[2012] AATA 536

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| Division | **GENERAL ADMINISTRATIVE DIVISION** |
| File Number | 2011/2695 |
| Re | Sumabe Pty Ltd |
|  | APPLICANT |
| And | Minister for Health and Ageing |
|  | RESPONDENT |

# Decision

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| Tribunal | **The Hon. Brian Tamberlin, QC, Deputy President****Professor G Johnston, AM, Member** |
| Date | **16 August 2012** |
| Place | **Sydney** |

The decision under review is affirmed.

.......[Sgd]................................................

**The Hon. Brian Tamberlin, QC,**

**Deputy President**

# Catchwords

HEALTH AND AGEING – Therapeutic Goods – registration of therapeutic goods products – whether therapeutic goods or food – whether goods had a tradition of use as foods in the form in which they are presented – Australian and New Zealand tradition of use as a food – active ingredients of plant products – Garcinia – decision under review affirmed

# Legislation

Therapeutic Goods Act 1989(Cth) ss 3(1), 25, 26A, 60

# Secondary Materials

Explanatory Memorandum to the Therapeutics Goods Legislation Amendment Bill 1999

# REASONS FOR DECISION

**The Hon. Brian Tamberlin, QC, Deputy President;**

**Professor G Johnston AM, Member**

**16 August 2012**

1. This is an application for review of a decision made by a delegate of the Minister for Health and Ageing who, on 23 March 2011 cancelled the listing, on the Australian Register of Therapeutic Goods (the Register), pursuant to section 60 of the *Therapeutic Goods Act 1989* (the Act), of four products in respect of which the Applicant is the sponsor, namely:
	1. Leptin Green Coffee 800 (AUST-L178038);
	2. Leptin Green Coffee Pure Black (AUST-L178039);
	3. Leptin Cocoa Hot Chocolate (AUST-L178051); and
	4. Leptin Cocoa Hot Chocolate (AUST-L178441).
2. The four products, of which the Applicant is the sponsor, were listed on the Register on 1 December 2010.
3. The initial decision was reviewed and confirmed by another Ministerial delegate on 14 June 2011.

**OVERVIEW**

1. The legislation requires therapeutic goods, unless exempted, to be registered or listed on the Register, if they are to be manufactured or supplied, imported into or exported from, Australia.
2. There are higher risk medicines such as prescription medicines and lower risk medicines. The risk is estimated by reference to a range of considerations such as ingredients, dosage, and claims made for the goods. The Secretary of the Department can decide to register goods after approval under s 25 of the Act.
3. In the case of listed medicines, the Secretary is bound to list a medicine under s 26A of the Act without evaluation if the Applicant gives a certificate as to certain matters and this occurred in the present case. The Applicant must certify that the goods are eligible for listing.
4. The goods were delisted because the delegate of the Minister found that the goods were goods which *“(i) in Australia or New Zealand had a tradition of use as food for humans in the form in which they are presented”.* The accuracy of this finding is the issue in this review.
5. In accordance with s 3(1) of the Act, therapeutic goods are relevantly defined as goods:

 (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

 (i) for therapeutic use; …

The definition specifically excludes goods:

 (f) … which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

1. The expression “therapeutic use” means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or

 (b) influencing, inhibiting or modifying a physiological process in persons; or

 (c) testing the susceptibility of persons to a disease or ailment; or

 (d) influencing, controlling or preventing conception in persons; or

 (e) testing for pregnancy in persons; or

 (f) the replacement or modification of parts of the anatomy in persons.

1. In concluding that the goods came within the exclusion, the delegate found that there was a history of significant human consumption in Australia and New Zealand over a long period. The delegate found that the presentation of the goods was as a food for humans.
2. The Explanatory Memorandum which resulted in the insertion of the exclusion states:

a good which has a tradition of use in Australia or New Zealand is one which has a history of significant human consumption as a food in the broad community in Australia or New Zealand and for which there exists adequate knowledge.

1. There is no definition of “tradition of use” but the Macquarie Dictionary defines “tradition” to include: *“the handing down of statements, beliefs and customs from generation to generation especially by word of mouth”* or *“something which is handed down”*. The expression connotes a significant period of time and a sense of continuity and acceptance by later generations.
2. The terms of the Explanatory Memorandum refer to broad or widespread and significant consumption for use as a food, and this involves the concept that, as a consequence of the widespread use over time, there is knowledge of the operation and effect of the particular item.

**THE EVIDENCE**

1. Suzanne Bennett, a Director of Sumabe Pty Ltd, gave evidence that, prior to listing, the goods were supplied to health food and pharmacy outlets to attract traditional vitamin supplement consumers. The goods are marketed through these outlets. Ms Bennett does not purport to be a botanist or a pharmacologist but she has had experience in the distribution and marketing of the goods. She referred to the warnings, indications, formulations, messages and active ingredients described for the goods and attached photos of the packaging of the goods where the active ingredients are set out. For example, in relation to ‘Leptin Green Coffee 800’ active ingredients included *“1.2g of Coffea Arabica seed and Garcinia Quaesita fruit”*. The coffee ‘Leptin Green Coffee Pure Black’ includes as an active ingredient Coffea Arabica but does not contain Garcinia.
2. A third product ‘Leptin Cocoa Hot Chocolate’ contains as active ingredients cocoa and Coffea Arabica. Ms Bennett referred to details of the packaging and stated that she is not aware of any other products supplied in Australia which combine the same active ingredients.
3. Rachael Keenan, a Regulatory Consultant, says that the overall presentation of the goods is not as a food. In her opinion there is no tradition of use of the goods as a food in Australia or New Zealand. She agreed that she was not a botanist and was not in a position to draw distinctions between different types of Garcinia, such as ‘Garcinia Quaesita’ or ‘Garcinia Cambogia’. She refers to some of the ingredients which she says do not have a tradition of use as a food. She says the goods are presented as being for therapeutic use and are not presented as a food and they are likely to be taken for therapeutic purposes.
4. Mr Thomas, also called for the Applicant, has had 17 years’ experience in the marketing of pharmaceutical products and is Group General Manager of one of Australia’s largest distributors of complementary medicines and health food products. He cannot speak as to the active ingredients or their operation. He has examined the presentation of the goods and considers they are presented for therapeutic use in regard to the packaging, instruction, labelling and other considerations. He also expresses the view that the goods are likely to be taken for therapeutic use and that they do not present as a food because they contain ingredients that are not normally consumed as a food and they are not normally used as ingredients in food. He does not consider there is a traditional use of the goods in Australia and New Zealand as a food. He also says that the Green Coffee products do not involve roasting or grinding of coffee beans and that it would not be seen or used by a ‘barista’ in a typical coffee beverage. In relation to coffee he concluded that the use of the Coffea Arabica extract plus the traditional ingredients; the existence of warnings; the inclusion of therapeutic claims; the presentation and content of the directions for use; and the statements on the packaging; all represent the product as a listable therapeutic good.
5. Evidence was given for the Minister by Emeritus Professor Helen Leach who has experience and expertise in the history of food and who has extensively published in the area concerning the history of culinary traditions. She has a distinguished academic history in relation to culinary matters in Australia, New Zealand and elsewhere.
6. After examining all the relevant material she concludes that there is a tradition of use of all the goods in Australia and New Zealand as food for humans in the form in which they are presented.
7. In particular she relies on specific documents and records, such as official government statistics relating to imports; commercial advertisements; personal matters such as diaries reminiscences; and domestic records such as recipes intended for domestic use, to support her opinion.
8. Evidence was also given for the Minister by an expert plant biologist, Dr Hans Wohlmuth, that the plant known as ‘Garcinia Quaesita’ (the Malabar Tamarind), although a related species is clearly distinct from the plant ‘Garcinia Cambogia’. The effect of his evidence was not lessened in cross-examination. We accept that the two plants are different species. The consequence of this is that the view held by Ms Keenan that the presence of the Garcinia ingredient supports the view that products containing it are not a traditional food, has no foundation in fact.
9. Moreover, the Applicant’s submission in this respect in relation to Garcinia is in fact irrelevant because the question before this Tribunal is the meaning of the expression in the Act and we are not concerned with the food standard descriptions under other legislation and their applicability. The application and determination of food standards is a matter for a different regulatory regime.

**Newly Listed Products – Consumer Confusion**

1. During the hearing it became apparent that products with the same or similar active ingredient profiles to the goods under consideration are now on sale in Australia under different names and packaging.
2. Ms Bennett, amended her original statement to acknowledge that the same products as the goods in different packages were now available. When referring to ‘Green Coffee Pure Black’ she stated: *“We do have the same product under our direction in a different package as well, but it is under our control*.*”* Similar statements were made for the other goods under consideration.
3. In response to an email of 14 May 2012 from the Tribunal, the Applicant reported that Sumabe Holdings Pty Ltd presently held listings for six therapeutic goods specified in Schedule B as follows:
	* 1. Leptin Green Coffee 800 (AUST-L185742);
		2. Leptin GC800 (AUST-L185742);
		3. Leptin Green Coffee Pure Black (AUST-L185743);
		4. Leptin GC Pure Black (AUST-L185743);
		5. Leptin Cocoa Hot Chocolate (AUST-L185741); and
		6. Leptin Cacao Herbal Blend (AUST-L-185741).
4. The therapeutic goods (i), (iii) and (v) were for export only and not available in Australia. They carry the same numbers as the equivalent therapeutic goods (ii), (iv) and (vi) that are currently available in Australia. The latter goods are stated to be *“presented in a form different to the goods subject to the current proceedings to the extent that each of them have a different product name, in all other respect, those therapeutic goods are the same as the goods subject to the current proceedings*.*”*
5. Ms Bennett stated that Green Coffee 800 (AUST-L185742) *“goes directly from the overseas warehouse to our overseas purchaser”* and is not exported from Australia.
6. The Respondent produced an invoice for the product ‘Leptin GC800-Leptin Green Coffee 800’ purchased online on the first morning of the hearing. This indicated that it was possible to buy online in Australia a product described as ‘Leptin GC800-Leptin Green Coffee 800’. There was some confusion as to which product would be supplied to the Respondent.
7. Subsequently samples of ‘Cacao Herbal Blend’ and ‘GC Pure Black’ were provided to the Tribunal (Exhibit M). Comparison with the product boxes of ‘Cocoa Hot Chocolate’ and ‘Green Coffee Pure Black’ (Exhibit A) showed that the newly listed products had name changes (Cacao Herbal Blend for Cocoa Hot Chocolate; GC Pure Black for Green Coffee Pure Black) and textual changes on the packaging. As stated for the Applicant: *“But certainly what you will see on those boxes is that the decision has been taken to address head-on issues that arise from the title and the primary description of the goods”*. The Tribunal members were invited to open sachets of the newly listed products and we confirmed that they smelt of cocoa and coffee respectively.
8. While these newly listed products are not the subject of the current proceedings, two examples were in evidence. From an examination of these, it was apparent that the Applicant was able to address the Respondent’s objection to the names of the delisted products and the description on the packaging that led to their exclusion from being therapeutic goods under s 3(1)(f) of the Act as having a *“tradition of use as foods for humans in the form in which they are presented”*. Removing the terms ‘coffee’, ‘tea’ and ‘cocoa’ from the product names and changing the information on the packages made it clear that the products were more likely to be therapeutic goods and not versions of the traditionally consumed beverages coffee, tea and cocoa.
9. As presented, the delisted products could appear to potential consumers as enhanced coffee, tea and cocoa beverages to be prepared in the traditional manner. The consumer is being asked to pay a premium price for the goods as they contained extra ingredients and were claimed to be more beneficial to the consumer’s health for a range of conditions than the traditional goods. Premium pricing is a well-known practice in the pharmaceutical industry to suggest that such products are better than comparable products.
10. Ms Keenan provided the Tribunal with a range of Registered and Listed Therapeutic Goods *“that have an obvious tradition of usage as a food”*. These include Laxettes (presented as chocolate squares); Combantrin-1 (chocolate squares); Metamucil (orange powder to be mixed in water); Butter Menthols (sweet lozenges); and Dieters’ Regular Strength Slim Tea (presented as a tea). Only in the last example is the name of a traditional food in the name of the therapeutic product. It may be that the packaging and presentation of Dieters’ Regular Strength Slim Tea make it very clear that it is a therapeutic product rather than a food.
11. The Therapeutic Goods Administration (TGA) describes Listed Medicines as:

…usually considered to be relatively benign, so the regulations allow for sponsors to ‘self- assess’ their products in some situations. The majority of listed medicines are self-selected by consumers and used for self-treatment. They are all unscheduled medicines with well-known established ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens. These are assessed by the TGA for quality and safety but not efficacy.

1. The Act makes specific mention of the ‘presentation’ of therapeutic goods: *“the way in which the goods are presented”*; *“presented for supply in the way specified”*; and *“in the form in which they are presented”.*
2. As the majority of Listed Medicines are self-selected by consumers and used for self-treatment, the Tribunal considers that the accurate presentation of therapeutic goods to the consumer is important, consistent with the Act.
3. In the present case, the Tribunal considers that it is important that consumers do not mistake a Listed Medicine for a premium version of a widely consumed beverage with added ingredients on the basis of the name and presentation of the product, and use it inappropriately, that is, as a food and not a therapeutic good. A suitable name change and more appropriate packing information may avoid such mistaken identity by consumers.
4. The Secretary is bound to list a medicine under the Act without evaluation if an applicant certifies that the goods are eligible for listing. In order to avoid subsequent delisting, an application should avoid possible ‘danger signals’ such as encountered in the present case. The name and presentation of a product should not imply that it is a food rather than a therapeutic good.

**REASONING**

1. The Explanatory Memorandum requires consideration of the history of the item in question to see whether it has a significant history of human consumption; and a sufficiently broad use in Australia or New Zealand in respect of which there exists an understanding of its effects and characteristics in relation to the goods. Here it is clear from the packaging, the reference to the ‘coffee’, ‘cocoa’ and ‘hot chocolate’ that these are major presentation elements in the description of the goods on the face of the packaging. The references to ‘Green Coffee’ indicate that the product is a coffee *product* or a *type* of coffee. In the case of the cocoa product, this description is reinforced by the use of the words ‘hot chocolate’.
2. The ways in which the goods are ingested with milk, water and sweeteners, are also consistent with, but not determinative of, the conclusion that the goods are presented as a food.
3. Among the principle active ingredients of the products are coffee and cocoa. These ingredients are foods.
4. The references to cocoa and hot chocolate are made more than once, and in prominent positions on the packaging. In addition, the goods smell like coffee and cocoa and they are presented in sachets similar to the packaging of coffee and cocoa.
5. It is true that there are some indications that the goods have therapeutic effects in the form of directions as to use and warnings, and the products are sold in health stores and pharmacy outlets. We have taken these matters into account.
6. We are not here concerned with the question whether the goods can be marketed in accordance with the relevant food standard regulations.
7. The detailed, undisputed evidence of Professor Leach as to the history of the use of coffee and cocoa over more than a century in Australia and New Zealand strongly supports the conclusion that, in using the references to ‘coffee’ and ‘cocoa’, the goods are presented as having a tradition of use as food.
8. We consider that a reasonable buyer could properly consider that because the presentation of the goods refers to well-known products consumed over a period of time, they are therefore well-tried and proven as being safe for consumption. The warnings and some of the writing on the goods, if taken alone, could indicate to the careful consumer that there was some need for caution but the primary impression conveyed in the markets by the presentation of the goods in our view is that of presenting them as a ‘food’.
9. In reaching this conclusion we have also given weight to the expertise of Emeritus Professor Johnston, a member of the Tribunal, who has specialised in herbal medicines research and education over a substantial period, and who has considerable experience in the extraction, chemical characterisation and pharmacological evaluation of active ingredients from plants.
10. We consider that the extent of the active ingredients, coffee and cocoa, in conjunction with the other matters which we have referred to in detail above, and the expert evidence of Professor Leach, support our conclusion that the products are within the exclusion.
11. Accordingly, for these reasons the decision under review is affirmed.

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| I certify that the preceding 48 (forty-eight) paragraphs are a true copy of the reasons for the decision herein of The Hon. Brian Tamberlin, QC, Deputy President; and Professor G Johnston AM, Member. |

......[Sgd]........................................................

Associate

Dated 16 August 2012

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| Dates of hearing | **17 and 18 May 2012** |
| Counsel for the Applicant | **Mr M Vincent** |
| Solicitors for the Applicant | **Saunders & Saunders Legal**  |
| Counsel for the Respondent | **Dr J Renwick SC**  |
| Solicitor for the Respondent | **Australian Government Solicitor** |
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