

Complaint to TGA: Evolution Health, Liver Support Probiotic

Acknowledgement:

This complaint was stimulated by Monash University WAM Thursday 2 pm Group 1; worked up by Mal Vickers, then edited and submitted by Assoc Prof Ken Harvey.

Summary:

We allege this is a “high priority” complaint because eight justified CRP determinations have been published for Evolution Health Pty Ltd; five concerning their probiotic products.

Probiotics are defined by the WHO as, “live microorganisms, which, when administered in adequate amounts, confer a health benefit on the host”.

Whether probiotic supplementation benefits healthy individuals is questionable. The evidence is limited and inconsistent. Despite this, Evolution Health promote this product (which also contains choline) to the broad consumer market. They claim, “Based on scientific evidence, health benefits **may** include supporting liver health, assisting the metabolism of fat and assisting in the maintenance of healthy liver function”.

We could find no good scientific evidence to support these claims for the ingredients contained in this product.

We note that this product was listed on the ARTG on 3 April 2018 and the Therapeutic Goods (Permissible Indications) Determination No.1 of 2018 applies. Thus, the qualifier “**may**” is not allowed and the claims become absolute statements requiring scientific evidence.

In addition, the indication / claim, “Assisting in the metabolism of fat” was not found in the Permissible Indications or in the ARTG Public Summary.

Accordingly, we allege the advertising for Evolution Health, Liver Support Probiotic (ARTG ID: 301556) breaches the Therapeutic Goods Act 1989, s. 22(5) and the Therapeutic Goods Advertising Code, sections: 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(d).

Claims:

- Based on scientific evidence
- Supporting liver health
- Assisting in the metabolism of fat
- Assisting in the maintenance of healthy liver function
- A premium, targeted probiotic formula containing 5 strains of beneficial bacteria combined with Choline to support the health and function of the liver.

Complaint detail:

Product name: Life Space Liver Support Probiotic; ARTG ID: 301556

Sponsor: Evolution Health Pty Ltd

Sponsor Address: 6 McArthur Street, West Footscray, Vic, 3012

ARTG Start Date: 3/04/2018

Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support healthy digestive system function
- Maintain/support digestive system health
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support gastrointestinal system health
- Maintain/support healthy gastrointestinal function
- Maintain/support healthy liver function
- Maintain/support liver health

Complaint to TGA: Evolution Health, Liver Support Probiotic

- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Warnings

- No Warnings included on Record

Advertisement type: Internet

Where did it appear?

- <https://www.lifespaceprobiotics.com/product/liver-support-probiotic/>
- <https://www.chemistwarehouse.com.au/buy/87319/life-space-liver-health-probiotic-60-capsules>
- <https://www.bodyandsoul.com.au/feature/special-features/why-you-need-to-give-your-liver-some-love/news-story/1fed9a28d0f03ea58e92ce9fb6280df1>
- <https://www.superpharmacy.com.au/products/life-space-liver-support-probiotic-60-capsules>
- Etc

Date seen: 4 December 2018

Claims disputed and rationale:

Probiotics and the liver

A search of the medical and scientific literature was performed in relation to the health of the liver and probiotics.¹ Most human studies involved populations with morbidity or disease² and were not relevant to a normal healthy consumer considering the purchase of Liver Support Probiotic.

A 2018 review of 45 studies titled, “Probiotic supplementation in healthy adults: helpful or hype?” failed to support the ability of probiotics to cause persistent changes in gut microbiota or improve lipid profile in healthy adults. “Liver health” was not mentioned. The review concluded that the feasibility of probiotics consumption to provide benefits in healthy adults requires further investigation.³

See also, “Health Check: should healthy people take probiotic supplements?”⁴ and “Why we may be gambling our guts on probiotics”.⁵

It should also be noted that consumption of probiotics is not without risk; albeit rare and usually occurring in immunocompromised patients. A review of the safety of probiotics by Sanders et al concluded, “it is paramount that it is recognized that a general conclusion that “probiotics are safe” cannot be broadly made”.⁶ We suggest a safety warning should be considered by the TGA on probiotic products.

¹ <https://www.ncbi.nlm.nih.gov/pubmed?term=probiotic+supplementation+liver>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4323444/>

³ <https://www.ncbi.nlm.nih.gov/pubmed/29581563>

⁴ <https://theconversation.com/health-check-should-healthy-people-take-probiotic-supplements-95861>

⁵ <https://www.smh.com.au/lifestyle/health-and-wellness/why-we-may-be-gambling-our-guts-on-probiotics-20181023-p50bfc.html>

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3023597/>

Complaint to TGA: Evolution Health, Liver Support Probiotic

Choline and the liver

Choline is an essential nutrient related to the water-soluble B-complex vitamins, folate, pyridoxine, and B12, and to the essential amino acid methionine.⁷ Choline is widely distributed throughout the food supply, mostly in the form of phosphatidylcholine in membranes. Milk, liver, eggs and peanuts are particularly good sources of choline for the general population with wheat germ and dried soybeans good sources for vegetarians.⁸

A search of the medical and scientific literature was performed in relation to choline and the liver.⁹ Many studies were found which investigated choline supplementation in various diseases. However, we found no studies that investigated the effects of supplementation of choline on liver function in healthy participants.

Contact with the sponsor:

Contact with Evolution Health Pty Ltd was made by phone call on 30 November 2018 using the contact number 03 9828 9400 provided on their website.¹⁰ A representative of Evolution Health Pty Ltd undertook to provide details of the studies that supported their claims. An email address was provided.

On the 14 December 2018 an email was received from Lee Doyle, Consumer Care Naturopath at Evolution Health Pty Ltd. The email explained that the company had no legal obligation to provide information to consumers and would only provide information to the TGA under the appropriate regulatory processes.

Identification of previous complaints

A search of the CRP complaint register found that no previous complaint has been made about Liver Support Probiotic (ARTG 301556).

However, Evolution Health Pty Ltd has been named as a respondent company in eight previous CRP determinations (Appendix I). The eight CRP determinations list 65 previous breaches of the advertising Codes and Regulations.

Conclusion:

We allege the advertising for Liver Support Probiotic (ARTG ID: 301556) breaches the Therapeutic Goods Act 1989, s. 22(5) and the Therapeutic Goods Advertising Code, sections: 4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(d).

Dr Ken Harvey MBBS, FRCPA, AM Associate Professor
Department of Epidemiology and Preventive Medicine
School of Public Health and Preventive Medicine

Monash University Alfred Campus 553 St Kilda Rd
Melbourne VIC 3004
Mobile: +61 419181910

Email: kenneth.harvey@monash.edu
WWW: www.medreach.com.au

5 December 2018

⁷ <https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements/professional.aspx?productid=436>

⁸ <https://www.nrv.gov.au/nutrients/choline>

⁹ <https://www.ncbi.nlm.nih.gov/pubmed/?term=choline+supplementation+liver>

¹⁰ <https://www.lifespaceprobiotics.com/contact/>

Complaint to TGA: Evolution Health, Liver Support Probiotic

Screenshot 1: <https://www.lifespaceprobiotics.com/product/liver-support-probiotic/> (Accessed on 29/11/2018)



life-space™

Sale!



Liver Support Probiotic

A premium, targeted probiotic formula containing 5 strains of beneficial bacteria combined with Choline to support the health and function of the liver.

Based on scientific evidence, health benefits may include:

- Supporting liver health.
- Assisting the metabolism of fat.
- Assisting in the maintenance of healthy liver function.

Always read the label. Use only as directed.

~~AUD \$41.99~~ **AUD \$32.99**
inc. GST

Complaint to TGA: Evolution Health, Liver Support Probiotic

Screenshot 2: <https://www.lifespaceprobiotics.com/product/liver-support-probiotic/> (Accessed on 29/11/2018)

Ingredients

EACH VEGE-CAPSULE CONTAINS 6 BILLION CFU

<i>B. lactis</i> BI-04	2.0 Billion
<i>B. longum</i> BB536	2.0 Billion
<i>L. plantarum</i> CECT 7527	666 Million
<i>L. plantarum</i> CECT 7528	666 Million
<i>L. plantarum</i> CECT 7529	666 Million
Choline (from choline bitartrate 200.56 mg)	82.5mg

L. = Lactobacillus B. = Bifidobacterium CFU = Colony Forming Unit

Screenshot 3 <https://www.chemistwarehouse.com.au/buy/87319/life-space-liver%2%A0support%2%A0probiotic-60-capsules> (05/11/2018)

Chemist Warehouse WE BEAT EVERYONE'S PRICES AUSTRALIA'S CHEAPEST CHEMIST

Search for Products / Brands **SEARCH**

Frangrances Vitamins Beauty Skin Care Cosmetics Weight Loss Baby Care Sexual Health Quit Smoking Clearance
Prescriptions Medicines Cold & Flu Krill & Fish Oil Dental Household Hair Care Protein Best Sellers All Categories

FREE SHIPPING OVER \$99* \$50* AUSTRALIA'S #1 ONLINE PHARMACY LOWEST PRICE GUARANTEED

Home / Health / Vitamins / LifeSpace / LifeSpace 12 - 80 years

Love your liver **NEW** **1/2 PRICE**

Life Space Liver Support Probiotic 60 Capsules
Product ID: 87319
***** Write a review
\$19.99
SAVE \$22.00
Don't Pay RRP: \$41.99
QTY: 1 **ADD TO CART**

General Information
Life-Space Liver Support Probiotic Capsules have 5 multi-strain formula.
A premium, targeted probiotic formula containing 5 strains of beneficial bacteria combined with Choline to support the health and function of the liver.
Based on scientific evidence, health benefits may include:
- Supporting liver health.
- Assisting the metabolism of fat.
- Assisting in the maintenance of healthy liver function.

HO! HO! HO! HOW LOW CAN WE GO? CHRISTMAS CATALOGUE OUT NOW!
30th Sept. 30th December 2018
FREE SHIPPING ON ALL FRAGRANCE ORDERS No Minimum Spend!
Shop Now

GO healthy 1/2 PRICE OFFERS ENTIRE RANGE!

NEW **1/2 PRICE OFFERS ENTIRE RANGE!**

NEW **1/2 PRICE OFFERS ENTIRE RANGE!**

life-space Your probiotic specialists
Always read the label. Use only as directed.

A targeted probiotic product with added choline to support liver health and help with the metabolism of fat.

Complaint to TGA: Evolution Health, Liver Support Probiotic

Appendix I

CRP ID	Product	Respondent/s	Reg & Code Breaches	URL
2013/01/027	Healthy Essentials Probiotic 6	Evolution Health Pty Ltd, Alive Australian Publishing Pty Ltd	42C, 6(4)	http://www.tgacrp.com.au/complaint-register/?_id=2238
2014/05/004	NZ Mussel Oil	Evolution Health Pty Ltd	4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(4), 4(5), 6(3)	http://www.tgacrp.com.au/complaint-register/?_id=2568
2014/06/012	Elmore Oil	Evolution Health Pty Ltd	22(5), 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(h), 4(4), 4(7), 4(8), 5(2)	http://www.tgacrp.com.au/complaint-register/?_id=2585
2014/12/008	Life Space Probiotics	Evolution Health Pty Ltd	42DL(1)(c), 4(1)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(2)(d), 4(2)(e), 4(2)(i), 4(4), 5(2), 6(3)	http://www.tgacrp.com.au/complaint-register/?_id=2764
2015/04/004	Life Space 100 Billion Powder Probiotic	Pittwater Pharmacy; Evolution Health Pty Ltd	22(5), 4(1)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(4), 4(6)(b), 5(2), 6(3)	http://www.tgacrp.com.au/complaint-register/?_id=2859
2016/08/025	Life Space Probiotics	Evolution Health Pty Ltd; Sigma Pharmaceuticals Limited	22(5), 42DL(1)(c), 42DL(1)(f), 4(1)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(2)(d), 4(2)(e), 4(2)(g), 4(2)(h), 4(4), 4(7), 5(2), 6(3)	http://www.tgacrp.com.au/complaint-register/?_id=3080
2016/10/004	Lifespace Probiotics - Chemist Warehouse	Evolution Health Pty Ltd; Chemist Warehouse	4(2)(a), 4(2)(c), 4(2)(d), 4(5), 6(3)(c), 6(3)(d)	http://www.tgacrp.com.au/complaint-register/?_id=3134
2016/11/016	Inflacure	Evolution Health Pty Ltd T/A Healthy Essentials	4(2)(a), 4(2)(c), 4(2)(d), 4(2)(g), 6(3)(c), 6(3)(d)	http://www.tgacrp.com.au/complaint-register/?_id=3180