

Medicine advertising and the ASA

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The ASA's claims in respect of its regulation of medicine advertising are misleading.



Introduction

1. In prior articles published on bizcommunity on 22 May 2014 <https://www.bizcommunity.com/article/196/12/113667.html> and 29 May 2014 <https://www.bizcommunity.com/article/196/12/114027.html>, I highlighted the ASA's misleading standard letters addressed to non-member advertisers in which the ASA fails to disclose the fact that "non-members of the ASA are legally entitled to ignore the rulings and procedures of the ASA", thereby inducing non-members to participate in the ASA's procedures and pay it ASA appeal fees.
2. In this article, I shall discuss another serious illness within the ASA namely the ASA's false representations to the public of South Africa pursuant to which it usurped the role of the Medicines Control Council ("MCC") to regulate medicine advertising in South Africa, and attempted to cover up its misrepresentations.
3. For a number of years the ASA held itself out to the South African public as being authorised by the MCC to regulate Medicine Advertising in South Africa and made the false claims in its Code that it was doing so "in terms of **Section 18C of the Medicines and Related Substances Control Act No. 101 of 1965 ("the Medicines Act")**" in circumstances where this was to the knowledge of the ASA untrue.
4. On the strength of its false claim the ASA banned advertisements and extracted ASA appeal fees from the public and non-member advertisers.
5. In order to contextualise this discussion, it is necessary to consider certain aspects of the Medicines and Related

Substances Control Act No. 101 of 1965 ("the **Medicines Act**") and the Consumer Protection Act No. 68 of 2008 ("the Consumer Protection Act").

The Medicines Act

6. It is clear from the Medicines Act that the power to regulate medicines including the advertisement of medicines is vested in the Minister of Health, assisted by the MCC, the Director-General - Health and the Registrar of Medicines^[1]

7. The Medicines Act ^[2] deals with the advertisement of medicines and medicine labels and *inter alia* provides that the "minister may prescribe additional requirements for the labelling of medicines" ^[3] . Section 18c of the Medicines Act prescribes that the Minister of Health (not the ASA) shall make regulations relating to the marketing of medicines.

8. The Medicines Act^[4] prohibits the publication of any "false" or "misleading" advertisement concerning medicines and Section 29 creates offences *inter alia* for making "misleading" statements in connection with any medicine.

9. The Medicines Act ^[5] empowers the minister of health in consultation with the MCC to make regulations prescribing the particulars which must appear in medicines relating to advertisements or prohibit the inclusion of any particulars in a medicine advertisement. The enforcement of the Medicines Act is vested in the director-general - health (not the ASA).

10. The legislative and regulatory election to confer exclusive authority with respect to the advertising of medicines on the Director-General - Health and the MCC gives recognition to the fact that the regulation of medicine advertising is a complex endeavour requiring considerable and specific expertise. This need for expertise and experience in regulating medicine advertising is reflected in the composition of the MCC which is prescribed^[6] to be composed of at least three medical practitioners, of which one must be a paediatrician, another a specialist in internal medicine and another a specialist in public health, an expert in clinical pharmacology, an expert in pharmaceutical chemistry, an expert in toxicology and drug safety, an expert in biotechnology, a pharmacist who is an expert in pharmaceuticals, one person with knowledge in the study of adverse drug reactions, an expert in virology and microbiology, one person with specialised knowledge in veterinary clinical pharmacology, one veterinarian designated by the minister of agriculture, one person with knowledge of complementary medicines and a person with expertise in law.

11. The ASA lacks the considerable and specific expertise which the medicine regulations stipulate are to be held by the body authorised by the Medicines Act and its regulatory framework to administer medicine advertising. The ASA's lack of expertise and indeed its ignorance led to bizarre advertising bans that were contrary to the public interest and in fact a danger thereto^[7] .

The ASA's attempt to usurp the role of the MCC in regard to the regulation of medicine advertising

12. In a prior version of the ASA code^[8] the ASA represented to the public for a number of years that it was authorised to regulate references to advice in respect of diseases and medicine advertising "on behalf of the Department of Health: MCC" in terms of the Medicines Act, in circumstances where this was to the knowledge of the ASA untrue.

13. In the prior ASA code^[9] the ASA in its introduction and in [appendix a and f](#) thereto ("ASA's medicine code") the ASA made the following misrepresentations and false claims:

13.1 Appendix f of the ASA's Medicine Code (described by the ASA as relating to "references to disease in advertising"),

belonged to and was administered by the ASA "on behalf of the Department of Health: Medicines Control Council (MCC)";

13.2 Appendix a of the ASA's Medicines Code [and impliedly appendix f of the ASA's Medicines Code as it was said to have the same "owner" as appendix a namely the "Department of Health: MCC] was **"issued in terms of Section 18C of the Medicines and Related Substances Act..."**;

13.3 Appendix f of the ASA Medicine Code allegedly on the authority of the MCC outlawed advertisements which made or offered products, treatments or advice for certain "illnesses", unless the recommendations accorded with a full product registration by the MCC;

13.4 (An ASA organ described as) the MCA had been created and had the power to create the required enforcement mechanisms in respect of medicine advertising [10] .

14. In an "ASA ruling" published on its website[11] the ASA perpetuated its misrepresentations and false claim to have been authorised by the MCC to administer medicine advertising in South Africa as follows:

*"It is significant to note, however, that while the newly implemented appendix a, which was clearly compiled and introduced with the full knowledge and **approval of the MCC** has now taken effect, **the MCC have not made a single change to appendix f as contained in the Code. Appendix f is also listed as belonging to and having been implemented by the "Department of Health" Medicines Control Council**".*

15. In short, the ASA attempted to usurp the powers given to the MCC and the minister of health to regulate references to advice in respect of diseases in advertising and of medicines. The ASA did so contrary to the constitutional imperative of the rule of law and in contravention of the Medicines Act and its regulatory framework.

16. the department of health had to the ASA's knowledge as early as march 2011 disavowed the claims made by the ASA in regard to the ASA's medicine code and in particular appendix f thereof. Despite this, the ASA for years continued to "administer" the ASA's so-called medicine code purportedly on behalf of the MCC in terms of Section 18c of the Medicines Act and falsely held out to the public of South Africa that it was authorised by the MCC to do so.

17. The ASA on the strength of these misrepresentations and false statements banned advertisements and extracted ASA appeal fees from medicine advertisers for years.

The ASA's failure to correct the false impression that it was allegedly authorised by the MCC to regulate medicine advertising on behalf of the MCC.

18. On 4 February 2012, the ASA's board belatedly passed a resolution in which the ASA finally decided that the ASA's Medicine Code (appendices a and f to the prior ASA code) should no longer form part of the ASA Code. This decision of the ASA to finally remove the ASA's Medicine Code from the ASA code was partially and belatedly recorded in an ASA ruling[12] dated 16 August 2012, in which the ASA confirmed that:

"At a resolution passed by the ASA board on 4 February 2012, it was decided that appendix f should no longer form part of the ASA code. In terms of the ASA's articles of association, the directorate has to immediately give effect to any decision taken by the board..." (underlining added)

19. Despite resolving to delete the ASA medicine code from its code (and even after publication of the aforesaid ASA ruling) the ASA continued to publish its so-called medicine code on its website (initially as part of the ASA code) and then accessible by keyword search. To aggravate matters, the ASA continued (after its "deletion") to issue rulings against non-members of the ASA and extract ASA appeal fees premised upon the false representations contained in its "deleted" medicine code.

20. The ASA however tried to keep this secret in an attempt to cover up the fact that the ASA never had a mandate from the MCC to administer medicine advertising to begin with.

21. The ASA's initial failure and delay to transparently disclose its decision to delete the ASA's medicine code from the ASA code, formed the subject matter of a critique by an experienced advertising consultant (and former head of legal and regulatory affairs at the ASA), Gail Schimmel in an article published on Bizcommunity some time ago. See the full article entitled "[Appendicitis at the ASA?](#)".

22. In her article Schimmel commented that appendix f had "... *always been controversial*" as "it contains some mighty strange diseases such as "leg trouble" and "diseased ankles". Schimmel indicated that she had been rendered (at least temporarily) "completely speechless" and "upset" by what she described as the ASA having "*quietly nursed this little secret*". She indicated that she believed a press release about appendix f's death might have been appropriate and remarked that appendix f "*still appears on the website as part of the code in all its glory!*". Importantly, Schimmel commented that she was "deeply concerned that this is yet another symptom of an illness within the ASA" (emphasis added).

23. Section 41(3) of the Consumer Protection Act prohibits a failure "... *to correct an apparent misapprehension on the part of a consumer to the effect, that - "the supplier of any ... services has any particular status, affiliation, connection, sponsorship or approval that they do not have*" (emphasis added).

24. The ASA whose president was the ex-judge Mervyn King knew full well that the ASA had not been granted any authority from the MCC to regulate medicine adverting on the MCC's behalf and that it was in any event legally incompetent for the MCC to have delegated such functions to the ASA in terms of Section 18c of the Medicines Act or at all. He continued however to deliver ASA rulings which perpetuated and attempted to cover up the ASA's misrepresentations in this regard despite having given notice of his intention to resign shortly after the ASA decided to delete the medicine code and "quietly nurse its little secret".

25. Advertisers who have been subjected to a process or ruling of the ASA in regard to the ASA's so-called medicine code (including the former appendices a and f) may well have an actionable claim against the ASA in regard thereto.

26. The ASA's lack of expertise (as required by the Medicine Act) and ignorance in regard to medical matters also led to absurd ASA rulings banning truthful statements which are in the public interest such as "*Too much sugar may cause weight gain*[13]; "*Too much sugar may cause obesity*" and "*Too much sugar may cause diabetes*", despite the fact that these claims are self-evidently true. Indeed, the same claims were contained in a World Health Organisation Bulletin No. 2003, 81(8) entitled "Evidence to support a food-based dietary guideline on sugar consumption in South Africa", which was in the ASA's possession at the time it irrationally, irresponsibly and indeed dishonestly banned the public health warnings (emphasis added).

27. It is ironic and an indictment on the ASA (which holds itself out as a protector of the truth) that it has continued to attempt to keep "its little secret" rather than coming clean and correcting the misapprehensions it has created as required by the Consumer Protection Act and indeed the common law.

[For easy reference download the ASA's appendices a and f.](#)

[1] *The Medicines Act expressly includes advertising in the definition of the sale of medicine. Section 1 of the Medicines Act*

[2] *Section 18*

[3] *Section 18(5)*

[4] *Section 20(1)*

[5] *Section 35(x)*

[6] *Regulation 35 of GNR 510 of 10 April 2003: General Regulations (of the Medicine Act Regulations)*

[7] *See paragraph 26 below*

[8] *and [9] See some of the ASA's misrepresentations as attachments in this [Bizcommunity article](#)*

[10] *Paragraph 48.2 of Part D of Appendix a of the prior ASA Code*

[11] *In the matter 16710*

[12] *ASA ruling 20066*

[13] *ASA matter number 17484*

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