

# Complaint to TGA: Pharmacare Probiotic Chocolate Balls

## Acknowledgment:

This complaint was worked up by a Monash BMedSc Honours student as part of her research project on probiotics; it was then checked and submitted by Assoc Prof Ken Harvey.

## Complaint summary:

This complaint is about three Pharmacare brand products at the Food-Medicine interface that are not listed on the ARTG: **Nature's Way Kids Smart Probiotic Chocolate Balls, Nature's Way Restore Probiotic Choc Balls and Bioglan Healthy Kids Probiotic Choc Balls**. These products are not traditionally known as foods and they do not fit FSANZ Standard 2.5.3 (a food that is sold as fermented milk or 'yoghurt'). They also do not fit with Food Standard 1.2.7 (nutrition, health and related claims) because their high saturated fat and sugar content does not meet the FSANZ Nutrient Profiling Scoring Criterion. Using the Food-Medicine Interface Guidance Tool on the TGA website, these products best fit the criteria for therapeutic goods.

Accordingly, it is alleged that these products breach s.42DL(12) of the Therapeutic Goods Act 1989, (Compilation No. 72, 2019) because they are therapeutic goods not included on the ARTG. The claims made also breach many sections of the Therapeutic Goods Advertising Code (No.2) 2018 because the products fail to identify the specific strains of probiotics for which benefits are claimed and thus the claims cannot be substantiated.

In addition, claims that these products can 'build immunity, 'capable of boosting immunity', 'helping to defend against illnesses doing the rounds' and 'If you don't feel 100%, you can take the benefits of more than just one', lack evidence for the stated ingredients and are especially inappropriate given consumer concern about COVID-19.

## Introduction:

The availability of probiotics in both food and medicines, and the different regulatory systems applicable, confuse consumers trying to establish if the health benefits claimed are evidence-based. The TGA notes that probiotics are often positioned at the food-medicine interface.<sup>1</sup>

Pharmacare Laboratories Pty Ltd brands,<sup>2</sup> **Nature's Way Kids Smart Probiotic Chocolate Balls, Nature's Way Restore Probiotic Choc Balls and Bioglan Healthy Kids Probiotic Choc Balls** provide a nice example of this problem. They are the subject of this complaint.

Probiotic products that are clearly covered by a FSANZ food standard, or that are traditionally used as foods in Australia or New Zealand in the form they are presented in, are regulated as foods.<sup>3</sup> Food products such as yoghurt contain probiotics and are allowed to make general low-level health claims, as set out in Food Standard 1.2.7. For example, yoghurt or fermented milk containing at least 10<sup>8</sup> CFU/g (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*) can claim to improve lactose digestion on individuals who have difficulty digesting lactose.<sup>4</sup>

There are more than 200 pre-approved food-health relationships in the Standard.<sup>5</sup> Foods carrying health claims must meet certain conditions in the Standard, including nutrient profiling scoring criterion (NPSC). There are **no** pre-approved food-health relationships for the general term 'probiotic'.

Alternatively, food business can self-substantiate a food-health relationship (by following the process for systematic review as described in Schedule 6 of the Food Standards Code).

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<sup>1</sup> <https://www.tga.gov.au/book-page/advertising-interface-products>

<sup>2</sup> <https://www.pharmacare.com.au/our-brands/>

<sup>3</sup> <https://www.foodstandards.gov.au/code/Pages/default.aspx>

<sup>4</sup> <https://www.legislation.gov.au/Details/F2018C00942>

<sup>5</sup> <https://www.legislation.gov.au/Details/F2017C00711>

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There are currently **ten** self-substantiated food-health relationships for probiotics by specific food businesses as of 15 June 2020.<sup>6</sup>

**Three** companies (The Beauty Chef, McPherson's Consumer Products Pty Ltd, and Body Science International Pty Ltd) have provided self-substantiated health claims for unspecified 'probiotics' (see Appendix). The claims are, 'promote intestinal health', 'contribute to healthy digestion', and 'support the health of the digestive/ intestinal flora/ microflora/ microbiome'. The claims do not specify the strains of probiotics responsible for the claimed benefits. This is unsatisfactory (and misleading) as current evidence suggests that the benefits of probiotics are strain specific.<sup>7,8</sup> This issue will be raised with the NSW Food Authority.

**Three** companies provided self-substantiated health claims for specific probiotic micro-organisms. These were, The Beauty Chef, '*Lactobacillus rhamnosus GUT5Y™* contribute(s) to skin health and digestive wellbeing'; Kerry Ingredients Australia Pty Ltd, '*Ganeden BC30 and Bacillus coagulans GBI-30 6086* supports digestive health' and Meade Farm Pty Ltd, '*Lactobacillus casei 431* used in Caldermeade brand Immune Support Natural Yoghurt has been proven to support human immune system and *Bifidobacterium (BB12)* used in Caldermeade brand Bowel Support Natural Yoghurt has been proven to support human bowel system'.

**None of these claims were submitted by Pharmacare Laboratories Pty Ltd or their brands Nature's Way or Bioglan.**<sup>9</sup>

Nature's Way Kids Smart Probiotic Chocolate Balls, Nature's Way Restore Probiotic Choc Balls and Bioglan Healthy Kids Probiotic Choc Balls are not traditionally regarded as foods and do not appear to fit FSANZ Standard 2.5.3 (a food that is sold as fermented milk or 'yoghurt').<sup>10</sup> In addition, these products do not meet the FSANZ Nutrient Profiling Scoring Criterion because of their high saturated fat and sugar content.<sup>11</sup> Regardless, they are making therapeutic claims (see below).

Using the Food-Medicine Interface Guidance Tool on the TGA website, all three products appear to be therapeutic goods, not food, but they are not listed on the ARTG.

## Complaint details

It is alleged that Nature's Way Kids Smart Probiotic Chocolate Balls, Nature's Way Restore Probiotic Choc Balls and Bioglan Healthy Kids Probiotic Choc Balls breach s.42DL(12) of the Therapeutic Goods Act 1989, (Compilation No. 72, 2019) because they are therapeutic goods not included on the ARTG.<sup>12</sup> The claims made also breach many sections of the Therapeutic Goods Advertising Code (No.2) 2018 because the products fail to identify the specific stains of probiotics for which benefits are claimed and thus the claims cannot be substantiated.

In addition, vague claims that these products can 'build immunity, 'capable of boosting immunity', 'helping to defend against illnesses doing the rounds' and 'If you don't feel 100%, you can take the benefits of more than just one' lack evidence for the stated ingredients and are especially inappropriate given consumer concern about COVID-19.

<sup>6</sup> <https://www.foodstandards.gov.au/industry/labelling/fhr/Pages/default.aspx?k=probiotic>

<sup>7</sup> <https://pubmed.ncbi.nlm.nih.gov/20130080/>.

<sup>8</sup> <https://pubmed.ncbi.nlm.nih.gov/29026729/>

<sup>9</sup> <https://www.pharmacare.com.au/our-brands/>

<sup>10</sup> <https://www.legislation.gov.au/Series/F2015L00413>

<sup>11</sup> <https://www.foodstandards.gov.au/industry/labelling/Pages/Short-guide-for-industry-to-the-NPSC.aspx>

<sup>12</sup> <https://www.legislation.gov.au/Details/C2019C00066>

# Complaint to TGA: Pharmicare Probiotic Chocolate Balls

Products (screen shots accessed on 8 June 2020 appended):

## Nature's Way Kids Smart Probiotic Chocolate Balls

- <https://www.naturesway.com.au/product/kids-smart-probiotic-chocolate-balls-50s>
- <https://www.chemistwarehouse.com.au/buy/66542/nature-s-way-kids-probiotic-balls-50>
- <https://www.goodpricepharmacy.com.au/nature-s-way-kids-smart-probiotic-choc-balls-50-pack>
- <https://www.priceline.com.au/nature-s-way-kids-smart-probiotic-choc-balls-50-pack>
- <https://www.pharmacy4less.com.au/nature-s-way-kids-smart-probiotic-choc-balls-x-50-4.html>
- <https://shop.coles.com.au/a/springwood/product/natures-way-kids-smart-probiotic-chocolate-balls?cid=wsm>
- <https://www.health365.com.au/natures-way-kids-smart-probiotic-choc-balls-50s>
- <https://www.superpharmacy.com.au/products/natures-way-kids-smart-probiotic-50-125g-choc-balls>
- <https://vitaminonly.com.au/products/natures-way-kids-yoghurt-probiotic-balls-50>
- <https://www.yourdiscountchemist.com.au/natures-way-kids-probiotic-choc-balls-50.html>
- <https://mouthsofmums.com.au/rate-it/beauty-supplements-wellness-toiletries/kids-vitamins/natures-way-kids-smart-probiotic-choc-balls/>
- <https://tellmebaby.com.au/product/natures-way-kids-smart-probiotic-choc-balls/>
- <https://discountchemist.com.au/product/natures-way-kids-smart-probiotic-50-choc-balls/>
- <https://vitaminsforall.com.au/product/natures-way-kids-smart-probiotic-choc-balls-50s/>

## Nature's Way Restore Probiotic Choc Balls

- <https://www.naturesway.com.au/product/nw-restore-probiotic-choc-balls-60s>
- <https://www.goodpricepharmacy.com.au/nature-s-way-restore-probiotic-choc-balls-60-pack>
- <https://www.chemistwarehouse.com.au/buy/65979/nature-s-way-restore-probiotic-chocolate-balls-60>
- <https://shop.coles.com.au/a/springwood/product/natures-way-restore-pro-biotic-choc-balls?cid=wsm>
- <https://www.superpharmacy.com.au/products/natures-way-restore-daily-probiotic-for-inner-health-60-chocolate-balls>
- <https://www.woolworths.com.au/shop/productdetails/711581/nature-s-way-restore-daily-probiotic-chocballs>
- <https://www.chemistdirect.com.au/nature-s-way-restore-daily-probiotic-chocolate-balls-x-60>
- <https://www.chempro.com.au/Natures-Way-Restore-Probiotic-90-Capsules-Bonus-Probiotic-Chocolate-Balls>
- <https://www.yourdiscountchemist.com.au/natures-way-restore-probiotic-choc-balls-60.html>
- <https://www.pharmacy4less.com.au/nature-s-way-restore-daily-probiotic-choc-balls-60-4.html>
- <https://discountchemist.com.au/product/natures-way-restore-daily-probiotic-chocballs-60-balls-150g/>
- <https://www.kmart.com.au/product/natures-way-restore-probiotic-choc-balls-150g/2924385>
- <https://www.chemistdiscountcentre.com.au/?./naturopathica#!/prod/105949/natures-way-restore-probiotic-60-chocolate-balls>
- <https://vitaminsforall.com.au/product/natures-way-restore-probiotic-choc-balls-60s/>

## Bioglan Healthy Kids Probiotic Choc Balls

- <https://www.bioglan.com.au/products/vitamins/kids-choc-probiotic-balls/>
- <https://www.chemistwarehouse.com.au/buy/65052/bioglan-gummies-probiotic-50-chocolate-balls>
- <https://www.holistichealthandbeautyshop.com/probiotic-50-choc-balls-x-3-pack-bioglan-healthy-kids/>

# Complaint to TGA: Pharmacare Probiotic Chocolate Balls

- <https://www.chempro.com.au/BIOGLAN-KIDS-GUMMIES-PROBIOTIC-BALLS-50>
- <https://www.goodpricepharmacy.com.au/bioglan-kids-probiotic-chocolate-balls-50-balls>
- <https://www.priceline.com.au/bioglan-kids-probiotic-choc-balls-50-pack>
- <https://www.pharmacy4less.com.au/bioglan-kids-probiotic-choc-balls-50-balls-4.html>
- <https://discountchemist.com.au/product/bioglan-healthy-kids-probiotic-50-choc-balls/>
- <https://localpharmacy.com.au/vitamins-supplements/bioglan/bioglan-gummies-probiotic-50-chocolate-balls.html>

## Claims:

### Nature's Way Kids Smart Probiotic Chocolate Balls

Listed on the official website<sup>13</sup>

- "Probiotics are the good bacteria found in the digestive tract, important for a happy tummy and wellbeing"
- "Beneficial to our health and capable of boosting immunity"

### Nature's Way Restore Probiotic Choc Balls

Listed on the official website<sup>14</sup>

- "Delicious way to support general well-being"

On the GoodPrice Pharmacy website<sup>15</sup>

- "Support your digestive health"
- "[supports] digestive health, intestinal function, energy production, and immunity"

On the Chemist Warehouse website<sup>16</sup>

- "If you don't feel 100%, you can take the benefits of more than just one"
- "When immune health matters"

### Bioglan Healthy Kids Probiotic Choc Balls

On the official website<sup>17</sup>

- "Support your kid's wellbeing and vitality"
- "Make it easier for your kids to top up their daily intake of probiotics to maintain a healthy digestive system"

On the Chemist Warehouse website<sup>18</sup>

- "Helps to maintain this balance whilst helping to defend against illnesses 'doing the rounds' at schools and childcare facilities"

On the Holistic Health & Beauty Shop website<sup>19</sup>

- "Helps to maintain this balance whilst helping to defend against illnesses 'doing the rounds' at schools and childcare facilities"

On the ChemPro Chemists website<sup>20</sup>

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<sup>13</sup> <https://www.naturesway.com.au/product/kids-smart-probiotic-chocolate-balls-50s>

<sup>14</sup> <https://www.naturesway.com.au/product/nw-restore-probiotic-choc-balls-60s>

<sup>15</sup> <https://www.goodpricepharmacy.com.au/nature-s-way-restore-probiotic-choc-balls-60-pack>

<sup>16</sup> <https://www.chemistwarehouse.com.au/buy/65979/nature-s-way-restore-probiotic-chocolate-balls-60>

<sup>17</sup> <https://www.bioglan.com.au/products/vitamins/kids-choc-probiotic-balls/>

<sup>18</sup> <https://www.chemistwarehouse.com.au/buy/65052/bioglan-gummies-probiotic-50-chocolate-balls>

<sup>19</sup> <https://www.holistichealthandbeautyshop.com/probiotic-50-choc-balls-x-3-pack-bioglan-healthy-kids/>

<sup>20</sup> <https://www.chempro.com.au/BIOGLAN-KIDS-GUMMIES-PROBIOTIC-BALLS-50>

# Complaint to TGA: Pharmacare Probiotic Chocolate Balls

- “The great taste means your kids will be encouraged to take these probiotics to keep their tummies healthy and build immunity”

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16 June 2020

## Screen shots and FSANZ Nutrient Profiling Calculations

### Nature’s Way Kids Smart Probiotic Chocolate Balls

Product	
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# Complaint to TGA: Pharmicare Probiotic Chocolate Balls

<p><b>Formulation</b></p>	<p>Ingredients: Premium Milk Chocolate [sugar, milk solids, cocoa, butter, cocoa mass, emulsifiers (soya lecithin,476), flavour], Glazing Agent (904), Inulin (5%)(prebiotic), Lactobacillus Acidophilus, Bifidobacterium Lactis.</p> <p>Contains milk and soy. May contain traces of tree nuts.</p> <p>NUTRITION INFORMATION</p> <table border="1"> <tr> <td colspan="3">Servings per Package: 50(1 ball)Serving Size: 2.5g</td> </tr> <tr> <td></td> <td>Avg Quantity</td> <td>Avg Quantity</td> </tr> <tr> <td></td> <td>per Serving</td> <td>per 100g</td> </tr> <tr> <td>Energy</td> <td>52kJ (12Cal)</td> <td>2074kJ (496Cal)</td> </tr> <tr> <td>Protein</td> <td>less than 1g</td> <td>4.3g</td> </tr> <tr> <td>Fat, total</td> <td>less than 1g</td> <td>26.4g</td> </tr> <tr> <td>-saturated</td> <td>less than 1g</td> <td>16.4g</td> </tr> <tr> <td>Carbohydrate</td> <td>1.6g</td> <td>64.2g</td> </tr> <tr> <td>-sugars</td> <td>1.5g</td> <td>58.8g</td> </tr> <tr> <td>Sodium</td> <td>less than 5mg</td> <td>154mg</td> </tr> <tr> <td>Lactobacillus acidophilus</td> <td>500 million cfu</td> <td>20 billion cfu</td> </tr> <tr> <td>Bifidobacterium lactis</td> <td>500 million cfu</td> <td>20 billion cfu</td> </tr> </table>	Servings per Package: 50(1 ball)Serving Size: 2.5g				Avg Quantity	Avg Quantity		per Serving	per 100g	Energy	52kJ (12Cal)	2074kJ (496Cal)	Protein	less than 1g	4.3g	Fat, total	less than 1g	26.4g	-saturated	less than 1g	16.4g	Carbohydrate	1.6g	64.2g	-sugars	1.5g	58.8g	Sodium	less than 5mg	154mg	Lactobacillus acidophilus	500 million cfu	20 billion cfu	Bifidobacterium lactis	500 million cfu	20 billion cfu																									
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## Nature's Way Restore Probiotic Choc Balls

<p><b>Product</b></p>	
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# Complaint to TGA: Pharmacare Probiotic Chocolate Balls

<b>Formulation</b>	Premium dark chocolate [sugar, cocoa butter, cocoa mass, emulsifiers (soya lecithin, 476), flavour], glazing agent (904), Inulin (5%) (prebiotic), Lactobacillus Acidophilus, Bifidobacterium Lactis.
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## Bioglan Healthy Kids Probiotic Choc Balls

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	Ingredients: Premium milk chocolate [sugar, milk solids, cocoa butter, cocoa mass, emulsifiers (soya lecithin, 476), flavour] Inulin (5%) (prebiotic), Lactobasillus Acidophilus, Bifidobacterium Lactis. Contains milk and soy. May contain traces of tree nuts.																																																																		
<b>FSANZ Nutrient Profiling Calculation</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: left;">Bioglan Healthy Kids Probiotic Choc Balls</th> </tr> <tr> <th colspan="3" style="text-align: left;">Category 2</th> </tr> <tr> <th colspan="3" style="text-align: left;">Tuesday, 9 June 2020</th> </tr> <tr> <th colspan="3" style="text-align: left;">Baseline Points:</th> </tr> <tr> <th style="text-align: left;">Nutrient Information</th> <th style="text-align: center;">Amount Entered</th> <th style="text-align: center;">Points earned</th> </tr> </thead> <tbody> <tr> <td>Energy</td> <td style="text-align: center;">2120</td> <td style="text-align: center;">6</td> </tr> <tr> <td>Saturated Fatty Acids</td> <td style="text-align: center;">16.4</td> <td style="text-align: center;">10</td> </tr> <tr> <td>Sugars</td> <td style="text-align: center;">53.7</td> <td style="text-align: center;">10</td> </tr> <tr> <td>Sodium</td> <td style="text-align: center;">95</td> <td style="text-align: center;">1</td> </tr> <tr> <td><b>Total Baseline Points</b></td> <td></td> <td style="text-align: center;"><b>27</b></td> </tr> <tr> <th colspan="3" style="text-align: left;">Modifying Points:</th> </tr> <tr> <th></th> <th style="text-align: center;">Amount Entered</th> <th style="text-align: center;">Points earned</th> </tr> <tr> <td>Non <i>fvnl</i> ingredients</td> <td style="text-align: center;">100%</td> <td rowspan="3" style="text-align: center;">0</td> </tr> <tr> <td><i>fvnl</i> Non-concentrated <i>fvnl</i> ingredients</td> <td style="text-align: center;">0%</td> </tr> <tr> <td>Concentrated fruit and vegetable ingredients</td> <td style="text-align: center;">0%</td> </tr> <tr> <td>Protein</td> <td style="text-align: center;">7.7</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Dietary Fibre</td> <td style="text-align: center;">7.4</td> <td style="text-align: center;">5</td> </tr> <tr> <td><b>Total Modifying Points</b></td> <td></td> <td style="text-align: center;"><b>5</b></td> </tr> <tr> <td><b>Final Score</b></td> <td></td> <td style="text-align: center;"><b>22</b></td> </tr> <tr> <td colspan="3"><b>Important</b></td> </tr> <tr> <td colspan="3">Check Standard 1.2.7 for conditions that apply for making a health claim.</td> </tr> <tr> <td colspan="3">Please print this page for your records.</td> </tr> </tbody> </table>			Bioglan Healthy Kids Probiotic Choc Balls			Category 2			Tuesday, 9 June 2020			Baseline Points:			Nutrient Information	Amount Entered	Points earned	Energy	2120	6	Saturated Fatty Acids	16.4	10	Sugars	53.7	10	Sodium	95	1	<b>Total Baseline Points</b>		<b>27</b>	Modifying Points:				Amount Entered	Points earned	Non <i>fvnl</i> ingredients	100%	0	<i>fvnl</i> Non-concentrated <i>fvnl</i> ingredients	0%	Concentrated fruit and vegetable ingredients	0%	Protein	7.7	0	Dietary Fibre	7.4	5	<b>Total Modifying Points</b>		<b>5</b>	<b>Final Score</b>		<b>22</b>	<b>Important</b>			Check Standard 1.2.7 for conditions that apply for making a health claim.			Please print this page for your records.		
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# Complaint to TGA: Pharmacare Probiotic Chocolate Balls

## Appendix: Screenshot of notified food-health relationships

<b>Food or property of food:</b> Probiotics	
<b>Health effect:</b> Probiotics contribute to healthy digestion	
<b>Business:</b> The Beauty Chef	
<b>Address:</b> Suite 11 & 12, Level 2, 402 New South Head Road Double Bay NSW 2028	
<b>Notification Date:</b> 12/11/2018	
<hr/>	
<b>Food or property of food:</b> Probiotics	
<b>Health effect:</b> Probiotics/ supports the health of the digestive/ intestinal flora/ microflora/ microbiome	
<b>Business:</b> McPherson's Consumer Products Pty Ltd	
<b>Address:</b> 105 Vanessa Street, Kingsgrove 2208 NSW AUSTRALIA	
<b>Notification Date:</b> 27/04/2020	
<hr/>	
<b>Food or property of food:</b> Probiotics	
<b>Health effect:</b> Probiotics contributes to healthy digestive system / intestinal function	
<b>Business:</b> McPherson's Consumer Products Pty Ltd	
<b>Address:</b> 105 Vanessa Street, Kingsgrove 2208 NSW AUSTRALIA	
<b>Notification Date:</b> 28/04/2020	
<hr/>	
<b>Food or property of food:</b> Probiotics	
<b>Health effect:</b> Promotes intestinal health	
<b>Business:</b> Body Science International Pty Ltd	
<b>Address:</b> 4/24-30 Dover Dr Burleigh Q 4220	
<b>Notification Date:</b> 9/06/2015	

<https://www.foodstandards.gov.au/industry/labelling/fhr/Pages/default.aspx?k=probiotic> , accessed on 15 June 2020