

Reconsideration work plan

CHEMICAL	Macrolide Antibiotics (Kitasamycin, Oleandomycin & Tylosin)	
REMAINING SCOPE	Efficacy (8.1), Antibiotic resistance (special data) (10.1)	
RECONSIDERATION ASSESSMENT PERIOD	41 months, see Attachment 1	
TIMEFRAME	START: 1 July 2015	FINISH: 29 March 2018
WORK PLAN DATE	1 July 2015. Amended 16 December 2015 (revision of expected dates for component reports).	

Stage	Details	Timeline
1. Nomination	In September 1999, Macrolide antibiotics were nominated for review by the Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR) as part of its antibiotic-resistance management program.	
2. Prioritisation	The APVMA considered JETACAR recommendations and prioritised the reconsideration of macrolide as part of its review program.	
3. Scoping and work plan	The original scope of the review was to assess the risk of transfer of antibiotic resistant determinants from animal to human as a result of the use of macrolide antibiotics in animal growth promotion. The review would also reconsider the efficacy of the products. Link to macrolide scoping document. Work plan – Published on 1 July 2015.	
4. Notice of reconsideration	Link to gazette. Reconsideration of the registration of affected products and their associated labels – Gazetted on 4 December 2001. s32 notices sent to holders in 2001-2002 detailing the scope of the review. Additional Notices sent to registration holders on 16 August 2017 and 9 November 2017 to include all registered products in the review.	
START DATE (clock starts)		01/07/2015
5. Assessment	Efficacy assessment for macrolide antibiotics was conducted in 2003. Antimicrobial resistance risk assessment was conducted in 2003. A review of a quantitative risk assessment of tylosin prepared by a registrant was conducted in 2005. The effects of sub-therapeutic administration of tylosin to food-producing animals on antimicrobial resistance was conducted in 2013.	Publication Dates:
6. Draft regulatory measure	Link to Proposed Regulatory Decisions.	30 November 2017
7. Consultation	<i>Details of consultation undertaken to date</i> A 3 month consultation period occurred in 2001-2002, following the notice of reconsideration. Link to gazette – Gazetted in December 2001 (Extended to May 2002: 6 months). <i>Consultation completed in February 2018</i> A 3-month public consultation period was conducted. Any further data or information submitted during consultation was taken into consideration before making the final regulatory decision.	30 November – 28 February 2018

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Stage	Details	Timeline
8. Regulatory decision	<p data-bbox="483 248 687 277"><u>Regulatory decisions</u></p> <p data-bbox="483 297 647 322">The APVMA has:</p> <ul data-bbox="483 342 1171 600" style="list-style-type: none"> <li data-bbox="483 342 1171 400">• Varied relevant particulars of registrations and label approvals of products containing tylosin <li data-bbox="483 421 970 450">• Affirmed those products and the new, labels <li data-bbox="483 470 1171 551">• Cancelled the registrations and associated label approvals of the product VET ONLY TRUBIN L-50 GROWTH PROMOTANT FOR PIGS (35806) <li data-bbox="483 571 1150 600">• Published the macrolide antibiotics regulatory decisions report 	29 March 2018
END DATE (regulatory decision)		29/03/2018
9. Implementation	<p data-bbox="483 817 1414 898">The APVMA has determined that one-year period ending 29 March 2019 is appropriate for the continued supply and use of registered products bearing cancelled labels, as well as the supply and use of product being cancelled.</p>	

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Attachment 1

AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS 1995 – S78B			
PERIOD WITHIN WHICH APVMA IS TO CONCLUDE RECONSIDERATIONS			
A + B + 2E + 3C + J + D + X			
A = the longest of the following periods (in months) relevant to the scope of the reconsideration			
<i>Item</i>	<i>Module level or type</i>	<i>Period for completion</i>	<i>Scope</i>
3.1	Toxicology – Level 1	13	
3.2	Toxicology – Level 2	9	
3.3	Toxicology – Level 3	5	
4.1	Toxicology (requiring poison schedule classification)	13	
7.1	Environment – Level 1	13	
7.2	Environment – Level 2	7	
7.3	Environment – Level 3	4	
TOTAL TIME FOR A		0	
B = the longest of the following periods (in months) relevant to the scope of the reconsideration			
<i>Item</i>	<i>Module level or type</i>	<i>Period for completion</i>	<i>Scope</i>
2.1	Chemistry – Level 1	13	
2.2	Chemistry – Level 2	9	
2.3	Chemistry – Level 3	6	
5.1	Residues – Level 1	13	
5.2	Residues – Level 2	8	
5.4	Residues – Level 4	4	
6.1	Occupational Health and Safety – Level 1	13	
6.2	Occupational Health and Safety – Level 2	7	
6.3	Occupational Health and Safety – Level 3	4	
9	Non-food trade	6	
10.1	Special data – Level 1	13	●
10.2	Special data – Level 2	7	
10.3	Special data – Level 3	7	
TOTAL TIME FOR B		13	
2E = the longest of the following periods (in months) relevant to the scope of the reconsideration			
<i>Item</i>	<i>Module level or type</i>	<i>Period for completion</i>	<i>Scope</i>
8.1	Efficacy and safety – Level 1	6	●
8.2	Efficacy and safety – Level 2	4	
8.3	Efficacy and safety – Level 3	3	
TOTAL TIME FOR E		2 x 6 = 12	
3C = the longest of the following periods (in months) relevant to the scope of the reconsideration			
<i>Item</i>	<i>Module level or type</i>	<i>Period for completion</i>	<i>Scope</i>
11.1	Finalisation – type 1	3	●
11.2	Finalisation – type 2	2	
11.3	Finalisation – type 3	2	
TOTAL TIME FOR C		3 x 3 = 9	
J = whichever is relevant			
	Consultation with jurisdictional coordinator	3	●
	In any other case	0	
TOTAL TIME FOR J		3	
D	TOTAL TIME FOR D	4	●
X = whichever is relevant			
	Appointment of an arbitrator under s.64	3	
	In any other case	0	●
TOTAL TIME FOR X		0	
TOTAL TIMEFRAME		41 months	