

CRP 6-700

COMPLAINTS RESOLUTION PANEL DETERMINATION

Complaint 6-700 (Swisse Calverv)

The complaint

1. A complaint was made that an advertisement for Swisse Calverv published in the July 2000 issue of Woman's Weekly was misleading in that it represents that the product:-
 - treats osteoporosis;
 - is based on 100 clinical studies of the product; and
 - is supported by world leading scientists and research professors.
2. At its meeting on 18 October 2000, the Panel formed the view that the advertisement represented that, based on 100 clinical studies, Calverv calcium complex M3 helps prevent and treat osteoporosis. Pursuant to regulation 42ZCAE the Panel required the sponsor, Swisse Natural Health Care Pty Ltd, to produce to the Panel the evidence upon which it relies to support that claim. The Panel indicated that, in the absence of a satisfactory response, the Panel was minded to find the complaint justified and to request that the advertisement be withdrawn from further publication.
3. In response, the sponsor provided material which it described as "data pertaining to the nutrients in the Swisse Calverv Calcium Complex M3, that have been shown to assist in the treatment of osteoporosis." It noted that any reference to Calverv and the treatment of osteoporosis is made in the context of Calverv being one of the aids, and not the only aid.
4. The sponsor accepted that the statement "based on 100 clinical studies" may have been "misinterpreted as 100 clinical studies carried out directly on the Swisse Calverv, which is not the case. The formula for Swisse Calverv is based on secondary studies that Swisse has researched..." The sponsor indicated it had agreed, following an approach by CHC, to modify the term "100 clinical studies" to "based on the assessment of world wide research", with effect around February 2001.

Panel consideration

5. The material provided by the sponsor in support of the claim that, based on 100 clinical studies, Calverv calcium complex M3 helps prevent and treat osteoporosis, comprised an article on the effect of zinc on cartilage calcification¹; an article on the role of trace minerals in osteoporosis²; an article on the role of magnesium deficiency in primary postmenopausal

¹ Kirsch et al: "Regulatory Roles of Zinc in Matrix Vesicle-Mediated Mineralization of Growth Plate Cartilage", Journal of Bone and Mineral research, Vol. 15, No. 2, 261-270 (2000).

² Saltman et al: "The Role of Trace Minerals in Osteoporosis", Journal of the American College of Nutrition, Vol. 12, No. 4, 384-3889 (1993).

osteoporosis³ and an extract, under the heading "Osteoporosis", from an unidentified publication referring to various studies, some in humans and some in animals, of a range of vitamins and minerals. None of this material referred to Swisse Calverv and there was no information before the Panel as to the ingredients of that product.

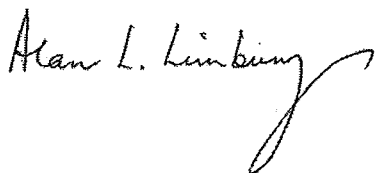
6. *Saltman et al.*² noted that the maintenance of optimal bone mineral density in postmenopausal women requires at least 1000mg/day of calcium and that copper, magnesium and zinc are essential in the development and maintenance of bone mineral density. There is no evidence before the Panel that Swisse Calverv contains any of these elements.
7. Leaving aside the reference to 100 clinical studies, which the sponsor admits were not done on Swisse Calverv, the sponsor has produced no evidence that Calverv calcium complex M3 helps prevent and treat osteoporosis. Accordingly the Panel finds the advertisement breaches clauses 4.1.1(b), 4.1.2(a) and 4.1.2.(c) of the Code and that the complaint is justified.

Sanctions

8. In accordance with subregulation 42ZCAI(1) of the Therapeutic Goods Regulations, the Panel requests Swisse Natural Health Care Pty Ltd:-
 - (a) to withdraw the advertisement from further publication; and
 - (b) within 14 days of being notified of this request, to provide evidence to the Panel of its compliance, such as copies of instructions to advertising agents or publishers.
9. Attention is drawn to the provisions of subregulations 42ZCAI(3) and (4) which permit the Panel to make recommendations to the Secretary in the event of non-compliance with this request, including a recommendation that the product be delisted. The sponsor is put on notice that, having regard to the number of complaints that have been upheld against it, namely 1-499(2), 8-399, 9-499, 15-699 and 1-900, and the sponsor's clear awareness of the requirements of the Regulations and the Code, the Panel is minded to recommend immediate delisting should the sponsor fail to comply with this request within the time specified.

Dated 24th November 2000

For the Panel



Alan L Limbury
Chairman

³ Abraham: "The Importance of Magnesium in the Management of Primary Postmenopausal Osteoporosis", J Nutr Med 2:165-78, 1991.