Complaints Resolution Panel

Complaint Form

Use this form to submit complaints about advertisements for therapeutic goods.

The advertisement

You MUST provide a copy of the advertisement you are complaining about, and indicate clearly where it was published. If it was published in a <u>magazine</u> or <u>newspaper</u>, state in which edition it appeared, the date, and the page number. If it was published in <u>outdoor media</u>, state the location and the date on which the advertisement was observed, and where possible provide a photograph of the advertisement. If it was published on the <u>internet</u>, state the website address and the date on which the advertisement was observed. If it was <u>broadcast</u>, identify the television or radio station, and the date and time of the advertisement.

Publication: http://www.liverdoctor.com/

Date/edition: October 23, 2008

The product advertised

Identify the therapeutic goods that are promoted in the advertisement. If possible, identify the party responsible for publishing the advertisement.

Numerous, an illustrative sample follows (Figures 5-13 below):

- ADRENAL PLUS SUPPORT TABLETS,
- ALLERGY RELIEF, DHEA CAPSULUS,
- BIOCELL COLLAGEN II (eternal youth capsules),
- FEM PRO (PROGESTERONE CREAM / MSM),
- Livatone®, Plus,
- Selenium Complete,
- MSM with Vitamin C Powder.

The sponsor of these products and the web site registrant is Health Direction Pty Ltd, 19 Little St., Camden, NSW 2570.

The administrative contact is: Dr. Sandra McCrae, 33 Elizabeth St., Camden, NSW, 2570; Phone: (02) 4655 4666; Fax: (02) 4655 9047

Confidentiality

You may request that your details be kept confidential, however it is recommended that you still provide contact details (below).

Please keep my personal details confidential: No

Details of the complaint

State clearly the nature of your complaint. It is not sufficient to highlight or quote words from the advertisement – explain what aspects of the advertisement are of concern to you, and why. If possible, identify sections of the Therapeutic Goods Advertising Code, Act, or Regulations you believe may have been breached in the advertisement. Attach a separate page if necessary.

This web site features a range of complementary medicine products, *a number of which DO NOT appear to be listed on the ARTG*, "specially formulated by Sandra Cabot" (Figures 1 & 2).

The web site states that Dr Sandra Cabot's professional name is Dr Sandra McRae and that she is a registered medical practitioner in NSW & QLD (Figure 3).

I have confirmed that Dr McCrae is registered in NSW (MPO: 064559) but cannot find an entry for her on the QLD medical register.

Her web site is registered in Australia (see: http://whois.domaintools.com/liverdoctor.com).

Registrant Details: Health Direction Pty Ltd; 19 Little St., Camden, NSW 2570

Domain Name: LIVERDOCTOR.COM

Administrative Contact: McRae, Sandra; 19 Little St., Camden, NSW 2570; +61.246558855

Registrar of Record: Enetica Pty Ltd; Record last updated on 2008-08-17

I submit that the content of this web site (appended) breaches:

• Section 42DL(1)(c)) of the Therapeutic Goods Act, 1989 (the Act) and Section 4(1)(a) and 5(2) of the Therapeutic Goods Advertising Code, 2007 (the Code), by promoting complementary medicines for diseases that have restricted representations (Figure 4);

- Section 42DL(1)(g) of the Act by promoting therapeutic goods not included on the ARTG (Figure 5-9 is just a sample).
- Section 4(1)(b); 4(2)(a); 4(2)(b), 4(2)(c)) of the Code; see details below;
- Section 4(6)(b)(iv) of the Code, by using professional recommendation (Figures 1-3); and
- Section 42DM of the Act, by the above multiple breaches of the Code.

Some illustrative concerns about misleading, unbalanced and unsupported promotional claims follow:

LIVATONE® PLUS 120 CAPSULES (in a page about "fatty liver")

"The "Livatone® Plus" contains the clinically proven dose of the herb Milk Thistle, which is the dose that has been proven to help repair liver damage in hundreds of European clinical trials." (Figure 10)

"The regular use of a liver tonic supports the repair of liver cells. It also supports the fat burning function of the liver which helps to keep weight under control." (Figure 11)

However, a recent Cochrane systematic review said: "No evidence supporting or refuting milk thistle for alcoholic and/or hepatitis B or C virus liver diseases. Milk thistle (Silybum marianum (L) Gaertneri) extracts have been used as medical remedies since the time of ancient Greece. Alcohol and hepatotoxic viruses are the major causes of liver diseases. Several trials have studied the effects of milk thistle for patients with liver diseases. This systematic review could not demonstrate significant effects of milk thistle on mortality or complications of liver diseases in patients with alcoholic and/or hepatitis B or C liver diseases combining all trials or high-quality trials. Low-quality trials suggested beneficial effects. High-quality randomised clinical trials on milk thistle versus placebo may be needed".

Rambaldi A, Jacobs BP, Gluud C. Milk thistle for alcoholic and/or hepatitis B or C virus liver diseases. Cochrane Database Syst Rev. 2007 Oct 17;(4)

http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003620/frame.html

In addition, I could find no references in PubMed (http://www.ncbi.nlm.nih.gov) to milk thistle and weight control.

Selenium Complete (in a page about "Hepatitis C")

"Selenium is traditionally known as "the viral birth control pill" and assists in inhibiting viral replication and reducing viral load. It is also a powerful antioxidant mineral that works synergistically with glutathione to assist in protection against further damage to liver cells" (Figure 12).

I could find no references in PubMed (http://www.ncbi.nlm.nih.gov) to selenium reducing the viral load in Hepatitis C infection.

MSM with Vitamin C Powder (in a page on gall bladder disease)

"MSM (Methyl-Sulphonyl-Methane) is an organic form of sulphur, which may assist in softening and preventing further scar tissue. Sulphur is also a vital component of healthy bile. Sulphur is needed to produce the powerful antioxidant called glutathione. Vitamin C will neutralize free radicals generated during the phase 1 detoxification pathway in the liver and reduce toxic damage and chemical overload. Toxic chemicals are far less dangerous if there is plenty of vitamin C in the liver. It also helps the liver to regulate cholesterol levels and improves immunity" (Figure 13).

I could find no references in PubMed (http://www.ncbi.nlm.nih.gov) to MSM and gall bladder disease, nor any clinically relevant articles about the above claims made for Vitamin C.

In summary, given these illustrative complaints, I believe the Therapeutic Goods Administration should be asked to review ALL products listed on this web site the for their compliance with the Act and the Code, including their listing status on the ARTG, see:

https://www.liverdoctor.com/index.php?page=shop&subpage=cat2

I submit that the multiple breaches of both the Therapeutic Goods Act and Therapeutic Goods Advertising Code documented above require the highest penalties to be applied, including the maximum fine allowable under the Act and a corrective advertising order.

I have also contacted the advertiser directly: No;

This matter is also the subject of legal action: No

The complainant

Complaints may be made anonymously, but you are encouraged to provide your contact details so that you can be advised of the outcome of your complaint. You may request (above) that your personal details not be provided to the advertiser or included in the published determination.

Name: Dr. Ken Harvey
Adjunct Senior Research Fellow
School of Public Health, La Trobe University

Postal address: 35 Mary St.
Hawthorn, Vic, 3122

Fax: (03) 9818 1875

I am associated with the therapeutic goods industry: No (if yes, see additional requirements below.)

Date: October 23 2007

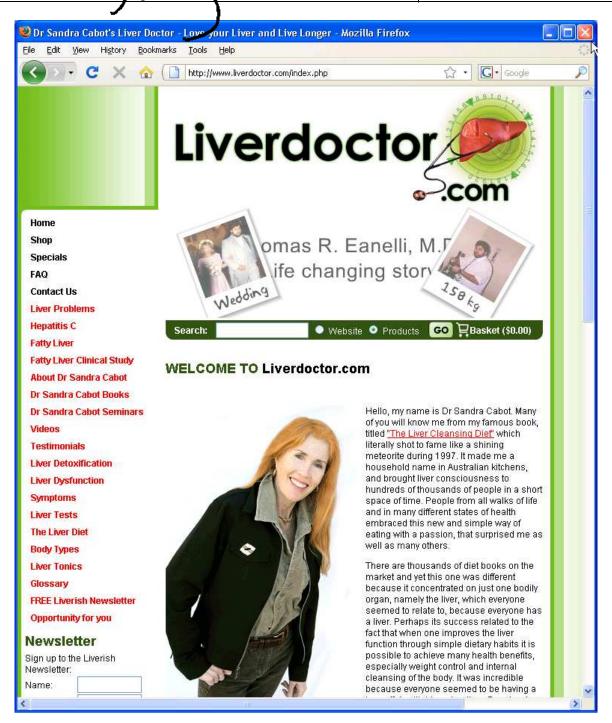


Figure 1 http://www.liverdoctor.com/index.php

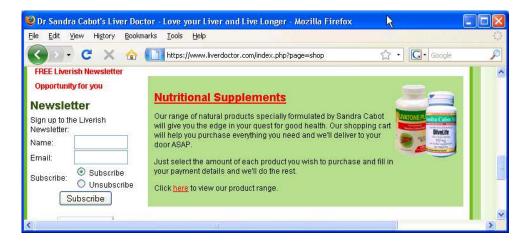


Figure 2 https://www.liverdoctor.com/index.php?page=shop

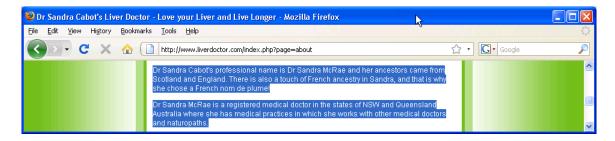


Figure 3 http://www.liverdoctor.com/index.php?page=about

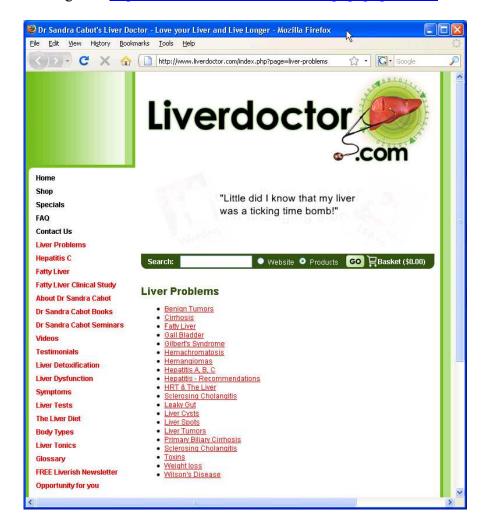


Figure 4 http://www.liverdoctor.com/index.php?page=liver-problems

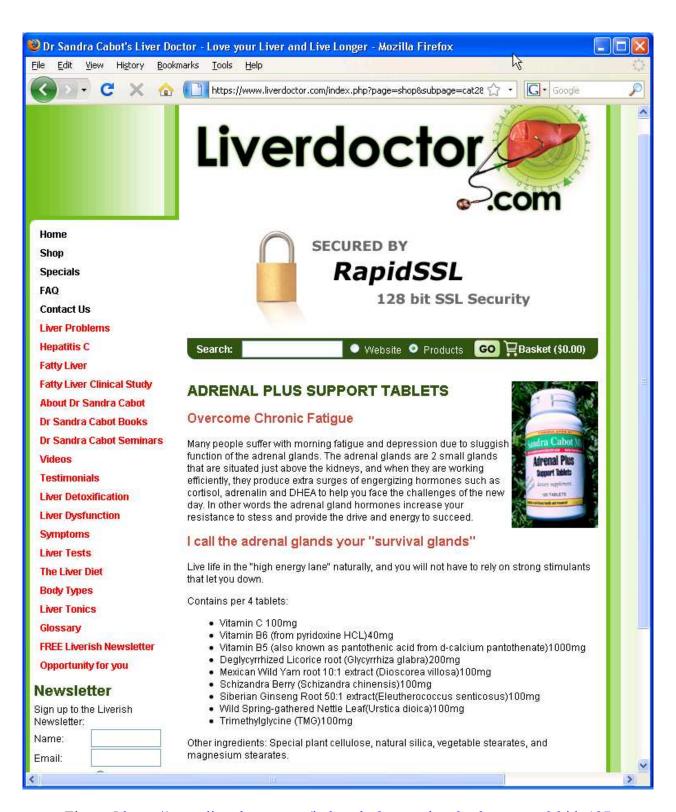


Figure 5 https://www.liverdoctor.com/index.php?page=shop&subpage=cat2&id=127

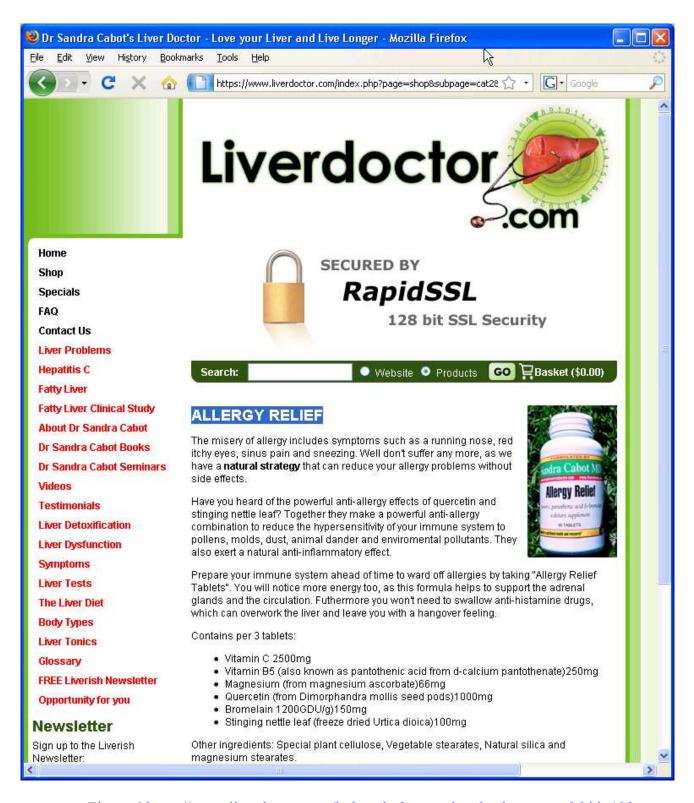


Figure 6 https://www.liverdoctor.com/index.php?page=shop&subpage=cat2&id=128



Figure 7 https://www.liverdoctor.com/index.php?page=shop&subpage=hrt-and-the-liver&id=134

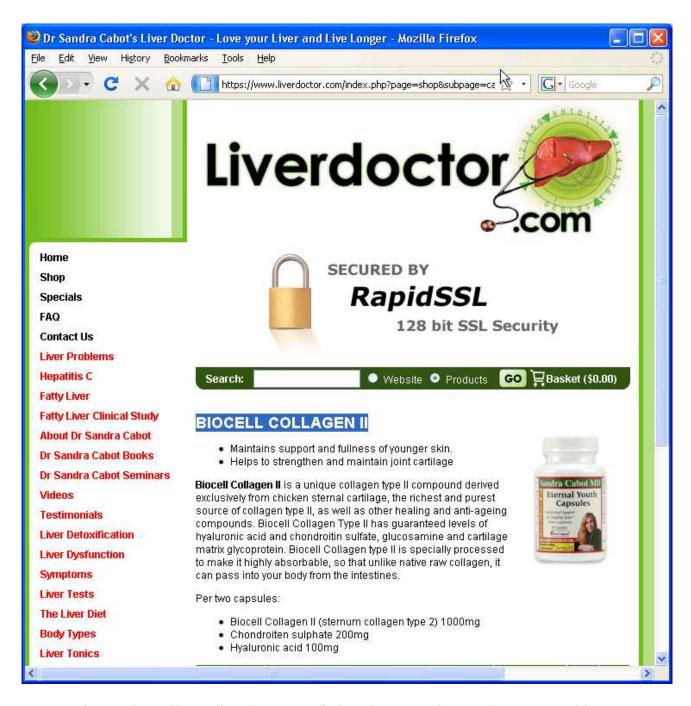


Figure 8 https://www.liverdoctor.com/index.php?page=shop&subpage=cat2&id=129

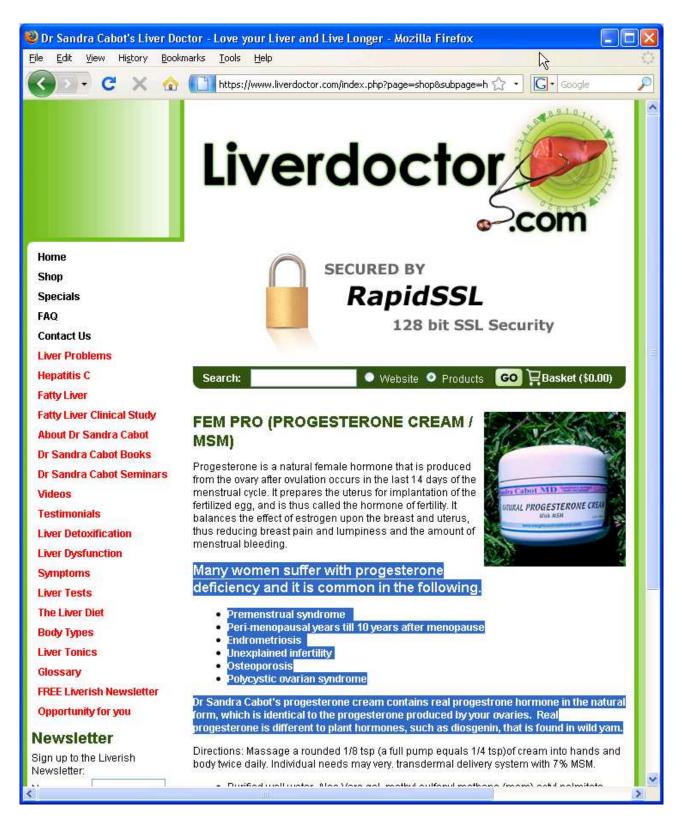


Figure 9 https://www.liverdoctor.com/index.php?page=shop&subpage=hrt-and-the-liver&id=136

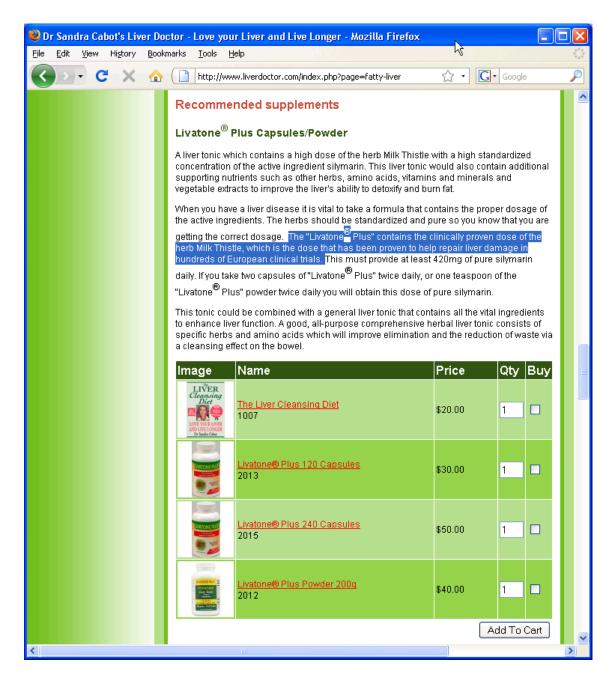


Figure 10 http://www.liverdoctor.com/index.php?page=fatty-liver

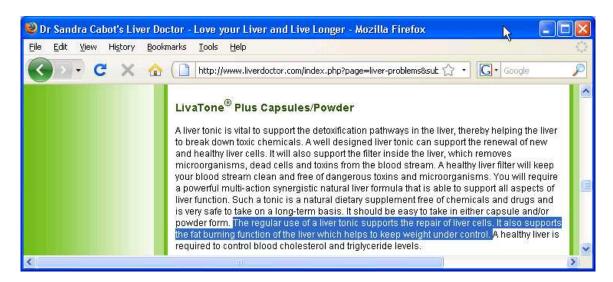


Figure 11 http://www.liverdoctor.com/index.php?page=liver-problems&subpage=hepatitis-recommendations



Figure 12 http://www.liverdoctor.com/index.php?page=hepatitis-c

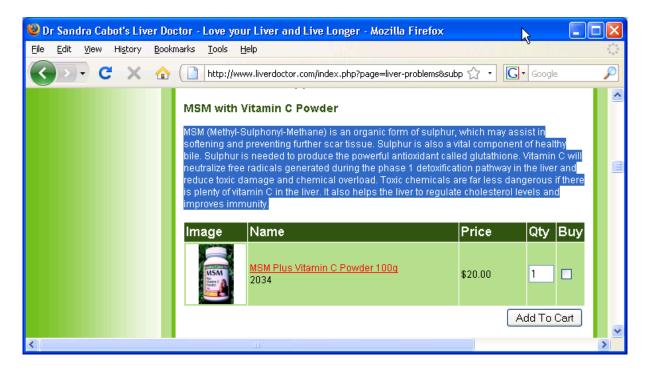


Figure 13 http://www.liverdoctor.com/index.php?page=liver-problems&subpage=gall-bladder