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8th May, 2020 The Secretary Scheduling Secretariat GPO Box 9848 Canberra ACT 2601

Dear Sir or Madam,

Re: Consultation: Proposed amendments to the Poisons Standard - Joint ACMS-ACCS #25: METHYLISOTHIAZOLINONE and METHYLCHLOROISOTHIAZOLINONE / ISOTHIAZOLINONES

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and wish to add the following comments in <u>support</u> of the proposed scheduling amendments for Methylisothiazolinone (MI) and Methylchloroisothiazolinone (MCI) and Isothiazolinones.

It has been widely reported that isothiazolinones, including MI and MCI, are sensitisers and MI, in particular, was responsible for what several researchers have described as an epidemic of contact allergy.^[1-6] This rise in the notoriety of these preservatives was so swift and so alarming that the American Contact Dermatitis Society named MI their 'allergen of the year' in 2013.^[7]

In Australia, the prevalence of MI allergy appears to be higher than reported elsewhere in the world, peaking in 2015 with 20.3% of patch test patients experiencing a positive reaction to MI.^[5] With such a high incidence of MI allergy it is vital that products containing MI and other isothiazolinones are adequately labelled, with clear warnings so that sensitised individuals can easily avoid these allergens.

On this basis, Ego Pharmaceuticals:

- Supports the proposed amendments to the entry for Methylisothiazolinone and Methylchloroisothiazolinone
- Supports the proposed inclusion of a new entry for Isothiazolinones in Schedule 6

Faithfully,



Fabrizio Spada, Ph.D. R&D Manager Ego Pharmaceuticals Pty Ltd

References

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- Lammintausta K, Aalto-Korte K, Ackerman L, Alanko K, Berry P, Hasan T, et al. An epidemic of contact allergy to methylisothiazolinone in Finland: ALLERGY TO METHYLISOTHIAZOLINONE. Contact Dermatitis 2014;70(3):184–5.
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- 6. Uter W, Aalto ☐ Korte K, Agner T, Andersen KE, Bircher AJ, Brans R, et al. The epidemic of methylisothiazolinone contact allergy in Europe: follow-up on changing exposures. J Eur Acad Dermatol Venereol 2020;34(2):333–9.
- 7. Castanedo-Tardana MP, Zug KA. Methylisothiazolinone. Dermatitis 2013;24(1):2-6.