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# AMA Submission to the Therapeutic Goods Administration – Proposed amendments to the Poisons Standard – November 2021

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The following feedback applies to the scheduling proposals referred to the Advisory Committee on Medicines Scheduling (ACMS #35) and joint ACMS/Advisory Committee on Chemicals Scheduling (ACCS) meetings (ACMS-ACCS #29), November 2021.

**Astodrimer sodium**

The AMA supports the new warning statements for astodrimer sodium to reflect the new indication for the prevention of recurrent bacterial vaginosis. The AMA agrees that there should be warning statements around longer period of use and that this should be overseen by a medical practitioner to ensure the patient is using this product appropriately and to confirm that bacterial vaginosis is present. Symptoms of bacterial vaginosis can be similar to other health conditions such as thrush, vaginitis or a sexually transmitted infection and so it is important that the diagnosis is confirmed before prolonged use.

The AMA generally opposes expanded consumer advertising for therapeutic products. Direct to consumer advertising of medicines may increase use, but not necessarily effective or rational use in line with quality use of medicines principles. While advertising may potentially increase awareness of certain health conditions and medicines, its primary purpose is to increase demand and sales for the advertiser's product and is therefore unlikely to be objective or unbiased. The AMA believes that pharmaceutical or other commercial industries should not be the main suppliers of patient information and education regarding health, disease, and treatment options. Patients should consult a registered health practitioner so they are provided with the most appropriate therapeutic options to suit their individual medical situation. Advertising to the public is about profits, not improving patient care.

**Flurbiprofen**

The AMA opposes the proposal to exempt throat sprays from scheduling with dosage limits as per the proposal for the treatment of adults over 18 years of age.

The AMA refers to the rejected 2017 proposal where the ACMS cited concerns around limited benefit to public health, limited in-market experience and concerns around fatal hypersensitivity

reaction[1]. These reasons warrant oversight from a pharmacist who will be able to refer the patient to a medical practitioner if the sore throat is of concern. The AMA believes there is sufficient existing access to low-dose flurbiprofen under the current scheduling arrangements.

**Choline salicylate**

The AMA supports the intention behind the proposal to create a schedule 3 entry for choline salicylate. The AMA notes that the therapeutic guidelines do not recommend teething gels due to the lack of efficacy evidence and the risk of harm. While having a specific schedule 3 entry may provide clarification around its use, the AMA is concerned that this scheduling proposal may not provide sufficient protection from adverse events as it is already included under the schedule 3 entry for salicylic acid. The TGA should carefully monitor adverse events should this amendment proceed to determine whether it has successfully reduced harm.

**Other comments**

The AMA is aware of concerns raised by other stakeholders with respect to the scheduling proposal for meloxicam and the implementation of the scheduling change for lidocaine. While the AMA has chosen not to comment on the use of these medicines in the context of veterinary care, the AMA encourages the TGA to give careful consideration to the concerns that have been raised to ensure that these decisions do not give rise to potential misuse in humans.

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[1] Therapeutic Goods Administration (2017) *Scheduling delegate's final decisions, June 2017.*