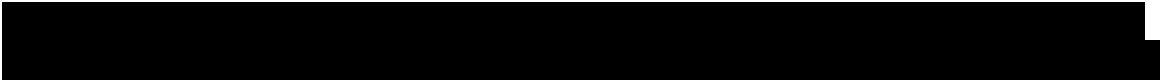


Listed medicine review checklist for the s22 [redacted] on s22 [redacted]



AUST L		
Product name		
Sponsor		
Reviewed by	Date	
Peer reviewed by	Date	

Summary of issues	
Action	

	TRIM link
Labels	
Web capture	

	Requirement	Relevant legislation	Comments/TRIM links to evidence
Required particulars on the label			
1	<p>Name of goods consistent with ARTG entry. Separate and distinct goods?</p> <p>Medicines are taken to be separate and distinct from other therapeutic goods if the medicines have:</p> <ul style="list-style-type: none"> - Different active ingredients - Different quantities of active ingredients - Different dosage form - Such other different characteristics as the regulations prescribe <p>from the therapeutic goods</p> <p><input type="checkbox"/> Check if deficient</p>		<p>Label</p> <p></p> <p>Website</p> <p></p>
2	<p>TGO 92 Schedule 1 substances or goods of substances declared</p> <p><input type="checkbox"/> Check if deficient</p>	Schedule 1 of TGO 92	<p>Label</p> <p></p> <p>Website</p> <p></p>
3	<p>Required warning statement and representations present, correct and complete</p> <p><input type="checkbox"/> Check if deficient</p>	Therapeutic Goods Permissible Ingredients Determination	<p>Label</p> <p></p> <p>Website</p> <p></p>

4	<u>Indication requirements</u> Required label statement present, correct and complete – note label statement is only required if the indication is actually used on the label or website <input type="checkbox"/> Check if deficient		Label
			Website
5	'Free from <ingredients>' claims are accurate <input type="checkbox"/> Check if deficient	Schedule 1 of TGO 92	

