SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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SAHPRA updates regarding the use of yohimbine in veterinary medicine

BACKGROUND

This communication is intended to inform stakeholders on the status of yohimbine for use in animals.

The substance yohimbine, is an antagonist acting at the alpha-1 and alpha-2-adrenoreceptors enhancing noradrenaline release and increasing sympathetic activity. It is used in game capture as a reversal for alpha-2 agonists such as medetomidine and xylazine. Although the mechanism of action of yohimbine has not been fully elucidated, it is typically known for its blockade of presynaptic alpha-2 adrenoceptors in noradrenergic cell body regions (locus coeruleus, lateral tegmental nuclei), resulting in increased brain noradrenaline cell firing and release in terminal areas. It also binds at varying degrees of affinity to D2 dopamine receptors, benzodiazepine binding sites, and 5-HT1A receptors. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity.

Yohimbine was declared undesirable by the Medicines Control Council in terms of section 23 of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) on 13 December 1978 - Notice 2/78. The effect of this notice was that its manufacture was to cease by 31 December 1978, with sale at wholesale and retail level ceasing on 30 June 1979. In the same year (1979), the definition of a “medicine” in the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) was amended to include veterinary medicines and the definition of “veterinary medicine” was inserted. These amendments came into effect on 21 March 1979.

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Yohimbine is classified in terms of the General Regulations published in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the Medicines Act) under Category C of Medicines, 1.4.3: Sedative antagonists. Class 1.4.3 of Category C is subject to registration in terms of the Medicines Act as per the declaration published in Gazette No. R. 2309 on 21 October 1983. Currently no yohimbine containing substances are registered in South Africa.

Although the potential benefits and risks of yohimbine in veterinary applications remain a topic of ongoing discussion, recent developments suggest potential benefits which have warranted a re-evaluation of its status for veterinary use in South Africa. Given the evolving nature of scientific understanding and the potential therapeutic benefits that yohimbine may offer in veterinary medicine, and after soliciting expert opinion, the Authority is of the view that the therapeutic use of yohimbine in animals may be in the public interest.

To enable the use of yohimbine in animals, SAHPRA is taking the following steps:

1. Recommend to the Minister of Health that yohimbine be included in the Schedules to the Medicines Act for veterinary use only.
2. Once the scheduling status of yohimbine has been gazetted, publish a notice amending MCC Notice 2/78 to rescind the declaration of undesirability and subsequent banning of yohimbine as a Category C medicine (medicines intended for veterinary use).
3. Once steps 1 and 2 have been completed successfully, stakeholders will be able to submit applications for registration of yohimbine as a Category C medicine. SAHPRA will also consider applications for the sale of yohimbine containing medicines (as a finished product) in terms of section 21 of the Medicines Act and regulation 29 of the General Regulations published in terms of the that Act.
4. SAHPRA has consulted with the Registrar of Act 36/1947 about the use of yohimbine. Both regulators strongly advise against unauthorised use of Yohimbine. Yohimbine is not registered in South Africa for treatment of any antiparasitic toxicity.

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Yohimbine will remain declared undesirable as it pertains to other categories of medicine. Once the steps outlined above have been completed, products may only be sold for veterinary use if registered or authorised by SAHPRA in terms of section 21 of the Medicines Act.

Thank you for your cooperation.

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Chief Executive Officer (CEO)
SAHPRA