

COMPLAINTS RESOLUTION PANEL DETERMINATION

Complaint 1-900 (Bio-Gel and Bio-S)

The complaint

1. A complaint was made that an advertisement for Bio-Gel and Bio-S published in the October 2000 edition of Dolly Magazine was entirely misleading in claiming that *"tests show that when you combine H Bio-Juven Bio-G with another of the company's product called Bio-S tablets it can be more effective in clearing pimples than the acne drug tetracycline"*. The sponsor, Swisse Natural Health Care Pty Ltd, made no response. In a telephone conversation with the Panel Secretary on the day of the hearing of the complaint, a representative of the sponsor stated that the product Bio-Gel was not listed on the Australian Register of Therapeutic Goods because it is a cosmetic product.
2. The complainant relied on information provided in response to a request made to the sponsor for details of the tests. The complainant stated:-

"It would appear from the material provided to me that the company makes claims that it has clinically tested its product for efficacy as against an acne drug tetracycline, when in fact it is basing this claim on a totally unrelated clinical study on the effect of zinc effervescent tablets as against oxtetracycline".

Panel consideration

3. The advertisement in question is headed "Pimple and acne breakthrough" and states: *"There's good news for one of our biggest nightmares. The zit war! A breakthrough natural gel is proving successful in the treatment of acne and pimples. The product is called H Bio-Juven Bio-Gel (known as Bio-G in some countries). It provides relief from inflammation and reduces the visible signs of acne"*. By referring to the treatment of acne and pimples and the relief of inflammation, the sponsor has made claims of therapeutic use for the product and it is thus a therapeutic good, as defined in the Therapeutic Goods Act. Thus promoted, it may not be lawfully marketed unless listed or registered and advertisements for it must comply with the Regulations and the Code.
4. The advertisement also contains the statement of which complaint is made: *"tests show that when you combine H Bio-Juven Bio-G with another of the company's product called Bio-S tablets it can be more effective in clearing pimples than the acne drug tetracycline"*.
5. The material provided by the sponsor to the complainant in response to the request for details of the tests to which the advertisement referred comprised:-
 - a leaflet referring to double blind clinical studies as having shown that H Bio-Juven Plantolin Bio-G reduced inflammation and the visible signs of acne by up to 85%. A "leading pharmacist" was quoted as referring to the product as the best topical treatment, prescription or otherwise, currently available;
 - a study of oral zinc in severe acne;
 - a page (headed "Acne Vulgaris") of an unidentified publication; and
 - a sponsor's leaflet headed "Answers to the most frequently asked questions", in which Bio-G is referred to as having been clinically tested.

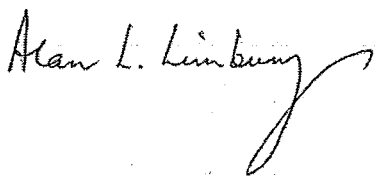
6. The Panel considers that none of the material put forward by the sponsor in response to the complainant's request for details of the tests mentioned in the advertisement establish that the products Bio-Gel and Bio-S have been clinically tested. The sponsor, many of whose advertisements have been found to have breached the Code and the Regulations in the past, and which consequently cannot assert ignorance of the applicable Code provisions or of the Regulations, had an opportunity to provide to the Panel evidence of clinical testing but declined to do so.
7. The Panel finds the advertisement to be in breach of clauses 4.1.1(b), 4.1.2(a) and 4.1.2(c) of the Code. Accordingly the Panel finds the complaint justified.
8. The Panel also notes that the advertisement appears also to be in breach of clauses 4.1.2(j) (in relation to Bio-S), 4.3 (in making comparison with tetracycline), 6.2(c) and 6.2(d) of the Code and Regulation 6(e) (in referring to the drug tetracycline). Further, the advertisement was published in association with another advertisement (for Swisse Student HD") which had an approval number. The advertisement for Bio-Gel and Bio-S had not been approved and did not have an approval number.

Sanctions

9. In accordance with subregulation 42ZCAI(1) of the Therapeutic Goods Regulations, the Panel requests Swisse Natural Health Care Pty Ltd:-
 - to withdraw the advertisement from further publication unless and until approval is obtained in accordance with the Regulations;
 - to publish in the next available issue of Dolly Magazine a retraction in the form and in accordance with the format requirements set out in the attachment to this determination; and
 - 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.
10. 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 listing of the goods be cancelled. The sponsor is put on notice that, should the sponsor fail to comply with this request within the time specified, the panel will have regard to the number of complaints that have been upheld against it, namely 1-499(2), 8-399, 9-499, 15-699 and 6-700 when deciding what recommendation to make to the Secretary.

Dated 24th November 2000

For the Panel



Alan L Limbury
Chairman

ATTACHMENT**Form****RETRACTION STATEMENT**

An advertisement in the October 2000 issue of Dolly Magazine for the two products H Bio-Juven Bio-G (also known as Bio-Gel), and Bio-S tablets has been found to be misleading and likely to arouse unwarranted and unrealistic expectations of product effectiveness, in breach of the Therapeutic Goods Advertising Code.

The advertisement claimed the Bio-Gel product, when combined with Bio-S tablets, had been shown by tests to be more effective in clearing pimples than the acne drug tetracycline.

When a complaint was made that this claim was misleading because no such tests had been conducted, the sponsor of the product, Swisse Natural Health Care Pty Ltd, failed to produce evidence of any such tests.

The Complaints Resolution Panel decided the complaint was justified and requested Swisse to publish this retraction.

Format

Size: 185mm x 110mm

Font: Heading
Type: Times New Roman
Size: 22 point
Case: Upper
Bold

Text
Times New Roman
12 point

Heading layout:

RETRACTION STATEMENT
by
SWISSE H BIO-JUVEN
about
BIO-GEL and BIO-S