Australian Government
Department of Health

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Complementary and OTC Medicines Branch (COMB)

LISTED MEDICINE TARGETED (EVIDENCE) REVIEW CHECKLIST

s22 [redacted]

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: s22 [redacted]	

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: s22 [redacted]	

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**
							s22 [redacted]

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? s22 [redacted]	

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: s22 [redacted] 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. s22 [redacted] 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 [#]			
s22 [redacted]	[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? ☐ Yes ☐ No Reasoning:	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? ☐ 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.	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): s22 [redacted]	

Section 11 – Relevant legislative provision(s)

	Evaluator's comments	Reviewer's comments
Select the relevant compliance breach(es) s22 [redacted]	☐ 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 ☐ 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	

s22 [redacted]

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><td>Category A</td><td>Category B</td><td>Category C</td></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
• Publications from various international regulatory authorities
• Texts that are relevant to the traditional paradigm
• Well-recognised evidence-based reference texts</td></tr>
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