Response to TGA Consultation:

Options for the future regulation of "low risk" products

We have provided some comments and proposals on two of the low risk products covered in this consultation document:

- Low risk registered non-prescription (OTC) medicines, rubefacients and chest rubs
- Certain complementary medicines - vitamins and minerals

In general we consider that the exclusion of these products from the therapeutic products regulatory framework could potentially result in a lowering of quality of the products being supplied if the manufacturing standards at not an appropriate level. This may cause consumer dissatisfaction and in some instances have efficacy implications. There may also be an impact on the export marketability of these products if the specialist regulator of therapeutic goods, TGA no longer has the responsibility.

There are however certain types of products which could have lesser regulatory burden such as exemption from listing and a potential "lighter touch" in terms of GMP manufacturing requirements without compromising the industry standards and impacting consumers. These proposals are included with our comments below:

Other low risk registered non-prescription (OTC) medicines

- We support the Option 2 that the eligibility of the active ingredients be reviewed to become Listable for products such as Chest Rubs and Rubefacient preparations for minor aches and pains of muscles (e.g. methyl salicylate, menthol, capsicum).
- Many of these products contain active ingredients which are well known and have established efficacy and safety profiles.
- We agree that this proposal would reduce the regulatory burden and therefore potentially reduce the costs of bringing these types of product to market especially if the GMP requirements are reduced under a further exemption (see below).
- As an additional recommendation, we propose that these products which are low risk containing active ingredients which become Listable should be considered for an Exemption from Listing and full GMP requirements.

  As products exempted from the requirements of listing on the ARTG and/or from medicine level GMP they would still remain subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance.

Vitamins and minerals (particularly water soluble ones at low doses)

- Before support can be given for changing the current regulatory approach for this class of low risk products, it will be necessary to have available the details of which specific vitamin and minerals would be considered suitable and the maximum levels and recommended dosages need to be specified.
- Excluding vitamin and mineral products from Part 3-3 of the Act could potentially result in lower quality products being supplied if manufacturing standards are not appropriate.

- In preference to all 'certain vitamin and mineral products' being exempt from the requirements of listing on the ARTG and/or from medicine level GMP, we propose that consideration be given to the exemption being linked to specific dosage forms. Examples of dosage forms which could qualify for such an exemption would be chewable tablets and soft 'gelatin-based' chews ('gummies').
- It is our preference that all vitamins and mineral products remain as therapeutic goods and therefore still subject to subject to post market compliance reviews, recall procedures and therapeutic goods advertising compliance.