1 Nov 2013

Scheduling Delegate
C/-Scheduling Secretariat
Office of Chemical Safety
Department of Health and Ageing
G P 0 Box 9848
CANBERRA ACT 2601

Dear Sir/Madam,

Re: Tylosin re-scheduling

Elanco appreciated the response from the scheduling delegate received which clearly outlines the reasons for the second deferral of the consideration of the schedule 5 entry for tylosin in the SUSMP. The flexibility demonstrated by the scheduling delegates and committees in their decision making on this issue given the challenges of due process experienced during this review are recognised and appreciated by Elanco.

It is useful to understand that in the absence of a proposed date for the macrolide review to be completed being provided by the APVMA, the scheduling delegates have undertaken the provision of an expert report for deliberation by the scheduling committees. The letter requested Elanco provide their considered response to the specialist report from a scientific perspective due to the delays in Elanco being given access to the report by the APVMA. In review of the expert review document provided by the APVMA, Elanco wishes to again refer the scheduling delegates and committees to the initial Elanco submission where the technical information pertinent to the re-scheduling review is contained and requests the information included within this dataset be used in response to the expert review. Elanco does not anticipate that it will need to provide any further technical information in response to the expert report provided by the APVMA; however, we remain available to provide clarifications in regard to specific technical aspects during face-to-face meetings.

In response to the letter, Elanco strongly re-confirms the original concerns as previously stated.. The key points are reiterated below:

1) The documents do not provide clarity on the complex interactions between areas such as the environment, animal species, specific pathogen, food handling practices and human clinical management practises in the outcomes of antibiotic resistance in people. In general the document expressed the possibility of macrolide resistance development and transfer but not the probability of public health impacts in Australia.
    a. An observation from the document, is that it could be greatly improved with specific AU data on:
        i. Contemporary surveillance data on target animal pathogens
        ii. Retail meat contamination
        iii. Human infectious disease surveillance data attributable to infections from animal origin
    b. Another observation is that the complexity of the data requires incorporation of the risk assessment process as outlined- in Part 10 for new antibiotic submissions (http://www.apvma.gov.au/morag_vet/vol_3/part_10_special.php. Use of the Part 10 framework is not apparent in the submitted documents.
2) Typically reviews of this nature are scrutinized globally and thus it is important that they are conducted by a multi-disciplinary expert group covering the major components (e.g. veterinary

medicine, human medicine, food microbiology, epidemiologist, statistician). Elanco re-states its strong preference for such a multi-disciplinary group to be formed to undertake the macrolide review as directed by JETACAR during which the tylosin re-scheduling review (including label claim wording) could be undertaken.

   a. Elanco has previously expressed full support for completion of the JETACAR recommendation 2) and repeats this support in this document. This recommendation from JETACAR intention on the completion of the macrolide review prior to the rescheduling assessment of Tylosin was also stated in the minutes of the NDPSC meeting 39.

3) Elanco acknowledges the obvious scientific expertise demonstrated within the specialist's report but respectfully points out that while the specialist may provide significant expertise to the issue, the views discussed are from a single source. Elanco would prefer that the review of the data presented by Elanco in June last year was reviewed by a multi-disciplinary team as suggested in Point 2. The Elanco interpretation of the total responses received to date on this issue, is that the submitted Elanco data has not yet been reviewed and responded to in an appropriate scientific manner. Elanco remains unclear whether the specialist response report was provided as a direct response to the data Elanco submitted or presented as an independent view of the sub-therapeutic use of tylosin.

Elanco remains concerned about the lack of progress in 2 key areas related to the above points

1) The APVMA refuse to indicate a time when the macrolide review will be undertaken and as Elanco views completion of this review process as the most appropriate path to make recommendations related to future scheduling and regulatory aspects of tylosin, we maintain our position that the JETACAR recommendations need to be completed. This has also been recognised in the recent release of the Senate review of JETACAR – Elanco maintains the view that if this issue is as important as is indicated then political support for the review should be available and the review actioned.
2) The paucity of local Australian surveillance data makes any interpretation of the broad spectrum of both in vitro and in vivo data presented within the specialist report difficult to quantify in terms of risks to human health following tylosin use in Australia.

Yours sincerely,

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Emerging Mktgs Regional Re/Res/Prod Manager