Office of Complementary Medicines
Listed Medicine Reviews

This form is to be used to provide a summary of the breaches raised following a proposal to cancel and a summary of the actions taken/proposed by the sponsor has taken.

The aim of this form is:

- To assist the Reviewer to ensure that all identified breaches were addressed and appropriate action is taken.
- To assist the Delegate to easily make a decision on how to proceed with the review without having to read through detailed documents and excessive information.
- A record of why a certain action was taken.
- To ensure that consistent decisions are made relating to the progress of the review.

This form can be used in most circumstances and is intended to be a working document until the cancellation or conclusion letter is sent. It should assist the reviewer to assess what information is still required.

Naming Convention: LMP Summary of P2C response <Target/Random> <ARTG #><Medicine Name>

1 Summary of Proposal to Cancel Response

Product			
Sponsor		TRIM Ref	
Delegate		'Proposal to cancel' response due date	

<only sign/complete once review proceeds to conclusion or cancellation, as this may be updated when additional information is received>

Has a response to the proposal to cancel letter been received?

☐ Yes ☐ No <to select - double click on the 'check boxes' and change the 'Default Value' to checked>

<Include any responses below in this table and describe. Include the date a response was received and summarise the information provided in a response, such as label will be updated in 4-6weeks and when the revised actual label was provided>

Date	Summary

s.37

Description of Breach	Actions to address breach
<The legislation and plain English version of breach>	<actions proposed by the sponsor to rectify breach>

Do these actions rectify the identified breaches?

☐ Yes ☐ No

What level of risk do these breaches pose on safety and consumer trust?

☐ High ☐ Medium ☐ Low

s.37

Do their proposed actions create any other potential compliance breaches?

☐ Yes ☐ No

Describe

Other comments/Relevant considerations

- <Anything else the Delegate should be aware of>

s.37

Recommendations

☐ Conclusion ☐ Cancellation ☐ Request further information ☐ Other (describe)

Reasoning			
Name			
Signature		Date	

<only sign once review proceeds to conclusion or cancellation, as this may be updated when additional information is received>

Delegate's Decision

☐ Agree with recommendations ☐ Propose alternative (describe)

Describe	<only if proposing alternative>		
Name			
Signature		Date	

Relevant documents

<Include in this table any documents that the delegate may need to consider in order to make this decision, such as the proposal to cancel letter, ARTG record summary, and response to the proposal to cancel letter.

The TRIM reference should have a hyperlink so that the delegate can click straight to the relevant document.

http://intranet.tga/information/trim-link-generator.htm Use this link to create a hyperlink to the TRIM document. Highlight the relevant Trim reference and right click or use Ctl+K and paste the hyperlink that has been generated

TRIM Ref	Document Name
	ARTG Record Summary
	Signed Proposal to cancel letter
	Proposal to cancel response
	Email from sponsor – time frame for implementation

Document 3

LISTED MEDICINE REVIEW CHECKLIST

TRIM Container	
ARTG Number (AUST L)	
Product Name	
Sponsor	

Guidance for using the review checklist

Saving this document into TRIM

- Save a copy in TRIM

Recording your evaluation

The information recorded in this checklist will be an **official record** of the evaluation and thought process that occurred in this compliance review. This information will support the release of compliance review outcomes to the public (see s.22) and any regulatory decisions made in relation to the product under review. **This information may be under scrutiny by a range of audiences (FOI, s60 Delegate, Federal Court Judge, ANAO audit, etc.) at any time.** As such, **it is critical that the flow of logic, rationale behind conclusions, materials considered during evaluation must all be documented in this evaluation checklist and understandable by any reader of this document.**

The checklists below (label, manufacturing and evidence, if applicable) **must contain** the information described in the table below. **Comment bubbles and/or tracked changes** may be used as a means of communication between the Evaluator and Reviewer during the evaluation process but **must not be present at the time of finalising the initial review checklist** (i.e. at the end of the Evaluation #1 stage). Once you start drafting a regulatory notice (if applicable), this checklist must be free of tracked changes and comments. If necessary, move information in comment bubbles into the columns.

Marked with	✓	N/A	C (#)
Circumstances where appropriate	Relevant regulatory requirement is satisfactorily complied with.	A legislative requirement is not applicable to the medicine.	Regulatory compliance issues (breaches of the legislation) are identified.
Deficiency box to be ticked?	No	No	Yes
Information to be included ('COMMENTS' column)	Information that describes how you determined that the medicine was compliant with the requirement. **Include enough information for any reader to understand how you came to that conclusion.** Links to evidence (that are recorded in TRIM) that helped you come to that determination e.g. captures of a website or relevant advertising material, a PDF copy of the label of the medicine etc.	Information that describes how you determined that the requirement is not applicable to the medicine under review. Include enough information for **any reader** to understand how you came to that conclusion.	Your comments about the compliance of the product including: • the relevant provisions of the legislation that have been breached (See TRIM s.22 for an explanation of the provisions); • why you think they have been breached including links to evidence (recorded in TRIM if applicable e.g. captures of advertising material); and • why you're recommending the breach be pursued and in what form (e.g. Proposal to Cancel or Deficiencies notice). s.37 [redacted] **Ensure you include enough information for any reader to understand why you have decided that an aspect of the medicine is non-compliant, why you recommended the breach be pursued or not and in what form.** Information for the publication of outcomes including: • the classification of the deficiency/breach as one of 'safety-related', 'efficacy-related' or 'minor'. Refer to *How to interpret the compliance review results* section of the Database for definitions of 'Issues related to safety' and 'Issues related to efficacy'. A classification is automatically assigned based on the 'Deficiency identified' checkbox and to which regulatory requirement it corresponds to. However, **in all circumstances** you must consider whether the classification of the deficiency is appropriate for your review circumstances. Do not solely rely on the default classification; and • a justification and rationale to support the classification of the identified breach. If the classification has changed from the one that has been assigned by default, ensure that the reason for this change is adequately documented.

Note: For each regulatory requirement, some of the relevant legislation has been hyperlinked in the checklist. The hyperlinked legislation is not an exhaustive list. Always think about whether it is necessary for you to consider legislation, definitions, explanatory notes and/or guidance material other than those referenced below.

What to do when safety-related deficiency is identified

When a safety-related deficiency is identified, you will need to consider the level of risk the deficiency poses on consumers or anyone that may come into contact with the medicine. This is particularly crucial for non-compliant stock that are out on the market or are ready to be released to the market. If you are unsure, consult your supervisor to determine whether to request advice from the Adverse Events and Medicine Defects Section (AEMDS) in Pharmacovigilance & Special Access Branch (PSAB).

The advice may be used to inform the review pathway you should take after Evaluation #1 (e.g. the type of regulatory notice sent such as a Proposal to cancel or Deficiencies Notice), how to pursue the safety-related deficiency or whether additional information needs to be requested from the sponsor (e.g. number of non-compliant units of the medicine remaining with the sponsor, wholesalers/distributers, retailers and consumers). In serious circumstances, PSAB may advise you to consider contacting the Recalls Section in the Manufacturing and Quality Branch to determine whether recall and non-recall actions for non-compliant stock are necessary.

As such, you will need to consider at what point during the review the seeking of advice is necessary. In most circumstances it is preferable that you include information about existing stock levels in any requests to PSAB. This information may need to be requested during the initial evaluation for significant safety related issues or may be done at the time of sending a regulatory notice. However, advice can also be sought from PSAB without this information.

s.37 [redacted]

Label

Relevant TRIM reference					
Type of label reviewed	Immediate	☐	Primary	☐	
1. Reviewed by			Date		
2. Peer reviewed by	(if necessary)		Date		
3. Reviewed by					
Summary of deficiencies/other issues	(e,g, NA if no issues)				
Action	s.37				
Grounds for Proposed action s.22					

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1 N/A	Pack Type 2 N/A	COMMENTS
Product type					
Required particulars on the label					
1. Name of goods consistent with ARTG entry. Separate and distinct goods? • Must be included on the 'main label' of the label.	- Paragraph 8(1)(a) of TGO 92 - Paragraph 9(1)(a) of TGO 92 - Subclause 9(2) of TGO 92	☐			

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1	Pack Type 2	COMMENTS
	- Clause 6 of TGO 92 for definition of 'name of the medicine' and 'main label' - Subclause 8(4) of TGO 92 - Subclauses 9(3), 9(5), 9(6) and 9(8) of TGO 92 - Subclause 9(4) of TGO 92 (all text oriented in same direction) - Subclause 10(7) of TGO 92 - Subsection 26A(2)(k) of the Act *(consider subsection 16(1A) of the Act for separate and distinct goods)*				
2. Formulation consistent with ARTG. •	Subsection 26A(2)(k) of the Act *(consider subsection 16(1A) of the Act for separate and distinct goods)*	☐			
3. Correct Australian approved names of all active ingredients. • It can be included **either** on the main label or side / rear panel The ingredient names on the ARTG may be different to the Sponsor's documents: pursue if the changes are not related to IHIN changes (the transition period to make the changes expires in 30 April 2023).	- Paragraph 8(1)(b) of TGO 92 - Subclauses 9(3), 9(5) and 9(6) of TGO 92 - Subclause 10(7) of TGO 92 - Clause 6 of TGO 92 for definition of 'name of an active ingredient' - Subclause 11(5) of TGO 92 - (inclusion of common names of vitamins)	☐			
4. Quantity or proportion of all active ingredients in the goods – with correct expression and units. • It can be included **either** on the main label or side / rear panel.	- Subclause 11(1) of TGO 92 - Paragraph 9(1)(c) of TGO 92 - Subclause 9(5), 9(6) of TGO 92 - Subclause 10(7) of TGO 92 - Subclause 11(2) of TGO 92 - Subclause 9(8) of TGO 92 for composite packs	☐			
5. TGO 92 Schedule 1 Substances of Groups of Substances declared.	- Paragraph 8(1)(j) of TGO 92 - Schedule 1 of TGO 92	☐			
6. Correct name of dosage form (main label) as entered in the ARTG e.g. soft capsule, etc. (eBS Code Tables)	- Paragraph 8(1)(d) of TGO 92 - Paragraph 9(1)(d) of TGO 92 - Paragraph 9(6)(a) of TGO 92 - Subclause 10(7) of TGO 92 for small containers Clause 6 of TGO 92 for the definition of name of dosage form	☐			
7. Quantity of the goods (main label).	- Paragraph 8(1)(e) of TGO 92 - Paragraph 9(1)(e) of TGO 92	☐			

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1	Pack Type 2	COMMENTS
	- Clause 6 of TGO 92 for definition of 'quantity of the medicine' - Subclauses 9(3), 9(5) and 9(6) of TGO 92 Subclause 10(7) of TGO 92 for small containers				
8. Required warning statements and representations present, correct and complete. *Primary therapeutic sunscreen products should include warning statements to the effect that prolonged exposure to the sun should be avoided, and it is important to wear protective clothing, hats and eyewear when exposed to the sun.*(These warning statements are linked to certain active ingredients. Check 26BB to ensure if these warning statements are applicable to your product before pursuing)	- Paragraph 8(1)(k) of TGO 92 - Paragraph 11(1)(d) of TGO 92 - Clause 6 of TGO 92 for definition of 'warning statements' - Medicines Advisory Statements Specification 2016 and SUSMP (the Poisons Standard) - Schedule 2 Part 2 of the Regulations in relation to required representations - Schedule 4 – Current Regulations - Therapeutic Goods (Permissible Ingredients) Determination – 26BB List for required warning statements linked to specific ingredients in newly listed medicines - Subsection 42DJ(2) of the Act in relation to required representations	☐			
8a. The sun protection factor (SPF) of the product preceded by the expression 'Sun Protection Factor' or 'SPF' (must be included on the main label) s.37	• Subclause 7(2) of TGO69 • Section 7 of the Sunscreen Standard AS/NZS 2604:2012 s.22	☐			
8b. Is the product a broad spectrum sunscreen? (Mandatory for all therapeutic sunscreens and cosmetic sunscreens with SPF 30 or above, mandatory for all secondary sunscreens for skin of SPF 4 or above) **Tick the deficiency box only if the sunscreen does not meet the broad spectrum requirements**	Section 7 of the Sunscreen Standard AS/NZS 2604:2012 s.22	☐			
9. Batch No. (with correct prefix). • Please note: sponsors may provide labels that are not part of a released	- Paragraph 8(1)(f) of TGO 92	☐			

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1	Pack Type 2	COMMENTS
batch and, therefore, do not have the batch number or expiry date (or the prefix) included on the label. • Ensure that space is provided for the Batch No. and Expiry date.	- Clause 6 of TGO 92 for definition of 'batch number' and 'batch number prefix' Subclause 10(7) of TGO 92 for small container				
10. Expiry date (with correct prefix). • Please note: sponsors may provide labels that are not part of a released batch and, therefore, do not have the batch number or expiry date (or the prefix) included on the label. • Ensure that space is provided for the Batch No. and Expiry date. • Terms such as 'Best By' or words to this effect are not acceptable because they relate to foods.	- Paragraph 8(1)(g) of TGO 92 - Clause 6 of TGO 92 for definition of 'expiry date' and 'expiry date prefix' - Subclause 10(11) of TGO 92 for composite packs - Subclause 10(7) of TGO 92 for small containers	☐			
11. Storage conditions.	- Paragraph 8(1)(h) of TGO 92 - Subclause 11(4) of TGO 92	☐			
12. Directions for use *The directions for use for a primary therapeutic sunscreen should include statements to the effect that the product should be applied to the skin in generous amounts over all of the exposed areas 20 minutes before sun exposure then reapply frequently and after swimming or towelling.*	- Paragraph 8(1)(l) of TGO 92 - Clause 6 of TGO 92 for definition of 'directions for use' - Paragraph 8(1)(m) of TGO 92 if the medicine requires some preparation before use - Subparagraph 8(1)(l)(ii) of TGO 92 if there is insufficient space on the label or primary pack and a package insert is provided pack - Section 7 of the Sunscreen Standard AS/NZS 2604:2012 s.22	☐			
13. Name and Australian address of sponsor/supplier (only name or trademark required for blisters). • Note: Supplier details may not be on eBS but should include sufficient information to allow the Australian sponsor or supplier to be uniquely identified.	- Paragraph 8(1)(i) of TGO 92 - Clause 6 of TGO 92 for definition of 'name and contact details', 'distributor' and 'sponsor' - Subclause 10(7) of TGO 92 for small containers	☐			
14. Indications/Statement of goods	- Paragraph 8(1)(n) of TGO 92 - Paragraph 28(5)(ab) of the Act	☐			

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1	Pack Type 2	COMMENTS
• Intended purpose/indications/claims present and consistent with the ARTG record (condition of listing). • Sunscreens are only permitted to include specific permitted indications. Check the Sunscreen Guidelines to see permitted indications. • **This includes indications/statements on the website.**					
15. AUST L (main label) – primary pack (or immediate container if no p/p).	- Subparagraph 7(2)(d)(i) of TGO 92 - Paragraph 15(1)(b) and (c) of the Regulations	☐			
16. For topical preparations only – name of any antimicrobial agents.	- Subclause 10(2) of TGO 92	☐			
General labelling requirements for above required particulars					
17. Legible & durable, English language. • All information that is required by TGO 92 to be on the label must be in English. • Other languages are allowed provided they are not misleading or breach the legislation.	- Paragraphs 7(2)(a), (b), (c) and (e) of TGO 92 - Paragraph 8(4) of TGO 92 - Paragraph 8(5) of TGO 92	☐			
18. Letter height of required particulars is ≥ 1.5 mm, AUST L ≥ 1mm. • Use the scaled magnifiers (with or without illumination) to measure letter height.	- Paragraphs 7(2)(d) of TGO 92 - Clause 6 of TGO 92 for definition of 'text size' - Paragraph 15(1)(b) and (c) of the Regulations	☐			
18a Does the main label include water resistance of the goods in hours or minutes (only applicable for the products with water resistance claims)	See s.22 for sunscreen standard AS/NZS 2604:2012	☐			
18b. Are 'Broad spectrum' and 'water resistant' claims printed in letters no larger than those used for the labelled SPF?	See s.22 For sunscreen standard AS/NZS 2604:2012	☐			
18c. Labelled SPF must be one of the following : 4, 6, 8, 10, 15,20, 25, 30, 40, 50 or 50 +	See s.22 For sunscreen standard AS/NZS 2604:2012	☐			

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1	Pack Type 2	COMMENTS
Note: SPF greater than 50+ is not permitted SPF's '30 +' is also not permitted - Exemptions apply if the product was listed before 2012 and no groupings have been made. Such product can comply with sunscreen standard 1998					
Ingredient requirements					
19. Any quantity restrictions complied with. • e.g. sunscreen actives, excipients.	• Therapeutic Goods (Permissible Ingredients) Determination – 26BB List • SUSMP (the *Poisons Standard)* • Schedule 4 of the Regulations	☐			
20. Expression of quantity/proportion – herbal ingredients (if any included as excipients and listed on the label).	- Paragraph 11(2)(i) of TGO 92	☐			
21. Ingredients are not included in a Schedule to the Poisons Standard or Appendix C of the Poisons Standard.	- Schedule 4, item 3 (c)(i) of the Therapeutic Goods Regulations 1990	☐			
Presentation and Advertising					
22. Webpage (where available) for the goods is compliant with the Therapeutic Goods Advertising Code?	- Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	☐			
23. Is the product eligible for listing? • i.e. the indications on the label **or** ARTG entry are not for the **treatment** of a serious form of a disease, condition, ailment or defect as explained in Part 4 of the Advertising Code • Please check all indications on the ARTG.	- Ineligible for listing paragraph 30(1A)(a) of the Act - Schedule 4, Item 7 of the Regulations - Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	☐			
24. The indications on the label/name of medicine don't reference or imply reference to a **prohibited** condition (specified under Part 4 of the Code)? • Note: the indication must be 'advertised', the ARTG entry does **not** constitute an advertisement.	- Prohibited representation paragraph 30(2)(ea) of the Act - Part 4 of the Code Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	☐			

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1	Pack Type 2	COMMENTS
• The label must be the actual label in use (not a draft) to be considered as part of presentation. • *Sunscreen products are allowed to make reference to skin cancers provided it has a SPF of 30 + and include relevant warning statements. Check the permitted indications for sunscreen*					
25. The indications on the label/name of medicine don't reference or imply reference to a **serious** condition under Part 4 of the Code? • Note: the indication must be 'advertised', and the ARTG entry does not constitute an advertisement. • The label must be the actual label in use (not a draft) to be considered as part of presentation.	- Restricted representations paragraph 30(2)(ea) of the Act - Part 4 of the Code - Definition of 'serious' Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	☐			
26. Name of goods is appropriate for a Listed medicine. • i.e. does not promote/promise a treatment/cure or sound similar to a Registered medicine.	- Subsection 3(5) Regulation 3A, Subregulation 11(1) and schedule 4 of the Regulations - Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	☐			
27. "Free from <ingredients>" claims are accurate (check PIs). s.22	- Paragraph 4(2)(c) of the Code - Subsection 3(5) of the Act	☐			
28. Presentation of the medicine is not "unacceptable". • This includes misleading claims (based on lack of evidence). • Is not capable of being misleading or confusing as to content or proper use. • Does not state or suggest that the goods have ingredients, components or characteristics that they do not have. • Is the name the same as another therapeutic good that contains different ingredients?	- Definition of 'presentation' subsection 3(1) of the Act - Subsection 3(5) of the Act - Regulation 3A of the Regulations	☐			

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1	Pack Type 2	COMMENTS
29. Other text and graphics are acceptable.	- Unacceptable presentation under - Subsection 3(5) of the Act	☐			
30. Statements are consistent with general principles of the Code (all indications on the ARTG must be checked).	Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	☐			
34a. Are the statements included on the label consistent with the sunscreen standard? *(Following are not permitted by the standard:* • *Terms such as waterproof, sunblock and sweat proof.* • *Claims relating the SPF to an increase in protection time.* • *Numerical claims of UVAPF* • *Claim that indicates or implies that the product does not need to be reapplied at regular intervals. (for example, 'all day protection')*	- See s.22 for sunscreen standard AS/NZS 2604:2012	☐			
31. No unacceptable endorsements, etc. *Examples include endorsement by a health practitioner, hospital, etc.* *Refer to section 16 of the Code*	- Section 24 of the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	☐			
32. Does not refer to the Act or suggest or imply the goods are recommended or approved by any government body.	- Paragraph 42DL(1)(e)(ii) of the Act - Subsection 24(6) of the Code	☐			
33. Does not refer to goods/substances/preparations in Schedules 3, 4 or 8 of SUSMP.	- Paragraph 42DL(1)(f) of the Act	☐			
34. Advertisement is unlikely to impact the consumer's ability to appropriately use the goods in line with their intended purpose. **the breach is not related to the lack of evidence.**	- Definition of 'presentation' subsection 3(1) of the Act - Subsection 3(5) of the Act - Regulation 3A of the Regulations	☐			
35. Advertisement is unlikely to impact the consumer's ability to safely use the goods	- Definition of 'presentation' subsection 3(1) of the Act - Subsection 3(5)(d) of the Act - Regulation 3A of the Regulations	☐			

Requirement	Relevant legislation	Deficiency Identified	Pack Type 1	Pack Type 2	COMMENTS
the breach is not related to the lack of evidence.					
36. Advertisement is unlikely to lead to harm or risks public health. **the breach is not related to the lack of evidence.**	-	☐			
Permitted indications requirements and ARTG entry					
37. Permitted indications requirements https://www.legislation.gov.au/Details/F2019L00262 s.37	• Ineligible for listing paragraph 30(1A)(a) of the Act • Schedule 4, Item 3 of the Regulations • Therapeutic Goods (Permissible Indications) Determination (No.1) 2019	☐			
38. Information included in the ARTG is correct s.37	- The certification under paragraph 26A(2)(k) of the Act - Therapeutic Goods Act 1989	☐			

Manufacturing

Relevant TRIM reference			
1. Reviewed by		Date	
2. Peer reviewed by	(if necessary)	Date	
3. Reviewed by Supervisor		Date	
Summary of issues to pursue in the P2C	s.37 (e,g, NA if no issues)		
Action	s.37		
Grounds for proposed action			

s.22

s.22

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
Product Manufacturer(s)				
1. Manufacturers included in the specifications/formulation documents are nominated in the ARTG entry and steps of manufacture are consistent.	- Paragraphs 26A(2)(h) and (i) of the Act - Paragraphs 28(5)(f) and (g) of the Act	☐		
2. Australian manufacturers included in the ARTG hold licences for the type of product, dosage form and the manufacturing steps	- Paragraph 26A(2)(e) of the Act - Paragraph 28(5B)(a) of the Act	☐		

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
that are nominated in the ARTG for the medicine.	- Manufacturers information database (MIS) in eBS			
3. Sponsor holds a valid clearance certificate for any overseas manufacturers for the type of product, dosage form and manufacturing steps that are nominated in the ARTG for the medicine.	- Subsection 26A(3) of the Act - Paragraph 28(5B)(b) of the Act - Manufacturers information database (MIS) in eBS	☐		

Finished Product Details and Testing Specifications

The finished product specification is the set of tests and limits applicable to the finished medicinal product to ensure that every batch is of satisfactory and consistent quality at release and throughout its shelf life.

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
4. Product name and/or product code(s) present and capable of uniquely identifying the product.	- Consistent throughout documentation. - Often not exactly identical to name in ARTG entry. - e.g. "Healthy life super omega-3 concentrated fish oil" in ARTG entry may be "fish oil concentrated" in documentation. s.37	N/A		
5. Date specification approved, version number, name and signature of company official.	s.37	N/A		
6. Dosage form (*stated and consistent with ARTG*). • Separate and distinct goods?	- Paragraph 26A(2)(k) *(consider subsection 16(1A) of the Act for separate and distinct goods*	☐		
7. Description of the physical appearance of the product. • Consistent with Certificate of Analysis?	s.37	N/A		
8. Description of pack/container size(s) and closure system. • *Applicable for certain iron-containing and essential oil products.*	- *TGO 95 – Child-resistant packaging requirements for medicines* - SUSMP (the *Poisons Standard)*	☐		
9. Recommended storage conditions included on finished product specification document.	- Paragraph 8(1)(h) of TGO 92 - Subclause 11(4) of TGO 92	N/A		

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
• Must be consistent with the label and TGO 92 requirements, and appear acceptable; e.g. probiotics normally stored at 2 – 8°C.				
10. Shelf-life included on finished product specification document (maximum five years in final container). • If the shelf-life is not present, it would suggest that stability data does not exist or stability testing may not have been performed.	- Clause 6 of TGO 92 for definition of 'expiry date' s.37	N/A		
Tests and limits for the finished dosage form are acceptable and consistent with relevant default standards, TGOs, and TGA guidelines. Specific tests are listed below Part 3-1 of the Act – Standards Section 13(2) of the Act (TGOs take precedence over pharmacopoeias) Subsection 26A(2)(d) of the Act TGO 100 – Microbiological standards for medicines British Pharmacopoeia (BP) *Available online via the Information Resources Catalogue (library)* European Pharmacopoeia (PH Eur) *Available online via the Information Resources Catalogue (library)*	United States Pharmacopoeia – National Formulary (USP-NF) *Available online via the Information Resources Catalogue (library)* BP Volume III – Formulated Preparations: Specific Monographs BP Volume III – Formulated Preparations: General Monographs: *Please see Attachment 1 for all dosage forms* BP Volume IV – Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products BP Volume IV – Materials for use in the Manufacture of Homoeopathic Preparations BP Volume V – Appendices *Please see Attachment 2 for relevant tests and assays*			
11. Test for SPF determination s.37	-See ISO 24444:2010 for specific test requirements. s.37 Refer to AS/NZS 2604:1998 for goods listed before 10 November 2012			

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
s.37				
12. Test for broad spectrum performance (if applicable) s.37	- See ISO 2444 for specific test requirements. s.37 Refer to AS/NZS 2604:1998 for goods listed before 10 November 2012	☐		
13. Water resistance checklist s.37	- See ISO 2444 for specific test requirements. s.37 Refer to AS/NZS 2604:1998 for goods listed before 10 November 2012	☐		
14. Assay for the content of preservative.	- Not a mandatory test but good quality control.	☐		

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
• Only applicable to liquid or semi-solid preparations especially with high water content e.g. cream, lotion.	- Where a liquid or semi-solid preparation, especially with high water content, does not assay for content of preservative, it *may* in some circumstances be worth considering for routine microbiological testing. - Multidose medicines may have anti-microbial agents that may require preservative efficacy testing. Please see Clause 10 of TGO 100.			
15. Microbial attributes of a non-sterile medicine	- Subsection 11(1) of TGO 100 - Paragraph 26A(2)(d) of the Act - BP Volume V– Appendix XVI D – Table 5.1.4.-1 - USP-NF Chapter <1111> Microbiological Examination of Nonsterile Products. Table 1 – Acceptance Criteria	☐		
16. Other testing as required (describe).	- BP Volume V – Appendices *Please see Attachment 2 for relevant tests and assays*	☐		
17. Stability data (if reviewed) supports the claimed shelf life and storage conditions	- Technical guide on the interpretation of PIC/S guide - Stability testing of Listed complementary medicines	☐		
18. The finished product does not contain a prohibited substance e.g. aristolochic acid.	- Schedule 9 or 10 of SUSMP (the *Poisons Standard)*	☐		

Formulation document

This section is used to check the requirements in the Formulation documentation also known as 'active ingredient details'.

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
19. Details of full product formulation present and consistent with the ARTG entry. • Each active ingredient and equivalent quantities must be able to be identified as correct for the purposes of verification against the product's label, ARTG and eligibility for listing requirements.	• Paragraph 26A(2)(k) of the Act. • *You may consider Separate and distinct goods - subsection 16(1A)of the Act*	☐		

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
20. All excipient ingredients are consistent with the ARTG entry. • Where the formulation includes a PI, confirm the PI number and, where relevant, that the quantity of PI is consistent with the ARTG entry.	• Paragraph 26A(2)(k) of the Act. *You may consider Separate and distinct goods - subsection 16(1A)of the Act*	☐		
21. Herbal ingredients including the botanical species, plant part and preparation type. • For extracts: – the amount of extract; – strength of extract (extraction ratio); – equivalent amount of dried or fresh plant; – extraction solvents; and – diluting medium (carrier).	- TGA approved terminology for medicines/herbal ingredients	☐		
22. Quantification of active ingredients in the finished product. • Analysis in each batch or on rotation: – satisfactory limits are applied, any overages specified are compatible with statutory limits. – 'restricted' ingredient(s) assayed in each batch (*unless justified*). • Quantified by input (QBI).	- BP Volume III – Formulated Preparations: Specific Monographs. - Subregulation 11(2) of the Regulations for restricted ingredients.	☐		

Certificate of Analysis

The Certificate of Analysis is a quality control document that confirms that the product meets its product specification. The test data should be accompanied by the acceptable test specifications, normally referenced, which the batch must comply with before release for supply.

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
Product name/product identification.	- Product name and/or product code(s) present and capable of uniquely identifying the product. - Consistent throughout documentation.	N/A		

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
	- Often not exactly identical to name in ARTG entry. - e.g. "Healthy life super omega-3 concentrated fish oil" in ARTG entry may be "fish oil concentrated" in documentation. - Include in manufacturer's spreadsheet if there is an issue.			
Date and batch number present.	s.37	N/A		
Name of manufacturer present and nominated on ARTG for **manufacture of dosage form** OR **release for supply** manufacturing steps. **If a deficiency is identified, tick the relevant box in the previous section(s)**	- Paragraphs 26A(2)(h) and (i) of the Act - Paragraphs 28(5)(f) and (g) of the Act - Paragraph 26A(2)(e) of the Act - Paragraph 28(5B)(a) of the Act s.37 - Subsection 26A(3) of the Act - Paragraph 28(5B)(b) of the Act	N/A		
Description of the physical appearance of the product. • Consistent with Product Specifications. • Dosage form consistent with the ARTG entry.	s.37 -	N/A		
Test for SPF determination **If a deficiency is identified, tick the relevant box in the previous section(s)**	-See s.22 for sunscreen standard AS/NZS 2604:2012 See ISO 24444:2010 for specific test requirements. Refer AS/NZS 2604:1998 for goods listed before 10 November 2012	N/A		
Test for broad spectrum performance **If a deficiency is identified, tick the relevant box in the previous section(s)**	-See s.22 for sunscreen standard AS/NZS 2604:2012 See ISO 24444:2010 for specific test requirements. Refer AS/NZS 2604:1998 for goods listed before 10 November 2012	N/A		

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
Water resistance (if applicable) **If a deficiency is identified, tick the relevant box in the previous section(s)**	-See s.22 for sunscreen standard AS/NZS 2604:2012	N/A		
Quantitative analysis for active ingredients / ingredient components / preservatives (if applicable) ***OR*** QBI (do not pursue unless restricted ingredients close to limit – assess the need to pursue with supervisor). **If a deficiency is identified, tick the relevant box in the previous section(s)**	- BP Volume III – Formulated Preparations: Specific Monographs. - Subregulation 11(2) of the Regulations for restricted ingredients	N/A		
Microbial assays. • Regular assay may not be required for all complementary medicines. • However, particular attention should be paid to products that are liquid and semi-solid preparations. **If a deficiency is identified, tick the relevant box in the previous section(s)**	- Clause 10 of TGO 100 – for multidose medicines - Subsection 11(2) of TGO 100	N/A		
Name and signature of appropriate official present.	s.37	N/A		
Any other notable issues relating to manufacturer s.37.	- TRIM ref: s.22	N/A		

Starting Material Specifications

This section is only required to be completed when reviewing raw material specifications, which are not always requested.

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
Material suitably characterised prior to formulation: • Herbal ingredients include: – botanical species; – plant part; and – preparation type. • For extracts:	- eBS Listed Medicines Validation Rules for naming conventions	N/A		

Requirement	Relevant Legislation	Deficiency Identified		COMMENTS
– the amount of extract; – strength of extract (extraction ratio); – equivalent amount of dried plant; – extraction solvents; and – diluting medium (carrier). **If a deficiency is identified, tick the relevant box in the previous section(s)**				
Raw material complies with relevant default standard, or compositional guideline or material otherwise satisfactorily identified. Raw material testing establishes an ingredient profile and demonstrates that it is the same ingredient that has been approved for use in Listed complementary medicines, thereby ensuring the quality and safety of the medicine. **If a deficiency is identified, tick the relevant box in the previous section(s)**	- Part 3-1 of the Act – Standards - Paragraph 26A(2)(d) of the Act Compositional guidelines: - http://www.tga.gov.au/industry/cm-cg.htm - British Pharmacopoeia (BP) - European Pharmacopoeia (PH Eur) - United States Pharmacopoeia – National Formulary (USP-NF)	N/A		
Assay of components: • 'restricted' and mandatory components. – Oxedrine: maximum daily (max. 30 mg.) – Alkaloids – Vitamin A from Retinyl palmitate – Identification Test **B** for Ginkgo biloba extracts (USP32-NF27) – Aristolochic acids (**must confirm the absence or be below current detection limits**). • When components are claimed on the label. Examples: DHA & EPA in Fish Oils.	SUSMP (the *Poisons Standard)* or other restrictions applicable to Listed complementary medicines - Therapeutic Goods (Permissible Ingredients) Determination – 26BB List **If a deficiency is identified, tick the relevant box in the previous section(s)**	N/A		

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Therapeutic Goods Administration

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Risk Assessment Tool & Investigation Checklist

Please ensure the below tool is completed following the guidance text in grey. Please delete or change the guidance text in answer boxes to black when completed. Ensure the tool is stored in the compliance lead investigation TRIM container.

Section 1 – Initial screening

SP Process Number	TRIM Container	Signal Process Owner

Type of the signal

- **Compliance Lead** ☐
- **ARTG Scanning** ☐

Q1. Details of the signal

For compliance leads, provide a brief background to cover the following points (relevant TRIM link should be attached):

- the date when it was received
- the source of the compliance lead
- summary of the issues described
- information provided

For ARTG Scanning, provide a brief description of the rational for recording it as a signal

s.22 [redacted]

s.37 [redacted]

- **Weak** ☐
- **Moderate** ☐
- **Strong** ☐
- **Cannot determine** ☐

Rationale:

Q3. Basic information about the medicine(s)

Medicine name/s and sponsor/manufacturer, and the licence status

e.g.

AUST L	Medicine Name	Sponsor/Manufacturer	License status as of 10 Aug 2023

(if a medicine is not on the ARTG, consider whether this investigation is required or if the case should be referred to Compliance Assessment and Monitoring Section)

s.22 [redacted]

Q4a. Is there a current consent under Section 14 or 14A of the Act for non-compliance?

- Check the TGA's online database of consents to import, supply or export therapeutic goods that do not comply with standards.

s.37 [redacted]

If yes, consider whether the s14 approval/application is relevant to the compliance lead.

Q4b. Is there an imposed Condition of Listing?

- Check the Therapeutic Goods (Listed Medicines—Conditions of Listing) Determination to find applicable conditions of listing for listed medicines
- Check the ARTG entry of the medicine, as Condition of Listing imposed by AEMDS will be included in the ARTG entry.

If yes, consider whether the condition(s) of listing imposed under section 28 of the Act and if it/they is/are relevant to the compliance lead.

Q4c. Is there an open review/signal investigation or recently closed review/signal investigation related to the subject medicine?

s.37 [redacted]

If yes, consider whether an investigation is required or if the issue can/should be referred to the evaluator/investigator undertaking the review/signal investigation.

Q4d. Are there any compliance signals that are similar/relevant to this assessment?

s.37 [redacted]

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If yes, provide details and consider consistent actioning

Q4e. Is further information required from the complainant/referee to progress the lead? Yes ☐ No ☐

If yes, provide what information is being requested.

Q7b. Requested information provided?

Yes ☐
No ☐

Q5a. Do you, Signal Process Owner (i.e. investigator) need to declare any conflict of interest in relation to this case?

If yes, please declare here any conflict of interest you may have, even if you are not sure if it constitutes a conflict of interest, and let your supervisor know before continuing with the investigation.

E.g. You have previously worked with the company subject of this investigation, you know the complainant or any person working for the company subject of this investigation, you have shares in the company subject of this investigation, etc.

Q5b. Are there any special requirements in relation to the level of confidentiality that this investigation must have?

If yes, please list here any applicable special requirements.

E.g. The complainant fears for his/her safety. Please indicate if this investigation requires additional level of confidentiality. Advice from RSBL may be required.

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Section 2– Initial assessment

Q6a. Information considered

s.37

Q6b. Summary of LCS considerations

Provide a summary of the identified issues and the potential compliance deficiencies based on the information listed in Q6a.

List of issues This is to break down the issues described in the complaint/referral or identified in ARTG scanning into sub-issues.	Detail of the potential compliance deficiencies Please include the relevant legislative provisions you considered.
s.22	

s.22	

Q7. Based on the considerations in Section 1 and Q6b, assess the risk posed by the identified potential compliance deficiencies.

Select the level of risk associated with identified potential compliance deficiencies and provide reasoning for your selection.

Refer to s.22 - Risk Assessment Tool and Matrix (s.22) for the risk assessment guidance.

Please consider factors such as:

- the risk of harm or injury related to a product itself (including whether the medicine targets a vulnerable population such as children, pregnant women or elderly)

- the indirect risk of harm from reliance on misleading or inaccurate information in lieu of seeking professional health care advice and treatment

-if the deficiencies would affect consumers trust in the TGA

Mild-Moderate ☐→ Go to Section 5, select the most appropriate low-level action

Elevated-Severe ☐→ Go to Section 3* and proceed with an investigation

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Summary of the risk assessment outcome

What harm(s) the issue may cause to consumers and/or the TGA/Government?

What is the likelihood of harm(s)?

Overall level of risk:

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Section 3 – LCS Investigation

Q8. LCS investigation

Provide a detailed description of the alleged breach(es) and the evidence used to determine whether this(ese) is(are) a verified breach(es). If unable to verify the breach(es) based on the information held, please indicate whether additional information is required and whether it would be required within this investigation (or within a compliance review).

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Table 1

Permitted indications in the ARTG entry and/or permissible indications in the Determination List the relevant permitted indications in the ARTG entry of the medicine.	**Indications of the medicine that are in question** Consider the definition of 'advertise' and 'presentation' in the Act and list the indications in question.	**Differences in meaning and intent**

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Table 2

Legislation potentially breached and reasons Common breaches to section 26A, 28 and 30 of the Act should be considered. If relevant, please also consider criminal offences and civil penalties provisions included in the Attachment 3.	**Evidence currently held** Use this section to include website links, TRIM links to copies of labels, advertising captures, ARTG summaries, lab testing results and any other relevant evidence.	**Additional information from the sponsor required to confirm breach**
s.22		

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Q9a. Outcome of investigation?	**Breach of TG Act identified** ☐ **Progress to Section 4** **Potential breach of TG Act identified** ☐ **Progress to Section 4** **Potential other breach** ☐ **Likely to be referred, Progress to Section 5** **No breach identified** ☐ **Progress to Section 5**
Q9b. Has the risk rating changed since Q9? If the answer is yes, provide your reasonings as to why the risk rating has changed.	No ☐ Yes ☐

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Section 4 – Relevant Medicine & Sponsor compliance history

Q10. Are there any relevant LCS compliance signals about this medicine and this sponsor?

If yes, provide details (and their relevance to this signal) and links if applicable.

Yes ☐
No ☐

s.37

Q11. Are there any other relevant compliance signals held by the TGA for this medicine?

If yes, provide details and links if applicable.

Yes ☐
No ☐

s.37

If yes

s.37

Q12. Does the sponsor have any relevant issues detected through compliance reviews?

If yes, provide a summary of the details and links if applicable.

Yes ☐
No ☐

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If yes

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Q13. What is your rating of the sponsor's compliance history?

Provide brief reasons for this rating

- Good ☐
- Fair ☐
- Moderate ☐
- Poor ☐

Progress to Section 5

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Section 5 - Recommended Action

At this point you should consult decision tools in Attachments 2 for guidance.

Q14. Based on your assessment, select the recommended action(s) and provide a brief summary of your reasons for such decision

For your summary of reasons for recommended actions, please include the list of found or potential non-compliances/deficiencies, a summary of risk rating and other considerations if applicable s.37

If recommending to queue for a compliance review, please indicate here the recommended targeted review type.

Summary:	Multiple options may be applicable.
	Refer Internally ☐
	Specify to what area:
	Refer Externally ☐
	Specify to what area:
	Issue Correspondence ☐
	Educational Email ☐
	Obligations Notice ☐
	Warning letter ☐
	Infringement Notice ☐
	Other type of correspondence ☐
	Specify the type:
	Compliance review ☐
	Queue for compliance review ☐
	Initiate a priority compliance review ☐
	No further action ☐

Q15. Priority for action	E.g. (Low, Medium, High, Critical)		
Assessed by		Date	
Reviewed by		Date	
Comments/action items e.g. Do you, reviewer, need to declare any conflict of interest in relation to this case?			

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Attachment 1– Criminal offence and civil penalty provisions in the *Therapeutic Goods Act* that maybe applicable to listed medicines

Note: An infringement notice may be issued if the Secretary reasonably believes that a person has contravened an offence of strict liability (For strict liability, see section 6.1 of the *Criminal Code*) or a civil penalty provision within 12 months after the day on which the contravention is alleged to have taken place (see section 42YK of the Act).

Breaches	Civil penalty provisions	Criminal offence provisions
Failure to comply with a s31(2) notice If a person is given a notice under subsection 31(2) of the Act and the person fails to comply with the notice.		Subsection 31(4) Subsection 31(4B) and 31(5): an offence against Subsections 31(4B) is an offence of strict liability
Providing false or misleading information to a s31 notice If a person is given a notice under section 31 of the Act and the person provides false or misleading information or document in response to the notice.	Section 31AAA	Subsection 31(6) Subsection 31(7) and 31(8): an offence against Subsection 31(7) is an offence of strict liability
Breaching a condition of listing If a person does an act or omits to do an act, and that act or omission breaches a condition of listing of the goods.	Subsection 21B(2)	Subsections 21A(8) Subsections 21A(8A) and 21A(8B): an offence against Subsections 21A(8A) is an offence of strict liability
Making false or misleading statement in or in connection with a certification If a person, in or in connection with a certification of any matter under subsection 26A(2) of the Act, makes a statement that is false or misleading in a material particular.	Subsection 21B(1)	Subsection 21A(4) Subsection 21A(4A) and 21A(4B): an offence against Subsection 21A(4A) is an offence of strict liability
Advertising indication(s) not in the ARTG entry If a person, by any means, advertises therapeutic goods included in the Register for an indication that is not accepted in relation to that inclusion.	Subsection 21B(4)	Subsections 22(3) Subsections 22(5) and 22(5A): an offence against Subsections 22(5) is an offence of strict liability
Advertising a medicine as being endorsed by a government authority. If a person, by any means, advertises therapeutic goods which contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than those of the availability of the goods as a pharmaceutical benefit, or authorised or required by government or government authority, or prescribed by the regulations.	Subsection 42DLB(1) of the Act where subsection 42DLB(6) applies.	Subsection 42DL(2) of the Act where subsection 42DL(9) applies.
Advertising restricted representation(s)	Subsection 42DLB(1) of the Act where subsection 42DLB(4) applies.	Subsection 42DL(2) of the Act where subsection 42DL(7) applies.

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If a person advertises therapeutic goods (including directly or indirectly promoting the use of such goods) where the advertisement makes a restricted representation without an in-force approval or permission of the Secretary.		
Advertising prohibited representation(s) If a person advertises therapeutic goods (including directly or indirectly promoting the use of such goods) where the advertisement makes a prohibited representation without an in-force permission of the Secretary or the use of the prohibited representation is not in accordance with the in-force permission or a condition of the permission.	Subsection 42DLB(1) of the Act where subsection 42DLB(2) applies.	Subsection 42DL(2) of the Act where subsection 42DL(5) applies.
Non-compliance with the Code Non-compliance with the *Therapeutic Goods Advertising Code*.	Subsection 42DMA(1)	Subsection 42DM(1) Subsection 42DM(2) Subsection 42DM(3) and 42DM(4): an offence against Subsection 42DM(3) is an offence of strict liability
Conducting manufacturing step(s) without a licence If a person has carried out manufacturing step(s) of therapeutic goods without a licence that authorises to do so.	Subsection 35A(1)	Subsection 35(1) Subsection 35(4) Subsection 35(4A) and Subsection 35(4B): an offence against Subsection 35(4A) is an offence of strict liability
Manufacture/supply/import/export of counterfeit goods If a person intentionally manufactures or supplies or imports/exports (to/from Australia) therapeutic goods that are counterfeit (defined in subsection 42E(2)).	Section 42EA	It is an offence under Subsection 42E(1) if the person knows that fact (the goods are counterfeit) or is reckless as to whether the fact exists.

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Attachment 2 - Recommended compliance and/or enforcement actions and priority for action

s.37



Table 1. Risk Assessment Tool

TRIM Reference:		**Summary of the risk assessment outcome**
AUST L:		Please include an executive summary of the assessed issues and the outcomes of the risk assessment, the overall risk rating and the recommended actions.
Product Name:		
Sponsor Name:		
Completed by:	**Date:**	
Peer reviewed by:	**Date:**	
Reviewed by	**Date:**	

Assessment questions	Potential compliance issue(s) and risk assessment	Reviewer comments
What harm(s) the issue may cause to consumers? Insignificant, minor, moderate, major, or catastrophic.		
What is the likelihood of harm(s)? Rare, unlikely, possible, likely, or almost certain.		
Level of risk to consumer Consequence x Likelihood		
What reputational harm(s) (e.g., if no action is taken) the issue may cause to the organisation/government?		

Insignificant, minor, moderate, major, or catastrophic.		
What is the likelihood of reputational harm(s) (e.g., if no action is taken)? Rare, unlikely, possible, likely, or almost certain.		
Level of risk to the organisation/government Consequence x Likelihood		
Recommendation		

Table 2. Risk Assessment Matrix

		Likelihood				
		1	2	3	4	5
Consequence		Rare	Unlikely	Possible	Likely	Almost certain
1	Insignificant	Mild 1	Mild 2	Mild 3	Mild 4	Moderate 5
2	Minor	Mild 2	Mild 4	Moderate 6	Moderate 8	Elevated 10
3	Moderate	Mild 3	Moderate 6	Elevated 9	Elevated 12	Severe 15
4	Major	Moderate 4	Moderate 8	Elevated 12	Severe 16	Severe 20
5	Catastrophic	Elevated 5	Elevated 10	Severe 15	Severe 20	Severe 25

Table 3. Guidance for using the Risk Assessment Tool and the Risk Assessment Matrix

General guidance

- Each issue considered in the Risk Assessment Tool (RAT) must correspond with a potential breach under the *Therapeutic Goods Act* (the Act). If not, it is likely not an issue for the Listing Compliance Section (LCS) to deal with.
- Table 3 (below) provides guidance in using the RAT s.37 [redacted]
s.37 [redacted]
s.37 [redacted]
- Prior to the risk assessment, you may check if any previously provided safety-related advice from Adverse Event & Medicine Defect Section (AEMDS) is relevant to your compliance issue (s.22 [redacted]).
- If you are unable to determine the risk level of a compliance issue based on the available information and resources, you may discuss with your EL1 and consider seeking advice from other areas within the TGA:
    - You may contact the Toxicology Section s.22 [redacted] @health.gov.au) in relation to safety implications of chemical issues and long-term safety concerns.
    - You may contact AEMDS (adr.reports@health.gov.au) in relation to safety implications of quality or medicine defect issues. You may also contact them obtaining information regarding whether a compliance issue has caused harm(s) to consumers.

Assessment questions	s.37 [redacted]
What harm(s) the issue may cause to consumers? Insignificant, minor, moderate, major, or catastrophic.	

	s.37

	s.37
What is the likelihood of harm(s)? Rare, unlikely, possible, likely, or almost certain.	
Level of risk to consumer Consequence x Likelihood	
What reputational harm(s) (e.g., if no action is taken) the issue	

may cause to the organisation/government? Insignificant, minor, moderate, major, or catastrophic.	s.37
What is the likelihood of reputational harm(s) (e.g., if no action is taken)? Rare, unlikely, possible, likely, or almost certain.	

	s.37
Level of risk to the organisation/government Consequence x Likelihood	
Recommendation	


s.37

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Therapeutic Goods Administration

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Complementary and OTC Medicines Branch (COMB)

ARTG Scanning Discussion Notes

Purpose

This document is used to record details of the ARTG Scanning Discussion[1] and record the risk assessment outcome (using the Risk Assessment Tool s.22 as guidance) of each signal, including discussion points and the decision reached. The officer who is responsible for taking notes of the Discussion should complete the document electronically (the text in grey is for guidance only which should be deleted upon the completion of the document) and save it to TRIM Container s.22 following the below naming convention:

'LMP - ARTG Scanning Discussion Notes - 202x Week xx (the week of listing) - AUST L (include all the AUST L numbers of medicines that are decided to be signals) - DD MM YY (the date of the Discussion, e.g., 26 Sep 2022)'

Date and time	
New listings for Discussion	e.g. 2022 Week 1 new listings (TRIM reference)

Participants

Name	Details
	Please include person's position and contact detail.

s.37

Notes of Discussion

AUST L – Medicine Name	Notes of Discussion	Signal?
s.22	For medicine that is a signal (highlight the medicine AUST L and name in yellow), please include the key points of the discussion including: - the identified potential compliance issue(s); - the risk assessment (using the risk assessment tool (pending TRIM link)); and - the decision made (highlight in yellow) and the relevant rationales. Example: **Potential Compliance Issue:** s.22 **Decision:** s.22	YES

	s.22	
s.22		NO

Author details (include contact details and date note prepared)	

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Therapeutic Goods Administration

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LISTED MEDICINE TARGETED (EVIDENCE) REVIEW CHECKLIST

All information in GREEN is for guidance and is to be deleted when the checklist is complete.

All information in BLUE is to be filled in with the appropriate information and changed to black font.

Purpose

s.37 [redacted]

The evidence will be evaluated in accordance with the current Evidence Guidelines (Version 4.0 June 2022) (s.22 [redacted]).

This document is:

- the official record of the evaluation process
- used as part of the decision-making process
- completed electronically and saved to the relevant compliance review container in TRIM.

Section 1 - Medicine Identification	
Name of the medicine	[Name of the medicine]
AUST L	[Number]
Sponsor name	[Sponsor name]
Sponsor contact details	[Address and contact email]
Most recent certification under section 26A of the Act	[Date]

Section 2 - Request for information		
	Evaluator's comments	**Reviewer's comments**
Did the sponsor comply with the s31 notice? s31 notice: [TRIM link]	Yes ☐ No ☐ Reason: **If yes**, include the TRIM link and date the response was received. List the information/documents provided. **If no, because no response was received**, include details of the attempt(s) to contact the sponsor, and skip to section 12. **If no, because the sponsor has failed to provide the requested information/documents (and no satisfactory justification has been provided)**, include your reasoning and skip to section 12.	

Section 3 - Indications		
	Evaluator's comments	**Reviewer's comments**
Are the indications on the medicine's label and advertising consistent with the medicine's ARTG entry?	Yes ☐ No ☐ Reason: s.37	

Complete either option A or B for section 3 – delete the unused table.

Section 4 - Evidence sources [Option A – the sponsor has provided their bibliography using the table in Attachment 2 of the s31 notice]	
Bibliography of evidence sources	[TRIM link]

Section 4 - Evidence sources [Option B – the sponsor has not provided their bibliography using Attachment 2 of the s31 notice. Complete the table below using the information provided by the sponsor]							
Evidence reference number	**Indication(s) supported by evidence source**	**Author(s)**	**Citation information**	**Publisher**	**Year**	**URL (if available)**	**Copy of the source**
							Include the TRIM link and whether the copy was provided by the sponsor or sourced through the IRRS library.

Section 5 - Minimum evidence requirements

	Evaluator's comments	Reviewer's comments
Based on the body of evidence provided, has the sponsor met the minimum evidence requirements for the subject indication(s)? Refer to Attachment 1 for the minimum evidence requirements for scientific and traditional indications.	Yes ☐ No ☐ Reason: Has the sponsor provided a satisfactory justification for why the body of evidence, despite not meeting the minimum requirements, is of sufficient quality and relevance to conclude that the medicine's efficacy is acceptable? If you are satisfied that the sponsor has not met the minimum evidence requirements for the type of indication, and no acceptable justification has been provided, detail your reasoning (e.g. the body of evidence has a high risk of bias) and skip to section 12.	

Section 6 - Search protocol

	Evaluator's comments	Reviewer's comments
Based on the sponsor's response to item 5 in the s31 notice, have they sufficiently demonstrated that the body of evidence reflects a balanced view of the evidence landscape in relation to the medicine's efficacy?	Yes ☐ No ☐ Reason: Include the TRIM link to the sponsor's response. If the sponsor has provided a search protocol, is the protocol robust (i.e. conceptually logical, explicit, and reproducible) and has their approach identified all potential relevant published literature (both positive and negative) relating to their medicine's efficacy? Refer to pages 13–21 of the Evidence guidelines for further guidance on search protocols. The IRRS library staff can also assist with reviewing a sponsor's search protocol. To request their assistance, email s.22 If the sponsor has provided some other means of demonstration, has their approach sufficiently identified relevant published literature (both positive and negative) relating to their medicine's efficacy?	

Section 7- Evaluation of evidence sources

Sponsor's evaluation: [TRIM link]

Ref [#] Copy and paste reference row for evaluation	[Indication(s)]	Is the evidence source relevant to the medicine? If not, do you accept the sponsor's justification for why it should still be considered?	Is the evidence source of high quality? If the quality is moderate or below, do you accept the sponsor's justification for why the results can be trusted?

of multiple evidence sources as required.		☐ Yes ☐ No Reasoning: Consider whether the sponsor has demonstrated that the therapeutic benefit described in the evidence source can be extrapolated to the medicine. Elements such as the active ingredient/formulation, target population, dosage, rout of administration, frequency and duration of use should be identical or similar to the medicine, otherwise its relevant should be justified by the sponsor.	☐ Yes ☐ No Reasoning: Consider whether the sponsor has demonstrated that we can be confident that the therapeutic effect reported in the evidence is correct. The sponsor's classification of the evidence source's quality should be based on the GRADE system (GRADE Handbook) or an equivalent quality evaluation framework.

Section 8 – Contradicting evidence [Optional section if included in the s31 notice – otherwise delete this table]

	Evaluator's comments	Reviewer's comments
Based on the sponsor's response to item 7 in the s31 notice, has the sponsor demonstrated that their medicine is efficacious despite contradicting evidence?	Yes ☐ No ☐ Reason: The sponsor's reasons must include substantiation with data. Consider whether, on balance, the sponsor's evidence/reasons for the medicine's efficacy outweighed the evidence showing that the subject ingredient/formulation does not produce the subject indication(s).	

Section 9 – Critical appraisal of body of evidence

	Evaluator's comments	Reviewer's comments
Based on the sponsor's response to item [7/8] in the s31 notice, has the sponsor satisfactorily demonstrated that their medicine is efficacious?	Yes ☐ No ☐ Reason: Based on the evidence submitted by the sponsor, is it open to the Delegate to conclude that the medicine's efficacy is acceptable? Consider whether the sponsor's reasoning/critical appraisal is logical, reasonable, and based on data that a reasonable person would be confident is true and accurate.	

	If the sponsor's body of evidence includes sources that are: – missing critical information – are not identical/similar to the medicine – are of low quality (i.e. are subject to significant bias or confounding) – include a mix of both positive and negative findings has the sponsor acknowledged these limitations and provided an acceptable justification as to how and why these issues do not impact on the conclusion that the medicine's efficacy is acceptable?	

Section 10 – Other issues

	Evaluator's comments	Reviewer's comments
Does the medicine have any evident safety-related issues?	Yes ☐ No ☐ Summary of the issue(s), risk assessment(s) and recommended action(s): s.37	

Section 11 – Relevant legislative provision(s)

	Evaluator's comments	Reviewer's comments
Select the relevant compliance breach(es) If you are recommending an infringement notice, include	☐ 26A(2)(ja)(i) - The applicant must certify that the applicant holds information or evidence to support each indication proposed to be accepted in relation to the inclusion of the medicine in the Register	

the relevant offence provision(s).	☐ 28(5)(ab) - the registration or listing of therapeutic goods (the ***subject goods***) is subject to the condition that the person in relation to whom the subject goods are registered or listed will not, by any means, advertise the subject goods for an indication other than those accepted in relation to the inclusion of the goods in the Register ☐ 28(7)(c) - the listing of the medicine is subject to the following condition; a condition that the person in relation to whom the medicine is listed has, at all times while the medicine remains listed, information or evidence that supports the indication and complies with the requirements (if any) specified in a determination under subsection 26A(2B) ☐ 28(7)(d) - the listing of the medicine is subject to the following condition; a condition that, at any time while the medicine remains listed, the person will, if asked to do so by the Secretary, give the information or evidence to the Secretary ☐ 30(1C) - the Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26A, cancel the listing of the medicine if: (a) the Secretary, under section 31, gives to the person a notice requiring the person to give to the Secretary information or documents relating to the medicine; and (b) the notice is given for the purposes of ascertaining whether any of the certifications by the person under subsection 26A(2) or (2A) in relation to the medicine are incorrect; and (c) the person fails to comply with the notice within 20 working days after the notice is given. ☐ 30(2)(a) - the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if it appears to the Secretary that the efficacy of the goods is unacceptable ☐ Other – [specify] ☐ No compliance breaches	

Section 12 - Recommended and agreed action(s)

Recommended action(s) To be completed by the evaluator. Multiple options can be selected	☐ Conclusion ☐ Obligation's notice ☐ Deficiencies notice ☐ Proposal to cancel ☐ Infringement notice

	☐ Other – [specify] Reason:
Agreed action(s)	Comments from the reviewer (EL1) and agreed actions going forward

Section 13 - Evaluation participants

Role	Name and position	Date
Evaluated by	[Evaluator's name and position]	[date completed]
Peer reviewed by (if required)	[Evaluator's name and position]	[date completed]
Reviewed by	[Reviewer's name and position]	[date completed]

Attachment 1

From Listed medicines evidence guidelines (Version 4.0 June 2022, section 4.4).

The different types of indications and the corresponding types of evidence that may be included in evidence packages are outlined in **Table 4**. These are general minimum evidence requirements to be included in an efficacy evidence package, which may not necessarily be sufficient in all cases.

The options presented in **Table 4** may not be suitable for every medicine. These requirements represent the lowest threshold below which the efficacy of the medicine cannot be reasonably assessed. This means that a minimum number of evidence sources from the categories of evidence described above should be included in the evidence package to be critically appraised as part of the body of evidence.

As with all other aspects of an evidence package, where a sponsor diverges from these guidelines, justifications should be included in the evidence package to explain why the body of evidence compiled is of sufficient quality and relevance to conclude that the medicine's efficacy is acceptable.

Table 1: Minimum evidence requirements for scientific and traditional indications

<table>
<tr><th colspan="3">Minimum evidence requirements</th></tr>
<tr><th colspan="3">Scientific indications</th></tr>
<tr><td rowspan="2">Minimum evidence requirements</td><td>Non-specific indications:</td><td>Specific indications:</td></tr>
<tr><td>Minimum of two from Category B or Category C</td><td>Minimum of one from Category A
OR
Minimum of one from Category B AND two from Category C</td></tr>
<tr><th>Category A</th><th>Category B</th><th>Category C</th></tr>
<tr><td>Double blind randomised controlled trials (including cross-over trials)</td><td>Observational studies, for example: cohort and case-controlled studies</td><td>Non-systematic, generalised reviews – including databases</td></tr>
<tr><td rowspan="3">Systematic reviews</td><td rowspan="3">Comparative studies (non-controlled)</td><td>Publicised international regulatory authority articles</td></tr>
<tr><td>Evidence-based reference texts - scientific</td></tr>
<tr><td>Scientific monographs</td></tr>
<tr><th colspan="3">Traditional indications</th></tr>
<tr><td colspan="2">Minimum evidence requirements</td><td>Minimum of two from 'Traditional Evidence to support tradition of use'</td></tr>
<tr><th colspan="3">Traditional Evidence to support tradition of use</th></tr>
<tr><td colspan="3">• Materia medica
• Official pharmacopoeias
• Monographs</td></tr>
</table>

- Publications from various international regulatory authorities
- Texts that are relevant to the traditional paradigm
- Well-recognised evidence-based reference texts

ARTG Scanning Tool and Signals Database

These columns are filled by SET after extracting the list of new medicines					These columns are filled by the responsible LCS officer for all the new medicines (please consult 'Scanning Policy' tab)								
Basic information of the new medicines					Does the medicine's name clearly suggest a likely therapeutic use, and/or refer to its formulation or component of its formulation? Note: when the intention of the name is unclear, you may clarify it through ARTG record, sponsor's website or external website	If indication, state the therapeutic target If formulation, state the ingredient(s) Note: state therapeutic target(s) first and then the ingredient(s), use comma and semicolon to separate. E.g., eye, kidney; vitamin c, iron, turmeric powder	What are the potential compliance issues (and their likelihood) indicated/predicted by the name of the medicine? Note: in the case where you clarified the medicine name through the sponsor's website, you may also note here the advertising breaches on the sponsor's website about the medicine.			Was this medicine discussed during ARTG Scanning meeting?	Was this medicine flagged as a signal of non-compliance? Note: If you identify potential compliance issues that are not directly linked to the new medicine, do **not**	TRIM Link to the week's Discussion Notes for signals Note: only include the TRIM Link in the row of the signal	The responsible officer for actioning the signal
AUST L	Medicine Name	Sponsor Name	Date Listed	Year & Week Listed	What the name suggests?	Explanatory Notes	Potential compliance issues	Likelihood	Explanatory Notes2	Assessed?	Signal?	Discussion Notes	Work Process Manager
s.22													

s.22 s.37 s.37

Week Starting	Year. Weeks	Medicines risk assessed	Medicines are deemed signals
10-Jul-23	23.28	6	6
17-Jul-23	23.29	4	4
24-Jul-23	23.30	4	4
31-Jul-23	23.31	7	7
07-Aug-23	23.32	9	9
14-Aug-23	23.33	1	1
21-Aug-23	23.34	2	7
28-Aug-23	23.35	0	8
04-Sep-23	23.36	6	6
11-Sep-23	23.37	10	10
18-Sep-23	23.38	4	4
25-Sep-23	23.39	4	4
02-Oct-23	23.40	3	3
09-Oct-23	23.41	3	3
16-Oct-23	23.42	4	4
23-Oct-23	23.43	12	12
30-Oct-23	23.44	3	3
06-Nov-23	23.45	4	4
13-Nov-23	23.46	6	6
20-Nov-23	23.47	6	6
27-Nov-23	23.48	6	6
04-Dec-23	23.49	6	6
11-Dec-23	23.50	3	3
18-Dec-23	23.51	5	5
25-Dec-23	23.52	6	6
01-Jan-24	24.01		
08-Jan-24	24.02	1	1
15-Jan-24	24.03	1	1

otes

Staff	Times of duties/year
	2
	1
	10
	16
	17
	6

.22

.22

s.37

REFERENCE

The cells in this sheet are protected. To unprotect the sheet and make edits the password is 'REFERENCE'

Variable	Description (shows in drop-down lists)	Notes
What the name suggests?	Unclear	
What the name suggests?	Indication	
What the name suggests?	Formulation	
What the name suggests?	Combination (Indication & Formulation)	
Potential compliance issues	None	
Potential compliance issues	Name suggesting ingredients not in the ARTG/Determination	
Potential compliance issues	Name suggesting indications not in the ARTG/Determination	
Potential compliance issues	Name suggesting restricted/prohibited representations	
Potential compliance issues	Name is confusing/misleading	
Potential compliance issues	Advertising breaches on sponsor's website about this medicine	
Potential compliance issues	Multiple/Other issues	
Likelihood	N.A.	
Likelihood	Unlikely	
Likelihood	Possibly	
Likelihood	Probable	
Likelihood	Highly Likely	
Assessed?	Y	yes
Assessed?	N	no
Signal?	Y	yes
Signal?	N	no

Analysis of educational correspondence sent as part of signal investigations	
Date of meeting	10 June 2026
Period analysed	s.22
Date of analysis	
Attendees	s.22

Minutes (pre-drafted by Signal team members, finalised by Signal team members on 15 July 2026)

- The following documents were consulted for the creation of these minutes:
  s.22

No	AUST L	Signal details	Assurance rating	Assurance completed
1	s.22	**Reference number:** [redacted] **Product name:** [redacted] **Sponsor:** [redacted] **Signal owner:** [redacted] **Action taken:** Obligations notice **Background:** Anonymous complaint regarding product having non-compliant advertising: - claims beyond those permitted by ARTG entry - misleading/restricted/prohibited statements - missing mandatory health warning statements - non-compliant testimonials Note for [redacted] - Ingredients in the medicine do not appear to require any warning statements as per 26BB - The only indication in the ARTG entry 'Enhance/improve/promote immune defence/immunity' does not have any requirements as per 26BF - The only warning as per the ARTG entry required is [redacted] - Obligations notice sent to sponsor on [redacted] regarding making: claims beyond those permitted by ARTG entry and misleading statements. Notice to also refer sponsor to general requirements around advertising rules. **Outcome of initial correspondence:** Response from sponsor on [redacted] advised changes made to the website and also committed to ensuring testimonials were compliant. On cursory assessment of product's advertisement, issues of non-compliance appear to be addressed. **Proposed post-assurance action:** NFA **Reason for Proposed post-assurance action:** On cursory assessment of product's advertisement, issues of non-compliance appear to be addressed.	Positive	Yes

		Team discussion: Team agreeable to the above		
2	s.22	**Reference number:** **Product name:** **Sponsor:** **Signal owner:** **Action taken:** Warning letter **Background:** Internal referral from RCB regarding product (not exhaustive): - having incorrect warning statements displayed on website - making claims beyond permitted indications - making comparator claims - endorsement by health professionals making several statements/claims - being delivered in a large sachet than a glass jar which is what is depicted on the website that appears to lack critical health information Note for - Actual product itself appears to have relevant warning statements therefore NFA with regards to this - Warning letter sent in relation to non-compliant aspects of advertising - The TGO 92 requirement to display active ingredients in a tabulated format appears to only apply to registered goods not listed goods therefore NFA with respect to this **Outcome of initial correspondence:** On sponsor advised they updated their website however not all compliance issues were found to be addressed On sponsor was advised of the outstanding compliance issues with their website On , sponsor advised it engaged a consultant to inspect the entirety of their website and they will be making changes ASAP with updated website to be live by On sponsor advised they made additional changes on their website and on examination on the same day it appears to be compliant. **Proposed post-assurance action:** NFA	Positive	Yes

		Reason for Proposed post-assurance action: Sponsor has brought the website into compliance **Team discussion:** Team agreeable with the above		
3	s.22	**Reference number:** **Product name:** **Sponsor:** **Signal owner:** **Action taken:** Obligation Notice **Background:** • ARTG Scanning identified the medicine had the following **incompatible indications**: • • **Outcome of initial correspondence:** • In response to an Obligation Notice issued , the sponsor advised they would remove the following indication from the listing: • The sponsor updated the listing on (Product ID:). The removal of the above indication is taken to confirm that the medicine is intended to have a therapeutic use of . • **No** advertising for the product could be located on 19 and 28 May 2026.	Positive	Yes

Proposed post-assurance action:

- **Option 1**: Push advertising review until next assurance meeting.
- **Option 2**: Request explanation of the meaning of the name and potentially the label as well, in hopes that this signal can be closed out more quickly.

Reason for Proposed post-assurance action:

- While the concern raised in Obligation Notice was addressed (incompatible indications), the medicine still has the following accepted indications:

  [redacted]

- A medicine presented for supply as having a therapeutic use of [redacted] along with therapeutic uses related to [redacted] are at risk of having unacceptable presentation. The medicine Is also at risk of having unacceptable presentation if it makes or implies any representations related to [redacted].
- Further, despite being listed on [redacted], the product does not appear to be advertised. [redacted]
- [redacted]

Team discussion:

Closure email to be sent to the sponsor outlining obligations in regard to presentation and the need for this to be consistent with public health campaigns as per the Advertising Code

[redacted]