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Short Commentary

The Indications for Probiotics in Australia and Their Regulation

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Abstract

Currently, 510 self-certified products containing probiotics are listed on the Australian Register of Therapeutic Goods (ARTG). We found 48% contained only probiotic ingredients; the remainder had multiple additional ingredients. The indications used (and claims made) were mainly non-specific, appeared to lack evidence, and encouraged unnecessary use.

Body

Probiotics are defined as "live microorganisms that, when administered in adequate amounts, confer a health benefit on the host" [1]. The Therapeutic Goods Administration (TGA) regulates products containing probiotics as complementary medicines. Currently, all are listed products (labelled AUST L) for which sponsors self-certify regulatory compliance, including that they hold evidence for the indications selected [2].

We extracted public summary documents from the Australian Register of Therapeutic Goods (ARTG) by searching for common probiotic genera, 'Lactobacillus* or Bifidobacterium* or Streptococcus* or Saccharomyces* or Bacillus*' on 23 June 2021. A Python-based data extraction program automated the download of ARTG summaries and the extraction of permitted indications and ingredients. This software enabled the analysis of 510 products; 48% contained only probiotic ingredients, the remainder had multiple additional ingredients.

None of the probiotic ingredients listed in public summaries contained information about strains. This is a significant omission, given that the benefits of probiotics are strain-specific [3]. It also resulted in ARTG summaries listing the same probiotic microorganism in different dosages. For example, the public summary document of ARTG entry 339468, 'Probiotics for 60+ Year', lists *Lactobacillus plantarum* as an active ingredient four times, with three showing the same doses and one a different amount.

The most common permitted indications used for probiotic products were non-specific gastrointestinal and immune support that appeared to have little supporting evidence. For example, 'Maintain/support healthy digestion' and 'helps stimulate a healthy immune system response'. Although there is some evidence to suggest that specific probiotic strains are beneficial in preventing and treating specific conditions such as antibiotic-associated diarrhoea or irritable bowel syndrome, these were not among the ten most common permitted indications we found. Some permitted indications appeared to have no evidence to support them. For example, ARTG entry 353540, 'Inner health neuro balance' (ingredients: *Lactobacillus plantarum* and *Lactobacillus rhamnosus*) has 17 permitted indications including, 'Calms the mind', 'Maintain/support memory/mental recall' and 'Support healthy emotional/mood balance'.

Around 52% of all probiotic products reviewed contained non-probiotic ingredients. These combinations also appeared to have little evidence to support them apart from possibly broadening their market appeal. For example, some products contained vitamins and enzymes such as pyridoxine hydrochloride and amylase, none of which has been investigated to promote or assist the efficacy and growth of probiotics. It would be helpful if the TGA required permitted indications to be linked to ingredients.

Others have expressed concern that commercial interests, coupled with lack of sufficient medical regulation, make objective interpretation of the benefits of most probiotic products close to impossible [4]. We agree. The TGA should conduct post-marketing surveillance on probiotic products to ensure that the permitted indications (and claims made) are evidence-based.

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