[redacted]

Medicines Scheduling Secretariat
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2606
Australia

18th May 2020

Dear Sir/Madam,

Re: Public Submission – under Reg. 42ZCZK of the Therapeutic Goods Regulations 1990. ACMS meeting, June 2020

[redacted] refers to the pre-June 2020 Scheduling meeting notice. [redacted] would like comment on the proposed amendment to the scheduling of Oxymetazoline.

Oxymetazoline

[redacted] supports the proposal to exclude nasal preparations containing 0.05 per cent or less of Oxymetazoline from Schedule 2.

As already mentioned by the original Applicant, nasal sprays containing Phenylephrine have been available for General Sale since 1969 and given Oxymetazoline has similar pharmacodynamic and pharmacokinetic properties to Phenylephrine, the safety concerns related to Oxymetazoline nasal sprays are minimal. The proposal is also appropriate given the well-established safety profile of Oxymetazoline.

In UK, Canada, USA and New Zealand, Oxymetazoline nasal sprays are already available as General Sale. In Australia, Oxymetazoline has a long history of use as a Schedule 2 medicine. It also has a well-documented safety profile and low potential for abuse and misuse. This is supported by the information that the TGA had already identified i.e. from 01 January 1971 to 16 December 2019, the Database of Adverse Event Notifications (DAEN)[1] contained 136 reports of adverse events for products containing oxymetazoline as an active ingredient, with 122 reports where Oxymetazoline was the single suspected medicine.

[redacted]

[redacted]

[redacted]

[redacted]

The design of medicine labelling and the inclusion of appropriate warning statements play a critical role in ensuring the correct and safe use of any medicine. The low number of Adverse Events from the DAEN and [redacted] records show that the current warning statements from the Required Advisory Statements for Medicine Labels (RASML), along with clear directions for use for Oxymetazoline nasal sprays, have allowed consumers to follow the instructions and warnings on the product labels accurately.

The typical warnings and instructions for use found on Oxymetazoline nasal spray labels are:

- If congestion persists, consult your doctor or pharmacist
- Do not use for more than three days at a time unless advised by a doctor or pharmacist
- Frequent or prolonged use may cause nasal congestion to recur or worsen
- Do not give to children under 12 years of age (when indicated for cough, cold or flu which do not include dosage instructions for children aged under 12 years
- Do not give to children aged between ‘x’ and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner (when indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years, where 'x' is 6, 7, 8, 9, 10 or 11)
- Adults and children 6 years and over: 2-3 sprays into each nostril every 10-12 hours, as required. Do not exceed 2 doses in 24 hours.

[redacted] is of the view that these statements continue to remain appropriate for nasal preparations containing 0.05% or less of Oxymetazoline under a General Sales medicine classification.

Based on the safety data available for Oxymetazoline, [redacted] believes there is strong evidence to support the exclusion of nasal preparations containing 0.05 per cent or less of Oxymetazoline from Schedule 2.

[redacted]

[redacted]

[redacted]

[redacted]

Conclusion

[redacted] supports the proposal to exclude nasal preparations containing 0.05 per cent or less of Oxymetazoline from Schedule 2. The data provided shows that Adverse Events associated with Oxymetazoline nasal sprays are extremely low. The reclassification of Oxymetazoline nasal sprays are not expected to increase the potential risk of adverse events nor the potential for abuse or misuse given these products already have a long history of use with consumers and the instructions on the labels can be easily followed.

[redacted]

Thank you, and please contact us with any questions.

Yours sincerely,

[redacted]

References

1. Database of Adverse Event Notifications (DAEN) https://apps.tga.gov.au/Prod/daen/daen-entry.aspx

[redacted]