



s22

s22

Summary of Cease and Desist Response

Medicine/s	Medicine name/s and ARTG number/s (if relevant)		
Sponsor			
Response due date		TRIM Ref	

Q1. Has a response to the Cease and Desist notice been received?

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

s22

Date	Summary

Q2. What alleged contraventions were raised in the Cease and Desist notice and how have these been addressed?

s22

Description of the contravention	Actions to address the contravention
s22 [REDACTED]	s22 [REDACTED]

Q3a. Do these actions rectify the identified contraventions? (If you select 'No' or 'Partially' question Q3c must be complete)

Yes No Partially

Q3b. Have the actions, or will the proposed actions, create new (potential) contraventions (If you select 'Yes' question Q3c must be complete)

Yes No

Describe

Q3c. Non- or partially-rectified contraventions (Q3a), and/or newly created contraventions (Q3b):

Contravention	Evidence	Statement of reasons
s22 [REDACTED]	s22 [REDACTED]	

s22 s22 [REDACTED]	[REDACTED] [REDACTED]
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Q3e. Has the sponsor taken insufficient action to bring the medicine and/or its advertising into compliance? This includes insufficient proactive actions to address any contraventions not specifically identified (i.e. provided as an example) in the C&D notice.

Yes No

Reasoning	s22 [REDACTED] [REDACTED]
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Q4. Other comments/considerations

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The recommendation + decision process can be completed using two options (A and B). Under Option A, the evaluator's recommendation is reviewed by the relevant person (i.e. the leads manager, an EL1, etc.). Under Option B, the evaluation and decision is completed by the same person(s).

Option A - Evaluator's Recommendation

Recommendation	s22
Reasoning	
s22	

Option A - Leads manager's/Reviewer's Decision

Agree with recommendation Propose alternative (describe)

Describe	<only if proposing alternative>	
Name		Date
Signature	s22	

Option B – Recommendation and Decision

Recommendation	s22	
Reasoning		
Name		Date
Signature	s22	

Relevant documents

Include any documents that the lead manager may need to consider in order to make this decision

TRIM Ref	Document Name
	Cease and Desist notice
	Sponsor response(s)
	Evidence s22