

TGA-AHPRA-ACCC Complaint: Chemist Warehouse-Swisse-Voost AFL Grand Final Promotion

Summary

The Chemist Warehouse-Swisse-Voost AFL Grand Final Promotion distributed 110,000 cushions and sample packs to patrons attending last Saturday's Grand Final at the MCG and the AFL Grand Final Footy Show at the Rod Laver Arena. The packs contained a free sample of Swisse Ultiboost Magnesium tablets (60), and an exclusive offer (buy one, get one free) for the entire Voost range of complementary medicines including cranberry, glucosamine, fish oil, memory tablets and sleep tablets.

I submit that this Chemist Warehouse-Swisse promotion is irresponsible because it was distributed at public venues containing children of all ages. Patrons were encouraged to take the packs home. The container was not child-proof and had no information on the recommended upper limit of magnesium intake (as a supplement) for young children.

In my opinion, this promotion breached the Object of the Therapeutic Goods Advertising Code 2015 (the Code) and the spirit of s.4(8). The claims made on the product pack breached s.4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code. The promotion to children breached s.4(2)(j) of the Code. Furthermore, the Chemist Warehouse Voost Exclusive Offer (buy one, get one free) breached s.4(8) of the Code. I also submit that the pharmacist owners of Chemist Warehouse have breached s.133 of the National Law and Australian Consumer Law.

I ask the TGA, AHPRA and the ACCC to consult about this matter with a view to imposing suitable penalties. The Swisse product retails for \$20.99, 110,000 were distributed, this represents a retail value giveaway of \$2.31 million. I suggest this figure would make a suitable fine for the ACCC to impose.

The promotion:



In an Australian first, Chemist Warehouse (CW) is gearing up for a major promotion that will see the Pharmacy group place 100,000 seat cushions filled with premium product on all seats at the MCG ahead of this weekend's 2017 Toyota AFL Grand Final. The seat cushions will include a range of products from key suppliers along with exclusive grand final instore offers for all attendees.

Earlier this week, a whopping 180 vans delivered over 900 pallets of product to the iconic MCG. Dedicated Chemist Warehouse Group staff will face the huge task of delivering the seat cushions and setting up the bays ready for placing on every seat ahead of the hi-profile Saturday match. From 8.00 am today, 28 Sep, CW will see 300 staff and volunteers place 100,000 seat cushions, covering every MCG seat.

"This is unquestionably our biggest activation yet, and we are thrilled to be partnering with the AFL for the 2017 Toyota AFL Grand Final, one of Australia's most sought-after, and premiere sporting events," CW chief operating officer Mario Tascone said.

Additional CW staff will then go to Rod Laver Arena to set-up for the AFL Grand Final Footy Show, with a further 10,000 cushions. ¹

¹ <http://www.pharmacydaily.com.au/newsletters/pd-for-thu-28-sep-2017/68070>

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Chemist Warehouse CEO Mario Tascone distributing sample bags at the MCG on 28 September 2017.

<https://ajp.com.au/news/cwh-gains-prime-position-afl-grand-final/>



Contents of the sample bag

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The Swiss Magnesium free sample

EXCLUSIVE 2017 TOYOTA AFL GRAND FINAL OFFER

BUY ONE GET ONE FREE



ENTIRE VOOST RANGE



BUY ONE GET ONE FREE ON ANY VOOST PURCHASE IN STORE. 1 PER PERSON PER DAY. ONLY AVAILABLE AT CHEMIST WAREHOUSE STORES. OFFER EXPIRES 26/10/17.



The Chemist Warehouse Voost offer (buy one, get one free)

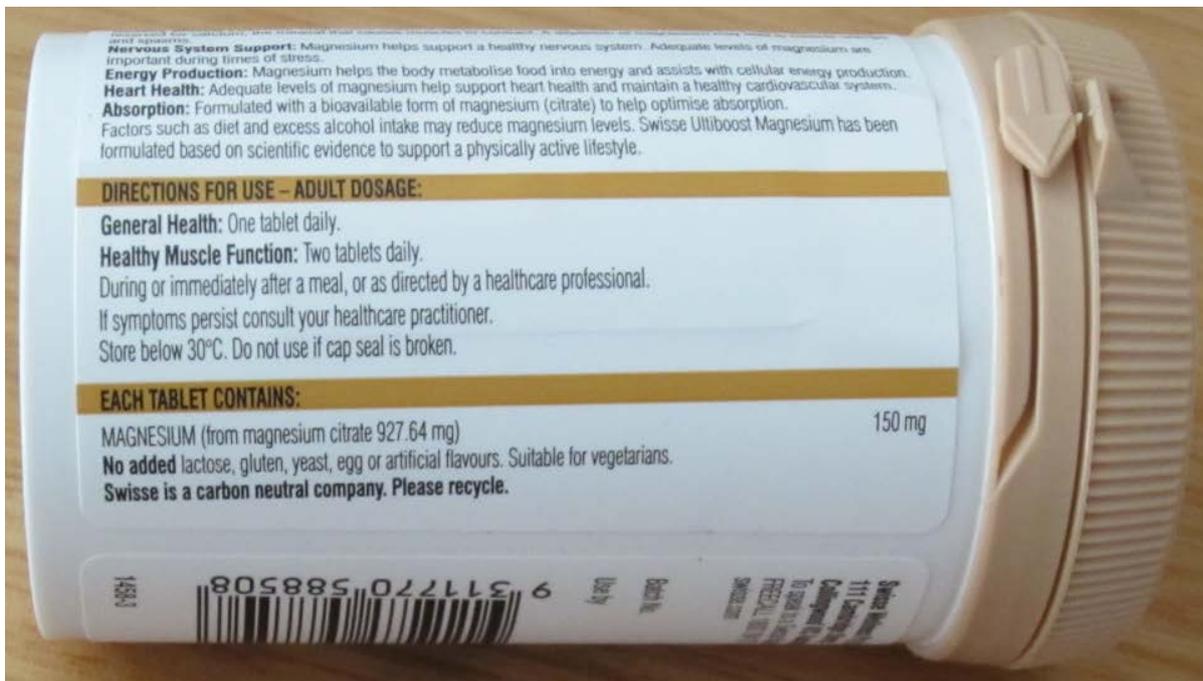
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The claims on the Swisse Ultiboost Magnesium pack (above & below):

- Supports healthy muscle function
- Provides nervous system support
- Assists energy production
- Based on scientific evidence
- Bone & Muscle Health
- Swisse Ultiboost Magnesium has been formulated based on scientific evidence to support a physically active lifestyle.

Directions for use – Adult Dosage -on the pack (below)

- General Health: One tablet daily.
- Healthy Muscle Function: Two tablets daily.
- During or immediately after a meal, or as directed by a healthcare professional.
- If symptoms persist consult your healthcare practitioner.
- Store below 30°C. Do not use if cap seal is broken.



The concerns

The Object of the Therapeutic Goods Advertising Code 2015 (the Code) is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer.²

This large-scale giveaway sends a poor message. Should therapeutic goods be given away to anyone without assessment? How are appropriate safety controls, such as protecting children from overdose, managed in such giveaways?

² <https://www.legislation.gov.au/Details/F2015L01787>

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The Chemist Warehouse promotional sample bag included a container of 60 Swisse Ultiboost Magnesium tablets, each containing 150 mg of magnesium from 927.64 mg of magnesium citrate (ARTG no: 21847).

I presume this complementary medicine was included because marketing people thought its claims to “support healthy muscle function, assist energy production, bone & muscle health” would resonate with the AFL Grand Final crowd watching elite footballers.

However, as detailed below these claims are only relevant if magnesium intake in the diet is grossly deficient. This is uncommon. Magnesium is widely distributed in the food supply in both plant and animal foods. Most green vegetables, legumes, peas, beans and nuts are rich in magnesium, as are some shellfish and spices. Most unrefined cereals are also reasonable sources.

Magnesium is a co-factor in more than 300 enzyme systems that regulate diverse biochemical reactions in the body, including protein synthesis, muscle and nerve function, blood glucose control, and blood pressure regulation. However, the human body can adapt to a wide range of magnesium intakes with absorption increasing if dietary levels are low and decreasing if dietary levels are high. The body contains about 760 mg of magnesium at birth and 25 g in adulthood. Just over half the body's magnesium is found in bone and a further third is found in muscles and soft tissues. The intracellular concentration is about ten times that of the extracellular fluid. Indicators used for estimating magnesium requirements have included serum magnesium, plasma ionised magnesium, intracellular magnesium, magnesium balance, estimates of tissue accretion in growth, magnesium tolerance tests and epidemiologic studies including meta-analysis.³

Defining magnesium deficiency is complex, in part because of the lack of available clinical tests for assessing total-body magnesium content. Currently, the serum magnesium concentration is the most clinically available test for assessing magnesium status but this test has not been properly validated as a reliable indicator of body magnesium status. For practical reasons, magnesium deficiency is defined as a serum concentration below the reference interval for the laboratory, but this is not necessarily related to a pathophysiologic state of deficiency. Plasma ionised magnesium may be an improvement on serum magnesium but requires further evaluation and the validity evidence for intracellular magnesium is limited.²

Pathological effects of primary nutritional deficiency of magnesium are rare in humans, unless low intakes are accompanied by prolonged diarrhoea or excessive urinary loss. The recommended upper limit of intake (as a supplement) for children 1-3 years is 65 mg/day, for 4-8 years is 110 mg/day and for children > 8 years and adults 350 mg/day.²

Hypermagnesemia is also rare because the kidneys excrete excess magnesium. However, the risk of magnesium toxicity increases with impaired renal function because the ability to remove excess magnesium is reduced or lost. Symptoms of magnesium toxicity can include hypotension, nausea, vomiting and lethargy before progressing to muscle weakness, difficulty breathing, irregular heartbeat and cardiac arrest.⁴

The promotional packs distributed by Chemist Warehouse containing a sample of 60 Swisse Ultiboost Magnesium tablets. They were distributed at venues containing children of all ages, many of whom may not have been closely supervised by their parents due to the excitement of the game. Patrons were encouraged to take the sample pack home. Many were seen collecting multiple discarded bags. The container was not child-proof and had no information on the recommended upper limit of magnesium intake (as a supplement) for young children (see above).

³ <https://www.nrv.gov.au/nutrients/magnesium>

⁴ <https://ods.od.nih.gov/factsheets/Magnesium-HealthProfessional/>

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I submit that the distribution of this sample is irresponsible and breaches the spirit of s.4(8) of the Code which states:

“An advertisement for therapeutic goods (other than therapeutic devices and sun screening preparations) must not contain an offer of a sample”.

Medicines (including complementary medicines) are not ordinary items of commerce and should not be treated as such with freebies and exclusive offers.

The claims on the product pack also breach s.4(1)(b), 4(2)(a), 4(2)(c) and 4(2)(f) of the Code as they cannot be substantiated for normal, healthy, people to whom they are directed. In addition, the promotion to children breach s.4(2)(j) of the Code. Furthermore, the Chemist Warehouse Voost Exclusive Offer (buy one, get one free), for their entire product range, including cranberry, glucosamine, fish oil, memory tablets and sleep tablets, breach s.4(8) of the Code.

Research concerning the Swisse claims:

First, the CRP Complaint register was searched for previous complaints. CRP 2015-07-023 Swisse Ultiboost Magnesium was found.⁵ Para 42 of this determination is relevant to the above claims:

“Moreover, the Panel did not find that the role played by magnesium within the body in a wide range of biological reactions meant that magnesium in supplemental form could be regarded as having specific therapeutic effects in healthy persons who were not deficient in magnesium.”

The following claims on the product pack, and the ARTG Public Summary document (attached), imply that magnesium supplementation in healthy people is beneficial:

- “Supports healthy muscle function”
- “Bone and muscle health”
- “Swisse Ultiboost Magnesium has been formulated based on scientific evidence to support a physically active lifestyle”
- “Assists energy production”,
- “General Health: One tablet daily. Healthy Muscle Function: Two tablets daily”.

These claims were reinforced by providing a free sample of Swisse Ultiboost Magnesium for 110,000 people attending the AFL Grand Final and the AFL Grand Final Footy Show.

A search of the scientific literature failed to substantiate these claims. The consensus from many studies is that on-going magnesium supplementation of physically active individuals, with adequate magnesium status, has not been shown to enhance physical performance or increase energy.^{6,7,8,9,10,11,12} Equally, the claim, “provides nervous system support” could not be substantiated for normal, healthy people, from a search of the scientific literature.

The U.S. federal government’s 2015-2020 Dietary Guidelines for Americans notes that:

“Nutritional needs should be met primarily from foods. ... Foods in nutrient-dense forms contain essential vitamins and minerals and also dietary fibre and other naturally occurring substances that may have positive health effects. In some cases, fortified foods and dietary supplements

⁵ http://www.tgacrp.com.au/complaint-register/?_search=magnesium&_id=2943

⁶ <https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements/professional.aspx?productid=998>

⁷ <https://www.ncbi.nlm.nih.gov/pubmed/9813870>

⁸ <https://www.ncbi.nlm.nih.gov/pubmed/1299490>

⁹ <https://www.ncbi.nlm.nih.gov/pubmed/17172008>

¹⁰ <https://www.ncbi.nlm.nih.gov/pubmed/11252079>

¹¹ <https://www.ncbi.nlm.nih.gov/pubmed/25945079>

¹² <http://ajcn.nutrition.org/content/100/3/974.long>

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may be useful in providing one or more nutrients that otherwise may be consumed in less-than-recommended amounts.¹³

There may be a place for magnesium supplementation in certain groups at risk of magnesium inadequacy, such as people with Crohn's disease, alcohol dependence, and older adults with chronic diseases, or who take medication that increase their risk of magnesium depletion.³ This is a medical decision, not a case for routine supplementation in normal, healthy people.

Conclusion:

I submit that the Chemist Warehouse-Swisse promotion breaches the Object of the Code and the spirit of s.4(8). In addition, the claims made on the product pack breach s.4(1)(b), 4(2)(a), 4(2)(c) 4(2)(f) and 4(2)(j) of the Code. Furthermore, the Chemist Warehouse Voost Exclusive Offer (buy one, get one free) breaches s.4(8) of the Code.

This promotion also raises the discrepancy between s.7(2) of the Code which relates to vitamins but not minerals; a matter which needs to be addressed in the forthcoming Code revision. In my opinion, a more definitive warning should be mandated by the Code for both vitamins and mineral supplements, e.g.

“Vitamin &/or mineral supplementation is no substitute for a balanced, healthy diet”.

Also, s.4(8) of the Code should be changed to, “must not contain or offer a sample”.

The promotion highlights the need for the TGA to address similar (and additional) unjustified claims on many ARTG Public Summary documents for magnesium; also claims on the Swiss web site¹⁴ (and many others).

Finally, the owners of Chemist Warehouse are Damien Michael Gance, Pharmacist, Registration number: PHA0000948460, and Mario Verrocchi, Pharmacist, Registration number: PHA0000960520, Principal place of practice: PRESTON, VIC, 3072.¹⁵ It can be argued that this promotion is in breach of s.133 (1)(b) of the National Law;¹⁶ also Australian Consumer Law.¹⁷

I ask the TGA, AHPRA and the ACCC to consult about this matter with a view to imposing suitable penalties. The Swisse product retails for \$20.99,¹⁴ 110,000 were distributed, thus this represents a retail value giveaway of \$2.31 million. I suggest this figure would make a suitable fine for the ACCC to impose.

Dr Ken Harvey AM
Associate Professor
School of Public Health and Preventive Medicine

Monash University
The Alfred Centre
99 Commercial Road
Melbourne VIC 3004
Mobile: +61 419181910
Email: kenneth.harvey@monash.edu
www.medreach.com.au

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¹³ <https://health.gov/dietaryguidelines/2015/guidelines/>

¹⁴ <https://swisse.com/en-au/products/vitamins-supplements/bones-joints-muscles/swisse-ultiboost-magnesium>

¹⁵ <https://ajp.com.au/news/chemist-warehouse-worth/>

¹⁶ [http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/f932b66241ecf1b7ca256e92000e23be/02566FDB9453A0CECA25768600149A94/\\$FILE/09-079a.pdf](http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/f932b66241ecf1b7ca256e92000e23be/02566FDB9453A0CECA25768600149A94/$FILE/09-079a.pdf)

¹⁷ <http://consumerlaw.gov.au/the-australian-consumer-law/>

Public Summary

Summary for ARTG Entry: 218472 Swisse Ultiboost Magnesium

ARTG entry for Medicine Listed
Sponsor Swisse Wellness Pty Ltd
Postal Address 111 Cambridge Street, Collingwood, VIC, 3066
 Australia
ARTG Start Date 12/12/2013
Product category Medicine
Status Active
Approval area Listed Medicines

Products

1. Swisse Ultiboost Magnesium

Product Type	Single Medicine Product	Effective date	18/08/2016
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Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Standard Indications

Specific Indications

Magnesium levels may be lower in women with PMS.
 Magnesium helps the body to metabolise carbohydrates and fats. Magnesium helps metabolise food into energy.
 Magnesium is involved in the production of cellular energy/may assist with/helps support cellular energy production.
 Magnesium helps support/assist/maintain healthy muscle function.
 Magnesium supports muscle relaxation by competitively binding to receptor sites normally reserved for calcium, which is the mineral that causes muscles to contract.
 A depletion of Magnesium, due to low dietary intake, may lead to muscle cramps and spasms/Magnesium supplementation may provide support for muscle cramps and spasms when dietary intake of magnesium is low.
 Calcium and magnesium work together to cause the contraction and relaxation of muscles.
 Magnesium supplementation may provide support for muscle cramps and spasms when dietary intake of magnesium is low/ Increased calcium and a depletion of magnesium, due to low dietary intake, may lead to muscle cramps.
 Magnesium helps support/maintain general health and wellbeing.
 Contains a form of bioavailable magnesium (citrate) to help magnesium absorption.
 Magnesium helps support a healthy nervous system/nervous system support.
 Adequate levels of magnesium are important during times of stress.
 Magnesium plays an important role in supporting adrenal health, the adrenal glands have a key role in the body's response to stress. Magnesium provides adrenal support during times of stress.
 Factors such as diet and excess alcohol intake may reduce magnesium levels
 Adequate levels of magnesium contribute to/help maintain a healthy cardiovascular system/help to support heart health/assists a healthy cardiovascular system.
 Magnesium plays a structural role in bones, it is also required for the transport of calcium across cell membranes.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Jar/Can	Not recorded				

Pack Size/Poison information

Pack Size	Poison Schedule
Components	
1. Formulation 1	
Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	
Active Ingredients	
Magnesium citrate	927.64 mg

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