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10 February 2020

The Secretariat  
ACCS/ACMS Committee  
Therapeutic Goods Administration  
Department of Health

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Dear Secretariat,

**Proposal to add “a definition of marker dyes and pigments in Part 1 of the Poisons Standard”.**

Animal Medicines Australia appreciates the opportunity to provide comment on the proposed amendments to the Poisons Standard to be considered at the March 2020 ACCS/ACMS Committee meeting.

I would also like to recognise the helpful clarifications provided by the Secretariat to Animal Medicines Australia staff that assisted in the development of this response.

Animal Medicines Australia’s comments specifically relate to veterinary chemical products and to other types of products that may have a purpose of identifying treated or selected animals. Our submission does not provide comment on dyes and pigments that may relate to agricultural chemical products, or products that are used in agricultural or other settings.

Animal Medicines Australia’s comments are structured as follows:

- **Background**
- **Scope of products and types**
- **Terminology**
- **Corrections to the table**
- **AMA’s Recommendations**

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About Animal Medicines Australia

AMA is the peak industry body representing the leaders of the animal medicines industry in Australia. AMA member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors.

AMA works closely with its members, a variety of organisations, and governments to promote an evidence-based approach to public policy. Additionally, AMA advocates for the responsible and judicious use of all veterinary medicines to improve and protect animal health and welfare.

## 1. Background

It is proposed to amend the Poisons Standard as follows:

### Part 1 of the Poisons Standard, Interpretation - New Entry

"**Marker dyes or pigments**" means any substance used to temporarily impart colour to:

- i. an agricultural product intended for spot- or boom -spraying to detect missed spots or to avoid spraying a plant or area multiple times; or
- ii. a veterinary product for the purpose of identifying treated or selected animals.

Animal Medicines Australia understands that the proposal is for marker dyes and pigments used in agricultural or animal settings to be specifically identified as distinct from other dyes and pigments. It is also noted that the current proposal does not seek to alter any current entries in the Poisons Standard, nor to exempt marker dyes and pigments from scheduling.

## 2. Scope of products and types

In an animal setting, the potential uses of, and products containing, marker dyes or pigments may be:

- included in the formulation of a veterinary chemical product (APVMA assessed/registered). This may include pour-on veterinary chemical products, such as lousicides and drenches for sheep and cattle, that contain a marker dye to allow for the identification of treated animals. The marker dye is an excipient and has no impact on pharmacodynamics and pharmacokinetics. Veterinary chemical products containing marker dyes are not purchased for use *as* a marker dye, but rather *contain* a marker dye to facilitate correct use.
- stand-alone products that are APVMA assessed/registered. Examples include scourable wool marker sprays that are applied separately to the animal.
- product types specified in Part 3 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* to be 'animal cosmetic products':  
*"Any product applied topically to the teeth, hair, fur or intact skin of an animal to cosmetically alter the animal's appearance or odour, that:*
  - (a) contains no antiseptic, antimicrobial, or antibiotic active constituent, and*
  - (b) is solely for cosmetic purposes; and*
  - (c) is not claimed to have any benefits other than cosmetic benefits; and*
  - (d) is not supplied or used for any therapeutic benefit other than to cosmetically alter the animal's appearance or odour."*

These products are declared not to be veterinary chemical products (and do not require registration by APVMA) as they are used *only* for marking or identifying selected animals. Examples include inks, chalks, paints, waxes, crayons and foams, and which may last from a few hours to several months.

This is similar to the nature of products captured under the definition of cosmetics and under the description and jurisdiction of the National Industrial Chemicals Notification and Assessment Scheme.

### 3. Terminology

It is important to standardise terminology to allow precise meaning and interpretation.

'Veterinary chemical product' has specific meaning under Division 1, part 5 of the *Agricultural and Veterinary Chemicals Code Act 1994*.

'Veterinary pesticide' is used in the table of the proposal but is not described with a regulatory definition and may cause confusion. Animal Medicines Australia believes that the term 'veterinary pesticide' may have been used under the state and territory system that applied prior to the operation of the National Registration Authority (now APVMA) under the *Agricultural and Veterinary Chemicals Code Act 1994*.

The Scheduling Secretariat also questioned whether a 'topical parasiticide' would be considered a 'veterinary parasiticide'. Animal Medicines Australia suggests that a more accurate description would be a veterinary chemical product that is applied topically.

Animal Medicines Australia suggests that the terminology used in the proposal should be consistent with that defined in the relevant legislation and by the APVMA.

It is worth noting that the following terms are not described in Australian legislation but have broad dictionary definitions:

- *Veterinary*: "of, relating to, practicing, or being the science and art of prevention, cure, or alleviation of disease and injury in animals and especially domestic animals" (<https://www.merriam-webster.com/dictionary/veterinary>)
- *Veterinary medicine*: the science and art that deals with the maintenance of health in and the prevention, alleviation, and cure of disease and injury in animals and especially domestic animals" (<https://www.merriam-webster.com/medical/veterinary%20medicine>)

Noting the application of the provisions *Agricultural and Veterinary Chemicals Code Regulations 1995* that identify certain products as *not* being veterinary chemical products, and the need to avoid the use of "veterinary" as a descriptor (because it infers a therapeutic claim or action), there appears to be a need for TGA to use a different descriptor or term for some animal products containing marker dyes or pigments. Animal Medicines Australia suggests 'animal cosmetic' or 'a product used on animals solely for cosmetic purposes', which would be consistent with the language used in the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

### 4. Corrections to the table

Animal Medicines Australia has identified a number of errors and inconsistencies in the proposal in relation to veterinary chemical products:

- The proposal incorrectly states that all of the 47 identified products "*are marketed purely as marker dyes*". With respect to the eleven veterinary chemical products identified in the table, only three are marketed as marker dyes.
- The proposal incorrectly identifies a number of veterinary chemical products as containing marker dyes when they do not. Eight of the eleven identified veterinary chemical products are hormone or steroid implants that contain a palpable, or 'detectable marker', made of metal to assist in tracing treated animals. These products do not contain any marker dyes or pigments.

- The remaining three veterinary chemical products have been correctly identified as containing a marker dye. Two of the products are labelled as ‘marker dyes’, have the same active constituent (hydrocarbon liquid as solvent) and the same instructions for use on the registered label. However, one has been identified in the proposal as a ‘veterinary medicine’ and the other has been listed as a ‘veterinary pesticide’. It is unclear why two identical products have been classified differently.

## 5. Animal Medicines Australia’s Recommendations

Based on the information provided in the proposal, it is difficult to assess the impact on veterinary chemical products associated with the inclusion of new definition for marker dyes and pigments. In addition, the errors identified by Animal Medicines Australia are likely to have created confusion for stakeholders regarding the different product types that underlie this proposal.

Animal Medicines Australia therefore recommends that:

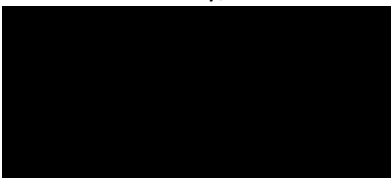
- the terms ‘veterinary pesticide’ and ‘veterinary medicine’ are replaced with ‘veterinary chemical product’, and that all terms are consistent with those used in the relevant legislation and by the APVMA;
- the Committee consider the use of ‘animal cosmetic’ to capture products used on animals that contain marker dyes and pigments but are not required to be registered by APVMA;
- the incorrect entries in the table of the proposal are rectified; and
- a revised proposal is released for stakeholder consultation. This would assist to ensure informed consent on the proposal.

Animal Medicines Australia hopes these comments will assist the Committee in their deliberations.

Animal Medicines Australia would also be very pleased to assist the TGA in the development of future consultation documents that relate to veterinary chemical products to facilitate productive engagement with our industry and its stakeholders.

Please let me know if you have any questions.

Yours sincerely,



Dr Charmian Bennett

Science and Technical Manager