

Technical Alert

TGA New Reviews for Traditional Medicines and Vitamin ‘Gummies’; Publication of review outcomes for biomarkers, sunscreens

Traditional medicines

On 30 July 2018 the TGA published on their website that they had received signals that traditional indications on some medicines are unlikely to be supported by appropriate traditional evidence and therefore maybe deficient in meeting regulatory requirements. In the second half of 2018 the TGA will be conducting random and targeted [reviews](#) of medicines with traditional claims.

Sponsors may review their evidence and indications against the current Evidence Guidelines. In particular, CMA notes that sponsors may wish to consider the evidence to justify the preparation type or type of extract within the medicine.

Gummy supplements

The TGA have also [provided](#) that they will be conducting reviews based on signals that the presentation of gummy supplements may be misleading to consumers. Gummy supplements are any listed complementary medicine on the ARTG with a ‘pastille’ dosage form.

In advance sponsors may wish to evaluate the overall presentation and content of the medicines to ensure they meet the Evidence Guideline requirements, that the goods contain at least 10% of the Australian recommended dietary intake (RDI) for any vitamins or minerals that are stated to be present, and provide at least 25% of the RDI if there is a reference to “supplementation” for the vitamin(s) or mineral(s).

Keeping CMA up-to-date with developments during the review process

CMA asks members to keep us informed of developments within these reviews, in particular if there is a new or unusual interpretation of the evidence guidelines or other approach that is inconsistent with what is suitable and has been accepted for traditional medicines and/or nutritional supplements at technical@cmaustralia.org.au

TGA publication of review outcomes for biomarkers, sunscreens.

The TGA have [published](#) that all 87 medicines reviewed for biomarkers – cholesterol and blood glucose – did not hold evidence to support the claims. This finding appears to be based on the TGA’s removal of the availability of any evidence base that industry may use, unless in controlled clinical trials of maintaining normal levels in healthy individuals. The TGA provide further advice about what to do with biomarker indication medicines under “information for sponsors” [here](#).

The TGA have also published the [outcomes](#) of the review of 94 sunscreen products with the advice that non-compliant products were given the opportunity to fix the issues or were cancelled from the ARTG.

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