Complaint to TGA: Nature's Care CoEnzyme Q10

Acknowledgement:

This complaint was worked up by the Monash University BMS3052 WAM Wednesday 11am student group 7; then edited, checked by Mal Vickers and submitted by Assoc Prof Ken Harvey.

Summary:

Coenzyme Q10 plays a central role in mitochondrial oxidative phosphorylation and the production of adenosine triphosphate (ATP). It also functions as an antioxidant in cell membranes and lipoproteins.

Except for rare genetic disorders, CoQ10 deficiency has not been described in the general population. It is assumed that normal biosynthesis, with or without a varied diet, provides enough CoQ10 to sustain energy production in healthy individuals.

The fundamental problem with the promotion of these products is that advertisers extrapolate from CoQ10's important role in the body, and possible role as adjunctive therapy in heart failure and myocardial reperfusion injury, to making implied claims that taking this product as a supplement will benefit normal healthy people.

This is a common logical fallacy employed by the complementary medicine industry to mislead the public and arouse unwarranted expectations of product effectiveness.

The Therapeutic Goods Advertising Complaint Resolution Panel (CRP) determination 2012/06/006 (Pharmalife CoQ10 Capsules) has addressed this issue (appended).

Accordingly, we allege that advertisements for Nature's Care Co-enzyme Q10 products breach the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(c) for claims 1-5 (below) because evidence to support these claims is lacking. We also allege a breach of s.7(2) of the Code because CoQ10 is a vitamin-like co-enzyme, s.7(2) applies, but the required caveat is lacking. Finally, for claim 6 (below) we allege a breach of the Therapeutic Goods Act 1989 s.22(5) because this indication is not found in the ARTG Public Summary documents for these products.

Claims:

1. Supports heart health. Maintains healthy heart tissue. Assists in the maintenance of a healthy cardiovascular system.
2. Supports production of energy in muscles. Assists muscle function and improve stamina and endurance. Boosts energy production (and levels). Improves oxygen capacity in athletes & the physically active for improved performance & energy.
3. May alleviate symptoms of fatigue, particularly when experienced with ageing. There may be an increased need for supplemental CoQ10 in elderly due to the body's ability to synthesise CoQ10 decreasing with age.
4. Potent antioxidant and powerful free radical scavenger.
5. Assists in the maintenance of normal cholesterol in healthy individuals.
6. Assists in maintenance of a healthy immune system.

Advertisement type: Internet

Where did it appear:

- http://healthycare.com.au/our-products/heart-health/item/hc-coenzyme-q10-150mg-100-capsules?category_id=69
- https://www.chemistwarehouse.com.au/Buy/67884/Healthy-Care-CoEnzyme-Q10-150mg-100-Capsules
- http://healthycare.com.au/our-products/heart-health/item/hc-coenzyme-q10-50mg-200-capsules?category_id=69
- https://www.chemistwarehouse.com.au/Buy/55034/Healthy-Care-CoEnzyme-Q10-50mg-200-

Capsules
- http://www.vitamore.com.au/products/functional/item/coenzyme-q10-150mg-30-capsules
- https://www.pharmacyonline.com.au/healthy-care-coenzyme-q10-150mg-cap-x-100
- https://natonic.com.au/en/healthy-care-coenzyme-q10-150mg-100-capsules
- https://www.westfield.com.au/products/chemist-warehouse/healthy-care-coenzyme-q10-150mg-100-capsules/515350a3-7761-4a17-b4f4-d96be938efc0
- http://www.epharmacy.com.au/product.asp?id=67884&pname=Healthy+Care+CoEnzyme+Q10+150mg+100+Capsules
- Etc.

Date seen: November 3, 2018

Products:

1. Healthy Care CoEnzyme Q10 150mg Capsules; ARTG ID: 202327
   Sponsor: Nature's Care Manufacture Pty Limited
   Active ingredients: ubidecarenone -150 mg
   ARTG Start Date 26/10/2012; Effective date 3/10/2018
   Permitted indications:
   - Antioxidant/Reduce free radicals formed in the body
   - Helps reduce/decrease free radical damage to body cells
   - Enhance/promote energy levels
   - Maintain/support energy levels
   - Maintain/support heat/energy production/thermogenesis
   - Maintain/support general health and wellbeing
   - Helps in the maintenance of healthy blood lipids/blood fats
   - Maintain/support cardiovascular system health
   - Maintain/support healthy cardiovascular system function
   - Maintain/support heart health
   - Helps enhance/improve/promote/increase physical/exercise performance
2. Healthy Care CoEnzyme Q10 50mg Capsules; ARTG ID: 154474
   Sponsor: Nature's Care Manufacture Pty Limited
   Active ingredients: ubidecarenone -50 mg
   ARTG Start Date 11/08/2008; Effective date 3/10/2018
   Permitted indications:
   - As above
3. Healthy Care CoEnzyme Q10 150mg Capsules; ARTG ID: 211675
   Sponsor: Nature's Care Manufacture Pty Limited
   Active ingredients: ubidecarenone -150 mg
   ARTG Start Date 2/07/2013; Effective date 3/10/2018
   Permitted indications:
   - As above
4. Vitamore CoEnzyme Q10 150mg Capsules ARTG ID: 199446
   Sponsor: Nature's Care Manufacture Pty Limited
   Active ingredients: ubidecarenone -150 mg
   ARTG Start Date 19/07/2012; Effective date 3/10/2018
   Permitted indications:
   - As above

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Screen shots:

http://healthycare.com.au/our-products/heart-health/item/hc-coenzyme-q10-150mg-100-capsules?category_id=69

http://healthycare.com.au/our-products/heart-health/item/hc-coenzyme-q10-50mg-200-capsules?category_id=69

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CoEnzyme Q10 150mg

Functional

30 Capsules

3.5/5 rating (2 votes)

Product Description

The heart is one of the most active tissues in the body that requires an adequate supply of CoEnzyme Q10 (CoQ10) for heart health. CoQ10, also known as ubiquinone, is produced naturally in the body as a powerful antioxidant and free radical scavenger. A high concentration of Q10 is found in human heart, kidney and liver, which plays an essential role in the production of energy in cells. CoQ10 also acts as an antioxidant to protect cell membranes from free radical damage and strengthen the body's antioxidant protection.

Supplementation of CoQ10 may help to support cardiovascular health, energy levels and assist in recovery following exercise. There may be an increased need for supplemental CoQ10 in elderly due to the body's ability to synthesise CoQ10 decreasing with age.

Specifications

- **Benefits:**
  - Supports heart health.
  - Supports production of energy in muscles.
  - Maintains healthy heart tissue.
  - Assists in the maintenance of a healthy cardiovascular system.
  - Boosts energy levels.
  - Potent antioxidant and powerful free radical scavenger.
  - Assists in the maintenance of normal cholesterol.
  - Improves oxygen capacity in athletes and physically active individuals for improved performance & energy.
  - May alleviate symptoms of fatigue, particularly when experienced with ageing.

http://www.vitamore.com.au/products/functional/item/coenzyme-q10-150mg-30-capsules

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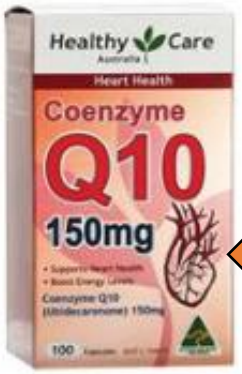

Healthy Care CoEnzyme Q10 150mg 100 Capsules

Product ID: 67884

★★★★★ 4.8 (13) Write a review

$25.99

SAVE $7.00

WAS: $32.99

QTY 1

ADD TO CART

General Information

Ubidecarenone (Coenzyme Q10) 150mg

Supports heart health.
Supports production of energy in muscles.
Maintains healthy heart tissue.
Assists in the maintenance of a healthy cardiovascular system.
Boosts energy levels.
Potent antioxidant.
May assist in the maintenance of normal cholesterol levels in healthy individuals.
Improves oxygen capacity in athletes & the physically active for improved performance & energy.
May alleviate symptoms of fatigue, particularly when experienced with ageing. CoQ10 levels naturally decrease with age.

ADDED BENEFITS:

Protects from free radical damage.

https://www.chemistwarehouse.com.au/Buy/67884/Healthy-Care-CoEnzyme-Q10-150mg-100-Capsules

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Claims disputed and rationale:

1. ***Supports heart health. Maintains healthy heart tissue. Assists in the maintenance of a healthy cardiovascular system.*** *The heart is one of the most active tissues in the body that requires an adequate supply of CoQ10 for heart health*.

   Zhou et al. (2005) conducted an RCT using **six healthy males** (mean age of 29.7 years) who were treated with 150mg CoQ10 for two weeks to **assess its potential effects on cardiovascular function**, as measured by participants VO2 max.[1] This parameter determines the maximum amount of oxygen required during exercise and is a good indicator of heart health. Participants had blood samples taken prior to and post high endurance exercise. These results were then statistically analyzed. No significant improvement in VO2 max was found after two weeks supplementation.

   A Cochrane review, (Flowers et al., 2014), evaluated the effect of CoQ10 supplementation for the **primary prevention of cardiovascular disease (CVD)**.[2]

   The review included trials administering CoQ10 as a single supplement in healthy adults, or those at high risk of CVD (but without a diagnosis of CVD), and assessed cardiovascular events or major CVD risk factors, such as blood pressure and lipid levels.

   They found six completed randomised controlled trials with a total of 218 participants randomised. All were conducted in participants at high risk of CVD. Two examined CoQ10 supplementation alone and four examined CoQ10 supplementation in patients on statin therapy.

   The trials were small and short-term, none measured cardiovascular events or adverse events, and two of the six trials were regarded as being at high risk of bias. Only a few small trials contributed to the analyses and ***no conclusions could be drawn***.

   Another Cochrane review (Ho et al, 2016) reviewed the **blood pressure lowering efficacy of coenzyme Q10 for primary hypertension**.[3] This review provided moderate-quality evidence that coenzyme Q10 **does not have a clinically significant effect on blood pressure.** In one of three trials reporting adverse effects, coenzyme Q10 was well tolerated. Due to the small number of individuals and studies available for analysis, more well-conducted trials are needed.

   References cited by other sponsors to support similar claims included:

   - Alehagen et al. (2015) which studied the ***combination of selenium and CoQ10 on cardiovascular mortality*** (KiSel-10 intervention study) over 4-years in an elderly selenium-deficient Swedish population.[4] This study was judged irrelevant due to combination therapy.
   - ***A Health Canada Monograph on CoQ10*** that cited studies in ***heart failure and protection of myocardial reperfusion injury*** (Rosenfeldt et al. 2007; Baggio et al. 1994; Langstone et al. 1988).[5] Also judged irrelevant to primary prevention in healthy people.
   - Shah et al. (2007) who found that one 50 mg dose of CoQ10 ***had no effect on ECG variable***s in 26 young health volunteers and exhibited only mild and transient effect on systolic blood pressure.[6]

   Another Cochrane review (Madmani ME, et al., 2014) looked at trials that assessed the beneficial

[1] https://www.ncbi.nlm.nih.gov/pubmed/16230985
[2] https://www.ncbi.nlm.nih.gov/pubmed/25474484
[3] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007435.pub3/full
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4666408/
[5] http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=ubiquinol&lang=eng
[6] https://www.ncbi.nlm.nih.gov/pubmed/17341532

and harmful effects of ***coenzyme Q10 in patients with heart failure***.[7] No conclusions could be drawn on the benefits or harms of coenzyme Q10 in heart failure as trials published to date lacked information on clinically relevant endpoints.

Furthermore, existing data were derived from small, heterogeneous trials that concentrated on physiological measures; their results are inconclusive. Until further evidence emerges to support the use of coenzyme Q10 in heart failure, the authors concluded there might be a need to re-evaluate whether further trials testing coenzyme Q10 in heart failure are desirable.

A more recent meta-analysis of the efficacy of ***coenzyme Q10 in patients with cardiac failure*** was performed by Lei and Liu (2017).[8] Compared with the meta-analysis published by Madmani in 2014 (above), the authors included 14 additional clinical investigations and 2149 more participants than in the previous meta-analysis. They also assessed the efficacy of coenzyme Q10 in the endpoints of mortality and NYHA classification.

They found that in patients with heart failure, the administration of coenzyme Q10 resulted in lower mortality and improved exercise capacity compared with the effects of placebo treatment. However, no significant difference was found between coenzyme Q10 and placebo in the endpoints of left heart ejection fraction and New York Heart Association (NYHA) cardiac function classification. They noted several limitations in their meta-analysis and concluded that more rigorous, large-sample, international trials were needed to confirm their results.

Another sponsor Gao L et al. (2012). '***Effects of coenzyme Q10 on vascular endothelial function in humans***: a meta-analysis of randomized controlled trials'. Atherosclerosis, 221: 311-316, was cited by another sponsor as supporting the effect of CoQ10 on the cardiovascular system.[9]

The authors noted that the effect of oral CoQ10 supplementation on endothelial function in patients with coronary artery disease, heart failure and diabetes mellitus had been investigated by many studies. However, the results of these studies were inconsistent, and the sample sizes were relatively small. As a result, the precise effect of CoQ10 supplementation on endothelial function has not been established.

They reviewed 5 studies involving 194 participants of whom 97 were randomly allocated to CoQ10 therapy and 97 to control. They noted that 44.3% of participants had diabetes, 34.5% had hypertension, and 27.8% had established coronary artery disease. They found that CoQ10 supplementation was associated with significant improvement in flow-dependent endothelial-mediated dilation (FMD), a functional parameter commonly used as a biomarker of vascular function.

The results were not broken down into participants with or without pre-existing disease so the relevance of this surrogate measure to a normal patient population is uncertain.

The authors concluded that to what extent CoQ10-mediated improvement in endothelial function is causally related to a reduction in cardiovascular events can only be determined by large, long-term randomized trials on clinical endpoints.

Taking all the above into account, we dispute the implied claim that taking supplementary CoQ10 in people without cardiovascular disease supports heart health, maintains healthy heart tissue and assists in the maintenance of a healthy cardiovascular system.

We allege this claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a) & 4(2)(c).

[7] https://www.ncbi.nlm.nih.gov/pubmed/24049047
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5525208/
[9] https://www.ncbi.nlm.nih.gov/pubmed/22088605

2. ***Supports production of energy in muscles. Assists muscle function and improve stamina and endurance. Boosts energy production (and levels). Improves oxygen capacity in athletes & the physically active for improved performance & energy.***

   Rosenfeldt et al. (2003) identified eleven studies published from 1990 to 1997, in which CoQ10 was tested for an effect on exercise capacity; six were positive and five showed no effect.

   Of the six positive trials, four were in trained sports persons, athletes, cyclists and skiers, and two involved untrained individuals. Subjects (n = 18 to 28 per study) were given CoQ10, 90 to 100 mg per day for 4 to 8 weeks. Benefits were observed in terms of improved maximum oxygen consumption, averaging 8% (range 3% to 18%) and improved exercise capacity, averaging 13% (range 5% to 33%).

   Five trials failed to show any statistically significant benefit of CoQ10. Four of these were in trained sports persons and one in untrained individuals. Trials included 10 to 19 subjects and the duration of treatment was four to eight weeks. Dosage and duration of therapy were similar in the two groups of studies.

   Whereas all the negative studies were published in peer-reviewed journals, only one of the six positive studies were published in this way, the other five being published as conference proceedings, probably not peer-reviewed and therefore carried less weight.

   The authors concluded that a modest improvement in exercise capacity may be observed with CoQ10 supplementation, but this is not a consistent finding. Inconsistencies in trial results may be due to small numbers of subjects enrolled and to differences in experimental design. Further larger randomised trials were indicated.[10]

   Mizuno et al. (2008) examined the effects of coenzyme Q10 administration on physical fatigue.[11] In a double-blinded, placebo-controlled, crossover design, 17 healthy Japanese volunteers were randomized to oral coenzyme Q10 (100 or 300 mg/d) or placebo administration for 8 days.

   As a fatigue-inducing physical task, subjects performed workload trials on a bicycle ergometer at fixed workloads twice for 2 h and then rested for 4 h. During the physical tasks, subjects performed non-workload trials with maximum velocity for 10 s at 30 min (30-min trial) after the start of physical tasks and 30 min before the end of the tasks (210-min trial).

   Following supplementation, mean systolic blood pressure, diastolic blood pressure, and heart rate in the coenzyme Q10–administered groups did not differ from those in the placebo group. There was no significant difference in the maximum velocities achieved at the 30-min and 210-min trials in the two arms of the trial. However, a change in maximum velocity from the 30- to the 210-min trial in the 300-mg coenzyme Q10–administered group was higher than that in the placebo group.

   The authors noted that to generalize these results, studies involving larger numbers of subjects and a variety of administration doses and time schedules were required.

   Cook et al. (2008) investigated whether acute (single dose) and/or chronic (14-days) supplementation of CoQ10 would improve exercise performance in 22 aerobically trained and 19 untrained male and female subjects.[12] Subjects were given 200 mg of the placebo or the CoQ10 supplement. Sixty minutes following supplement ingestion, subjects completed an isokinetic knee extension endurance test, a 30-second Wingate anaerobic capacity test, and a maximal cardiopulmonary graded exercise test interspersed with 30-minutes of recovery.

   In this study, both acute and chronic CoQ10 supplementation had no significant effect of indices

[10] https://www.ncbi.nlm.nih.gov/pubmed/14695924
[11] https://www.ncbi.nlm.nih.gov/pubmed/18272335
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2315638/

of muscle endurance and anaerobic capacity as determined by an isokinetic 50-repetition test and a 30-second Wingate anaerobic capacity test. Similarly, no significant differences were observed among groups in maximal oxygen uptake (VO2max) or ventilatory anaerobic threshold following CoQ10 supplementation. These findings were in accord with several previous studies which have also failed to demonstrate performance-enhancing effects in trained athletes and/or untrained individuals following CoQ10 supplementation.[13,14,15,16]

Based on the above, we allege this claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a) & 4(2)(c).

3. ***May alleviate symptoms of fatigue, particularly when experienced with ageing. There may be an increased need for supplemental CoQ10 in elderly due to the body's ability to synthesise CoQ10 decreasing with age.***

   There are inconsistencies with measurements of plasma levels of CoQ10 in individuals of different ages with varying levels of physical activity. Among young people, more physical activity may correlate with lower CoQ10 levels in plasma, but in older people, higher levels of physical activity are related to higher plasma levels of CoQ10. More physical activity in older people may thus negate any need for supplements of CoQ10.[17]

   Only rare cases of documented coenzyme Q10 deficiency with symptoms of weakness, fatigue, and seizures have been reported.[18] Thus it can be assumed that a varied diet and a normal in-vivo synthesis will supply enough CoQ10 to healthy individuals.[19]

   Small studies were found on the use of CoQ10 as a treatment for fatigue in patients with multiple sclerosis,[20] and chronic fatigue syndrome (in addition with NADH);[21] both concluded that larger and long-term follow-up studies were necessary to confirm any effect of CoQ10 in these conditions. A larger (n=103) Australian randomized, placebo-controlled trial determined if CoQ10 alleviated fatigue in the late-onset sequelae of poliomyelitis. A daily dose of 100 mg CoQ10 for 60 days was found to have no effect on fatigue.[22] In addition, these studies were not relevant to a healthy aging population.

   Conflicting results were found in two small double-blind placebo-controlled cross-over trials on the effect of CoQ10 supplementation on muscle fatigue in young health adults during bicycling exercise.[23,24] No effect was found on fatigue indices in a small randomized, double-blind, placebo-controlled trial of CoQ10 supplementation in obese subjects.[25]

   No studies were found on the effect of CoQ10 supplementation on fatigue in the elderly.

   In conclusion, the finding that CoQ10 levels decrease in the elderly does not appear to hold if they exercise (which is recommended because it produces a variety of health benefits). Also, the claim that CoQ10 supplementation may reduce fatigue in the elderly lacks an evidence base.

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[13] https://www.ncbi.nlm.nih.gov/pubmed/1844568
[14] https://www.ncbi.nlm.nih.gov/pubmed/8789577
[15] https://www.ncbi.nlm.nih.gov/pubmed/8550248
[16] https://www.ncbi.nlm.nih.gov/pubmed/9286743
[17] https://www.ncbi.nlm.nih.gov/pubmed/24384733
[18] https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements/professional.aspx?productid=938
[19] https://www.nature.com/articles/1600880
[20] https://www.ncbi.nlm.nih.gov/pubmed/25603363
[21] https://www.ncbi.nlm.nih.gov/pubmed/26212172
[22] https://www.ncbi.nlm.nih.gov/pubmed/26645517
[23] https://www.ncbi.nlm.nih.gov/pubmed/10333091
[24] https://www.ncbi.nlm.nih.gov/pubmed/18272335
[25] https://www.ncbi.nlm.nih.gov/pubmed/21370966

We allege this claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a) & 4(2)(c).

4. ***Potent antioxidant and powerful free radical scavenger. Q10 also acts as an antioxidant to protect cell membranes from free radical damage and strengthen the body's antioxidant protection.***

   This statement is in accord with scientific knowledge about the role of CoQ10 but provides no justification for its supplementation in healthy people.

   Current recommendations are that a healthy diet can provide all the antioxidants you need to fight free radical damage.[26,27]

   We allege this implied claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a) & 4(2)(c).

5. **Assists in the maintenance of normal cholesterol in healthy individuals.**

   Sunesen et al. (2001) noted that while the amount of CoQ10 in body plasma increased by 126% after 10 days of supplementation in 18 young, healthy volunteers (nine women, nine men), very-low-density-lipoprotein (VLDL), low-density-lipoprotein (LDL) and high-density-lipoprotein (HDL) levels did not statistically differ from baseline levels.[28]

   Similarly, Zhou et al. (2005) found no significant changes in lipid profile after CoQ10 supplementation for 2 weeks in six healthy young males.[1]

   Falah et al. (2018) investigated the effects of coenzyme Q10 supplementation on glycaemic control and markers of lipid profiles in diabetic haemodialysis patients (HD) in a randomized, double blind, placebo-controlled clinical trial of 60 patients.[29] They found that CoQ10 supplementation in diabetic HD patients for 12 weeks had beneficial effects on markers of insulin metabolism, but it did not affect fasting glucose, HbA1c and lipid profiles.

   Jorat et al. (2018) performed as systematic review and meta-analysis of randomized controlled trials on the effects of coenzyme Q10 supplementation on lipid profiles among patients with coronary artery disease.[30] They found that that CoQ10 supplementation significantly decreased total cholesterol and increased high-density lipoprotein ("good" cholesterol) but did not affect triglycerides or low-density lipoprotein ("bad" cholesterol) in patients with coronary artery disease.

   Zhang et al. 2018 investigated the effect of 24 weeks of 120 mg CoQ10 or placebo on CVD risk factors in 101 Chinese patients with dyslipidaemia.[31] On the 24th week, compared to placebo, CoQ10 supplementation modestly lowered blood pressure and reduced triglyceride and low-density lipoprotein cholesterol.

   In conclusion, CoQ10 could be considered as adjunct therapy in some patients with CVD poorly uncontrolled by conventional treatment. However, we dispute the implied claim that taking CoQ10as a supplement in healthy individuals assists in the maintenance of normal cholesterol (or the prevention of CVD).

   We allege this claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a) & 4(2)(c).

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[26] https://theconversation.com/health-check-the-untrue-story-of-antioxidants-vs-free-radicals-15920
[27] https://theconversation.com/what-are-antioxidants-and-are-they-truly-good-for-us-86062
[28] https://www.ncbi.nlm.nih.gov/pubmed/11305624
[29] https://www.ncbi.nlm.nih.gov/pubmed/30251010
[30] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6176512/
[31] https://www.ncbi.nlm.nih.gov/pubmed/29454678

6. **Assists in maintenance of a healthy immune system.**

   This claim is a breach of the Therapeutic Goods Act 1989 s.22(5) because this indication is not found in the ARTG Public Summary documents for these products.

Finally, we allege that as CoQ10 is a vitamin-like co-enzyme that s7(2) of the Code applies and that the absence of a statement to this effect is a breach of the Code.

Previous complaints:

Eight upheld complaints about Co10 products were found on the CRP web site, including one referred to the Secretary.[32] Typically, no outcome of the latter referral is available on the TGA web site.

CRP determination 2012/06/006 (Pharmalife CoQ10 Capsules) is especially relevant, para 29-33.

> 29. The Panel was generally satisfied that the active ingredient of the advertised product, co-enzyme Q10, was the subject of a range of research that supported a view that it could play a role in relation to heart health or cardiovascular health, heart function, ATP production, antioxidant effects, and some other aspects of human physiology. However, the Panel noted that for co-enzyme Q10 in the form of a supplement to offer clinically significant benefits in these respects, the consumer taking the supplement would need to have inadequate levels of co-enzyme Q10 in their diet and/or as a result of the natural production of co-enzyme Q10 in their bodies.
>
> 30. It appeared to the Panel that while some consumers do fall within this category, the ordinary and typical consumer viewing the advertisement would not necessarily derive any such benefits from co-enzyme Q10 supplementation at all, since an ordinary and typical consumer would most likely already obtain sufficient levels of co-enzyme Q10 through their diet or through the natural production of co-enzyme Q10 in the body.
>
> 31. The Panel was therefore satisfied that a primary question was whether the advertisement conveyed accurately and clearly that co-enzyme Q10 supplementation was only likely to offer the advertised benefits to that category of consumers with inadequate current levels of co-enzyme Q10, or whether it instead conveyed that any and all consumers would derive the advertised benefits through consumption of the advertised product.
>
> 32. The advertisement stated that "as you age, the naturally occurring levels of Coenzyme Q10 in your body declines, meaning energy is not as easily transported between the body's cells, resulting in a drop in your energy levels and endurance." In one sense, these words appeared to convey that some consumers would have a greater need for supplemental co-enzyme Q10 than others. However, it also implied that declining co-enzyme Q10 levels are always a result of ageing and will always have an appreciable effect on energy transfer between cells, energy levels, and endurance. The Panel was therefore satisfied that an ordinary and reasonable consumer would conclude that the claims about increased oxygen uptake, improved heart function, increased energy levels, muscle activity, reduced risk of cell damage, and other claims about the product's effects were true for any consumer, regardless of their current co-enzyme Q10 status.
>
> 33. The Panel was therefore satisfied that the representations had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code. These aspects of the complaint were therefore justified.

[32] http://www.tgacrp.com.au/complaint-register/?_search=Q10

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8 November 2018