Australian Government
Department of Health

Office use only

Complementary and OTC Medicines Branch (COMB)

Note for file

Purpose

s22 [redacted]

s22 [redacted]

s22 [redacted]

[redacted]

This form should be:

- used to record details of the evaluation conducted during the review process for the selected medicines of the s22 [redacted]
- used as part of a decision-making process
- completed electronically and saved to the relevant file in TRIM.

LISTED MEDICINE TARGETED REVIEW CHECKLIST

Type of event	Evaluation record [TRIM container no.]
Project	s22 [redacted] s22 [redacted]
Medicine details	Medicine Name (AUST L XXXX) Sponsor Name

Participants

Role	Name and position	Date
Evaluated by		
Peer reviewed by	(if required)	
Reviewed by		

Evaluation 1		
Q1. Did the sponsor respond to the RFI (dated XXXX)?	Yes ☐ If yes, include date of response and relevant TRIM link and proceed to question 2 No ☐ If not, include details of attempts to contact sponsor (email and phone) and proceed to question 7	
Q2. Details of information provided	Describe the type of information that was provided, e.g. label version and supply status, etc. Also, document stock levels here	
	Evaluator's comments	**Reviewer's comments**
Q3. Is the name of the medicine on the label consistent with the ARTG entry?	Describe your evaluation process, considerations, deficiencies found, etc.	
Q4. Is the name of the medicine separate and distinct from other therapeutic goods? *If deficiency found determine if it should be pursued as safety-related under Regulation 3A*	Describe your evaluation process, considerations, deficiencies found, etc.	
Q5. Are the required warning statements included and correct on the medicine label?	Describe your evaluation process, considerations, deficiencies found, etc.	

Q6. Does the medicine have other *evident* safety-related issues present on the label? *You are not requested to deliberately look for issues outside the project scope.*	No ☐ Yes ☐ If yes, complete the table below adding/removing rows as needed and consider requesting safety advice from AEMDS

Issue	Legislative contravention

[redacted]	s22 [redacted]
Q8. Please select the relevant compliance deficiencies found. *If other deficiencies identified in Q6, please add relevant codes if required.*	CATEGORY – LABEL ☐ LWSM – Warning statement(s) incorrect or missing from label ☐ PPUT – Presentation is unacceptable in relation to other text and graphics
Q9. Please select the relevant compliance breaches found. *If other compliance breaches identified in Q6, please add relevant codes if required.*	CATEGORY – OTHER ☐ 30(1A)(a) – [T007] – The medicine is not eligible for listing ☐ 30(2)(a) – [T013] - The presentation of the medicine is unacceptable
Evaluation 2 (if required)	
Q10. Did the sponsor provide a response to the initial decision letter?	Yes ☐ If yes, include date and TRIM link here and proceed to Q11 and updated Q8 and Q9 to reflect any changes to initial decision No ☐ If not, proceed to Q12 s22 [redacted]
Q11. Response and follow-up action	Describe sponsor's response, what action was taken, and include relevant TRIM links
Q12. Final Decision	s22 [redacted]

s22 [redacted]	

Author details (include contact details and date note prepared)	
Delegate details (include details when satisfied with the assessment above)	