

Ethical Standards in Healthcare Product Promotion

Pharmacists' perspective /
what we teach pharmacy students

Roy Jobson: Faculty of Pharmacy, Rhodes University, Grahamstown.

Goodies Bags

- Leadership course – BPharm III
- Drug company sponsorship
- 2006 – students received “goodies bags” with
 - About to expire unregistered medicines
 - Imported Toothpaste
 - Creams & lotions

Goodies Bags

- 2013 – students received small gifts of minimal value:
 - Branded pens
 - Lanyards
 - A bag

All Gifts Large and Small

“Professional guidelines recognize industry gifts as a conflict of interest and establish thresholds prohibiting the exchange of large gifts while expressly allowing for the exchange of small gifts such as pens, note pads, and coffee. Considerable evidence from the social sciences suggests that gifts of negligible value can influence the behavior of the recipient in ways the recipient does not always realize. Policies and guidelines that rely on arbitrary value limits for gift-giving or receipt should be reevaluated.”

[Katz D, Caplan AL, Merz JF. All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving. *The American Journal of Bioethics*. 2003;3(3):39–46. Republished: *The American Journal of Bioethics*, 2010; 10:10, 11-17.]

National Drug Policy for South Africa: 1996

“Issues related to pharmaceutical promotion and comparative independent sources of drug information will be included as a core component of all curricula of the health and pharmaceutical professions.”

House of Commons

Health Committee

The Influence of the Pharmaceutical Industry

Fourth Report of Session 2004–05

Volume I

Published on 5 April 2005

House of Commons

We recommend that the MHRA find ways of ensuring greater restraint in medicines promotion, particularly soon after launch. p5 (emphasis added)

The Department [of Health] seems unable to prioritise the interests of patients and public health over the interests of the pharmaceutical industry. We therefore recommend that sponsorship of the industry[1] pass from the Department of Health to the Department of Trade and Industry. p6 (emphasis added)

1. Now known as “responsibility for representing the interests of the industry”

House of Commons

- We need an industry which is led by the values of its scientists not those of its marketing force. p6 (emphasis added)
- We need an industry which is led by the values of its scientists not those of its marketing force. p6 (emphasis added)
- The pharmaceutical industry's promotional efforts are relentless and pervasive. The evidence presented [to the Committee] showed the lengths to which the industry goes to ensure that promotional messages reach their targets, and that these targets include not only prescribing groups, but patients and the general public. p76 (emphases added)

Horton (in response to ABPI [ESHLSG] guideline)

- “The guidelines are problematic as they contain claims that are demonstrably false.” (emphasis added)
- “The statements made in the ‘guidance’ certainly do not match the latest evidence about the behaviour of pharmaceutical companies today.” (emphasis added)

Horton R. Offline: Falling out with Pharma. Lancet. 2013;381:358 (2 February 2013)

Horton (in response to ABPI [ESHLSG] guideline)

- “. . . we found that the pharmaceutical industry is like any big organisation. Some people are *unscrupulous*. Others are better: they work hard to discover new medicines and to ensure drugs are tested fairly.” (emphases added)

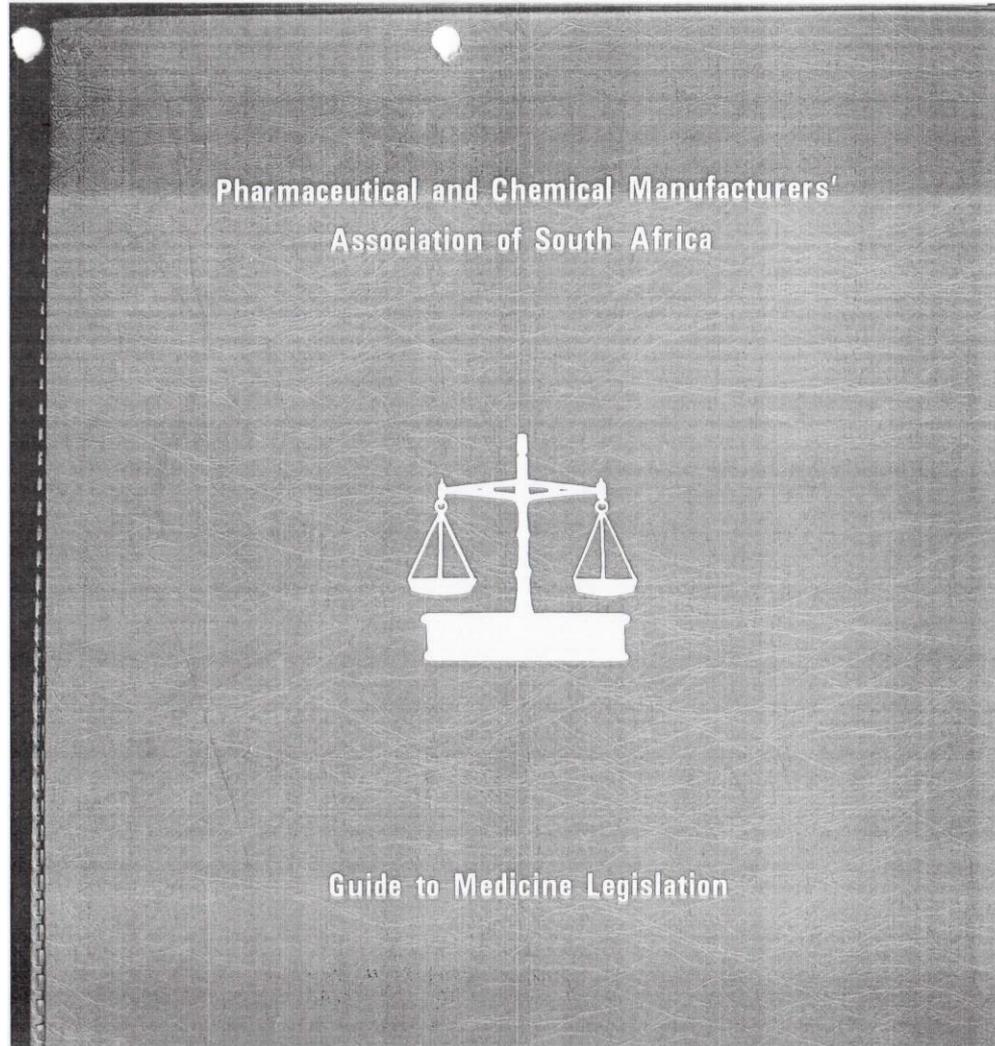
The Lancet withdraws support

Horton told the BMJ, “There can be very positive interactions with the industry, but only if based on reliable evidence and with the patient's interests centre stage. What is now much clearer is that several of the statements in the document do not stand up to scrutiny. Since there is no process to raise these matters in a joint working group (I have never been invited to the meetings), the only action we could take was to withdraw.” (emphasis added)

Hawkes N. Lancet withdraws its support of document on collaboration between doctors and drug industry. BMJ 2013;346:f770 (5 February 2013)

SA CODE FOR THE MARKETING OF HEALTH PRODUCTS

“Blue Book” circa 1985



“Blue Book” circa 1985

- 22 -

CHAPTER 10 : MARKETING OF MEDICINES

INDEX TO THIS CHAPTER

10.1 CODE OF MARKETING PRACTICE

Nearly 30 years ago . . .

“Blue Book” circa 1985

11.5 ADVERTISING AS CONTROLLED BY CODES OF STANDARDS ISSUED BY THE ADVERTISING STANDARDS AUTHORITY

11.5.1 Code of Advertising Practice

A copy of the Code of Advertising Practice follows.

The Medicines Control Council has approved the Code of the Advertising Standards Authority as a guide in the advertising of medicines.

(emphasis added)

SA CODE FOR THE MARKETING OF HEALTH PRODUCTS

2. INTRODUCTION TO-, APPLICATION AND INTERPRETATION OF THE CODE

2.1 Introduction

(page 4/47 paragraph 5)

This Code is issued in terms of section 18C of the Medicines and Related Substances Act No 101 of 1965, as amended, and is adopted by health products trade associations to signify the industry's commitment to ensure that the marketing of health products to healthcare professionals and the public is carried out in a responsible, ethical and professional manner, based on practical and scientifically validated information.
(emphases added)

18C Marketing of medicines

“The **Minister** shall, after consultation with the pharmaceutical industry and other stakeholders, make regulations relating to the marketing of medicines, and such regulations shall also provide for an enforceable Code of Practice.”
(emphases added)

Fatal Flaws in SA Code for the Marketing of Health products?

SA CODE FOR THE MARKETING OF HEALTH PRODUCTS

2. INTRODUCTION TO-, APPLICATION AND INTERPRETATION OF THE CODE

2.2 Application of the Code

2.2.2 The Code does not apply to the following situations:

2.2.2.3 The marketing or promotion of complementary medicines [regulated by Medicines and Related Substances Act, Act 101 of 1965] and Stock Remedies as defined under Act 36 of 1947.

(emphasis and brackets added) (page 6 of 47)

Another fatal flaw?

[Fiasco of 2002 “call up”/ “audit” of complementary medicines. The industry cannot abdicate responsibility.]

SA CODE FOR THE MARKETING OF HEALTH PRODUCTS

Glossary of SA Code for the Marketing
of Health Products – no definition of
“health product”? (Medicines and
Related Substances Amendment Bill
2012 – “product” – foodstuffs,
cosmetics, in vitro diagnostics,
[medicines and devices])

Self Regulation

Norris P, Herxheimer A, Lexchin J, Mansfield P. Drug promotion: what we know, what we have yet to learn – Reviews of materials in the WHO/HAI database on drug promotion. WHO, HAI. 2005

“Studies of promotion by drug company representatives suggest that the guidelines and regulations that should control them are ineffective.”

Effective:

“Government regulation of promotion is more effective than industry self-regulation

“Educating doctors about drug promotion influences attitudes and can improve skills

“Publicising deceptive promotion leads to improvements.”

Ineffective:

“Industry self-regulation

“Review by journal editors

“Guidelines/regulations for sales representatives or for advertisements

“Government control of post-marketing surveillance.”

Self Regulation

Brinchmann:

“It is important to have clear legislation covering the development, manufacturing, registration and marketing of medicines in place in all countries and have self-regulatory codes of conduct as an important and valuable supplement to promote ethical behaviour.” (my emphases)

[THE PEN IS AS MIGHTY AS THE SURGEON'S SCALPEL: Improving health communication impact. Consultation on Health and Environmental Communication Policy, Moscow, May 1998 page 61.]

Unscrupulous?

- Profits before patients? (primary concern is to shareholders not stakeholders?)
- Failure to disclose data to Regulators?
(gabapentin – Pfizer - \$3bn fine;
paroxetine - GSK)
- Pharmacy (& other health professionals')
students: examples set by seniors / role
models?

Unscrupulous?

Examples of pharmacists: (ASA substantiation)

BioSlim [pharmacist consultant – change wording.
MCC – illegal medicine.]

Ultima Fat Away [no claims should be extrapolated from animal work – including “broiler chickens”; “[The] one and only human study shows no clinical relevance in daily practice.”]

O2Lean [PhD – Thermolean – reference in the PhD dissertation to Thermolean: “according to manufacturer’s information” or similar statement.]

Unscrupulous?

Examples of pharmacists: (ASA substantiation)

Peel Away the Pounds [PhD Pharmacist! Seaweed absorbed through the skin.]

Stem Enhance [perused the articles provided, done own research, and can confirm the claims]

Unscrupulous?

Examples of doctors: (ASA substantiation)

BioBust [capsules to enlarge breasts]

Herbex [retired GP dabbled in homoeopathy – weight loss product]

Oscillococcinum [evidence is that 7 (unpredictable) individuals in 100 will benefit by average of 6 hours out of 7 days illness – this was “fudged” by doctor and Senior Counsel, misleading Judge in the ASA’s FAC.]

Unscrupulous?

Examples of doctors: (ASA substantiation)

Proxygen – oxygenate your body via your gut! [non-practising dr – businessman with MBA]

Detox tea – [ditto – laxative effect?]

Nivea cellulite cream [substantiator flown to Germany]

Orthopaedic surgeon – [glucosamine – unaware that it's a S3 substance]

Bedaquiline

(scrupulous?)

Professor Andreas Diacon motivated Tibotec, now Janssen Research and Development to provide Dr Dalene von Delft who had been diagnosed with MDR TB with bedaquiline. (emphasis added)

Unscrupulous?

Is this version of the Marketing Code and establishment of the Marketing Code Authority (MCA) not premature given its “fatal flaws”? Who does it serve, really?