Proposed changes to the Permissible Ingredients Determination - low-negligible risk

1. Easily-dissociable magnesium salts and laxative effects

The TGA proposes a warning statement to alert consumers to the risk of laxative-effect from products containing easily dissociable magnesium salts that provide more than 250 mg of elemental magnesium from the maximum recommended daily dose.

These requirements are proposed to apply to the existing warning statement requirement for magnesium hydroxide and bittern; and be in addition to the existing limits for magnesium sulfate salts and magnesium pyruvate.

The proposed specific requirements will provide a consistent approach to address the risks of diarrhoea for listed medicines, which do not currently alert consumers to this effect.

Agreed.

2. Andrographis paniculata and taste disturbance

The TGA is proposing an amendment to the requirements for Andrographis paniculata in the Therapeutic Goods (Permissible Ingredients) Determination. The proposed requirements are intended to address the risk of taste loss/taste disturbance effects associated with the use of Andrographis paniculata.

Agreed.

Dr Ken Harvey MBBS, FRCPA, AM
Associate Professor
School of Public Health and Preventive Medicine
Monash University
Alfred Campus
553 St Kilda Rd
Melbourne VIC 3004
Mobile: +61 419181910
Email: kenneth.harvey@monash.edu
WWW: www.medreach.com.au
25 August 2020