



Note for file

Purpose

s22

The scope of this labelling review is to check that the warning statements that is currently applicable to the ingredient *Andrographis paniculata* are present on the label for the medicine, as follows:

Azadirachta indica

The following warning statement is required on the label:

- (ANDROG) '*Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention*' (or words to that effect).

When for oral use, the following warning statement is required on the medicine label:

- (ANDROT) '*Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice*' (or words to that effect).

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Consequently, the evaluations for this sprint project will be targeted to assess:

- label warning statement requirements
- that the name of medicine is separate and distinct from other therapeutics goods.

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LISTED MEDICINE TARGETED REVIEW CHECKLIST

Type of event	Evaluation record [TRIM container no.]
Project	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 <input type="checkbox"/> If yes, include date of response and relevant TRIM link and proceed to question 2 No <input type="checkbox"/> 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? <i>If deficiency found determine if it should be pursued as safety-related under Regulation 3A</i>	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.	

<p>Q6. Does the medicine have other <u>evident</u> safety-related issues present on the label?</p> <p><i>You are not requested to deliberately look for issues outside the project scope.</i></p>	<p>No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> If yes, complete the table below adding/removing rows as needed and consider requesting safety advice from AEMDS</p> <table border="1" data-bbox="643 286 1471 510"> <thead> <tr> <th data-bbox="643 286 1058 360">Issue</th> <th data-bbox="1058 286 1471 360">Legislative contravention</th> </tr> </thead> <tbody> <tr> <td data-bbox="643 360 1058 434"></td> <td data-bbox="1058 360 1471 434"></td> </tr> <tr> <td data-bbox="643 434 1058 510"></td> <td data-bbox="1058 434 1471 510"></td> </tr> </tbody> </table>	Issue	Legislative contravention				
Issue	Legislative contravention						
<p>s22</p>	<p>s22</p>						
<p>Q8. Please select the relevant compliance deficiencies found.</p> <p><i>If other deficiencies identified in Q6, please add relevant codes if required.</i></p>	<p>CATEGORY – LABEL</p> <p><input type="checkbox"/> LWSM – Warning statement(s) incorrect or missing from label</p> <p><input type="checkbox"/> PPUT – Presentation is unacceptable in relation to other text and graphics</p>						
<p>Q9. Please select the relevant compliance breaches found.</p> <p><i>If other compliance breaches identified in Q6, please add relevant codes if required.</i></p>	<p>CATEGORY – OTHER</p> <p><input type="checkbox"/> 30(1A)(a) – [T007] – The medicine is not eligible for listing</p> <p><input type="checkbox"/> 30(2)(a) – [T013] – The presentation of the medicine is unacceptable</p>						
<p>Evaluation 2 (if required)</p>							
<p>Q10. Did the sponsor provide a response to the initial decision letter?</p>	<p>Yes <input type="checkbox"/> If yes, include date and TRIM link here and proceed to Q11 and updated Q8 and Q9 to reflect any changes to initial decision</p> <p>No <input type="checkbox"/> If not, proceed to Q12 s22</p>						
<p>Q11. Response and follow-up action</p>	<p>Describe sponsor’s response, what action was taken, and include relevant TRIM links</p>						
<p>Q12. Final Decision</p>	<p>s22</p>						

<p>s22</p>	
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Author details
(include contact details and date note prepared)

Delegate details
(include details when satisfied with the assessment above)
