How to sell your soul in 10 easy steps

Dr Roy Jobson

Although this deliberately provocative blog, which was published on Thoughtleader, on the Mail and Guardian website (http://www.thoughtleader.co.za/royjobson/2007/12/30/how-to-sell-your-soul-in-10-easy-steps/), was written while Professor Jobson was still a Council member of the Medicines Control Council (MCC), it is written in his personal capacity.

ssume I have no conscience or any morals. Assume I have a legitimately registered company or CC with hefty overdraft facilities. Here I am in South Africa just ready to make a buck from those most gullible of consumers — the worried (but wealthy) well, the health and wellness neurotics, the painted, dyed and cosmetic-dependent clientele of "natural" medicine.

The illiterate and physiology-informationdeprived usually don't have much spare disposable income, so any diffusion of their resources into my pockets would simply be an added bonus.

I've found an overseas manufacturer of a sure-fire best-seller in SA — "Tallerbrand" height-increase pills. (Read: "weight-loss remedies"; "hair-growth enhancers"; "bust-enlargement medications"; "penis-enlargement tablets"; "improved sexual-performance capsules"; "immune boosters"; etc). I just need to import the product, start marketing it, sit back and wait for the rands to roll in.

I would, however, have some red-tape hurdles to jump through. (These minor obstacles could possibly be helped along with a few "tokens of appreciation".)

- 1. I would state that the product is a natural "nutritional [or dietary] supplement" on all official documentation, especially customs, and thereby hopefully avoid any need to interact with the inspectors of the Medicines Regulatory Affairs (MRA) Cluster of the Department of Health (DoH). However, as Director General of Health Thami Mseleku has stated to Parliament's health portfolio committee, there is a lack of capacity in inspections so the chances are I'd get away with it anyway.
- 2. I would then submit an abbreviated application to the Medicines Control Council (MCC) for registration of my prod-

uct as part of the 2002 Complementary Medicines "call-up". This simple procedure would add my product to the over 20 000 applications said to have already been received by the MCC as of September 2006. Even though the call-up was for six months only, the applications have continued unabated — partly in order to obtain a NAPPI code (see below). A simple acknowledgement of receipt with an allocated application number, would enable me, albeit falsely, to advertise my product as being "registered with the MCC".

- 3. I would apply for a NAPPI (National Pharmaceutical Product/Pricing Index) code — so that your medical aid will pay for the product or at least make part of the payment. Fortunately NAPPI codes are free: you just fill in the forms, show proof of registration of your company, show that you have the correct licences or registration from the MCC/Pharmacv Council (not too difficult to obtain), and send along a copy of the label showing the ingredients. (The person/computer allocating the NAPPI code will probably not check the label for prohibited or scheduled substances, and would possibly not even be qualified to do so.) I would have little concern about how the purchase of my product and/or similar products would affect medical aid tariffs in general.
- 4. I would find a tame/shady pharmacist or medic friend who would agree to substantiate that the product works (doctors were amazed at how much taller I became within a few weeks of taking "Tallerbrand" pills!), just in case anyone submits a complaint to the Advertising Standards Authority (ASA).
- 5. I would advertise widely using obfuscatory phrases such as "helps to", "improves", "alleviates", "supports", or "assists the body with". No specific or definitive claim such as cures short stature, or

treats the vertically challenged etc. As none of the print or electronic media seem to have any ethical problems about accepting advertisements of this genre, I would have free reign until or unless someone complained to the ASA. Even then, my substantiation would probably be accepted by the ASA (provided my tame/shady pharmacist/medic's credentials are accepted - usually not a problem). As the ASA does not have anyone in its own structures who can assess medical or health-related claims (no, really!), if my expert says it's so, this "substantiation" must, according to the advertising code, be accepted as correct (no matter how absurd the claim). After that, a long, drawn out process of appeals, allegations of breaches of the code, and/or arbitration would ensure that I could cover legal fees and continue selling and profiting for months or even years - while the media continue to accept my advertising.

- 6. For my website, I would find a research article in any obscure journal that shows that the product (or just one ingredient) makes use of previously unused or unknown technology, which technology may have been endorsed by a Nobel Prize winner or person of similar stature. Molecular-structure hypotheses, laboratory tests and animal studies, rather than clinical trials with humans, would of course be emphasised. Extrapolations to living human beings can always be fudged. Besides which, none of the target market are likely to question "science".
- 7. I would find a salesperson oozing with charm, and in possession of a degree or diploma of some sort. This person could intercalate doses of scientific-sounding verbiage with common sense, and smoothly spout these, making the product appear highly credible. For example: "The Earth we grow our food in is now so deficient in nutrients especially vitamins, minerals and antioxidants that the produce of that soil (or an animal that

eats food growing in it) is similarly deficient. And this is why people are no longer growing as tall (retaining their hair, developing as large breasts or penises, enjoying sex, living as long) as they could. But science is here to help! Researchers have found a completely safe and natural revolutionary new product that has been shown to increase a person's height (lose weight, grow hair, enlarge breasts or penises, improve sex, counteract ageing) within weeks."

If the product cannot make claims of being revolutionary, it can easily be legitimised through claims of "traditional" use (even if this vague term applies to but one of multiple ingredients in a newly formulated product): e.g. "contains an indigenous herb, found only in a remote/ secret area (of an exotic island), traditionally used for hundreds or even thousands of years as part of religious ceremonies". No one will notice that the concentration of the herb may have been so highly diluted (for cost-saving measures) that any possible purported efficacy is completely nullified.

- 8. I would organise advertorial interviews on radio talk shows, and perhaps even on SABC3's 3 Talk with "gifts" for those who call in. (The presenter's unique ability to somewhat gushingly endorse rather dubious products and their accompanying smooth and rather dubious sales personae, especially those from the UK, is legendary.)
- 9. I would arrange that only "leading pharmacies" stock the product. All non-leading pharmacies would not be able to stock it but any so-called "health shop" could carry it.
- 10. I would start a distribution network locally (with a view to an international network, of course) whereby ordinary citizens are brainwashed into an uncritical belief in the product and, in line with the government's encouragement of small businesses, are encouraged to find their own customers and create their own micro-distribution networks. (This is not a pyramid scheme!) With "trickle-up" economics, I would benefit every time a new customer is found.

Any concerns a person may have about the quality of my product will most likely remain unanswered for many long years. The magic number of 20 000 complementary medicines, which the spokesperson for the DoH cited again in July 2007, means my product's application will wait its turn to be assessed. Since 2002, 14 000 products have been "assessed" according to the spokesperson. (In the ten months between the spokesperson's two virtually identical statements, it would appear that no significant progress was made in assessing these products.)

Contradicting the MCC's own website that the Medicines Act applies to all medicines, including complementary medicines, the director general stated to the health portfolio committee that complementary medicines do not need to be registered. The Democratic Alliance's Mike Waters, however, seems to have inside knowledge that my product would be checked for "content, source of origin and presence of heavy metals, dangerous substances and banned substances" by the MRA.

Thank goodness this is not true. If it were, my product would be a non-starter. My own sources indicate that the "assessment" referred to by the DoH spokesperson involves nothing more than the listing of a few administrative details about each product in a database. Earlier this year, I found numerous products containing prohibited ("banned"/"illegal") substances being advertised on South African websites, that had not been detected by the MRA in its assessment process. It is perhaps not surprising that the majority of these products were sexual-enhancement products.

Considering it's taken more than five years to "assess" 14 000 products and assuming that the total number has increased (some say there are now over 60 000 products on the market), and because there's no capacity according to the DG, it's surely going to take many, many years before any official ever gets to take even a glance at the "labelled" (not necessarily actual) ingredients of my product. It could well contain nothing more than finely ground silica dioxide (sand) bound with starch. There's nothing guite as natural as plain sand! But by then it wouldn't matter — I'd have made my money several times over.

When aircraft cannot produce documentation to show they've been correctly maintained, they are grounded. There's an independent body – the Civil Aviation Authority – checking on aircraft.

When condoms are found to be defective, they are recalled. There's an inde-

pendent body – the South African Bureau of Standards – checking on condoms

When defects or new risks related to registered (orthodox, Western, allopathic) medicines are found, they are recalled, withdrawn or have their registration cancelled. The MCC is the independent body that checks on (registered) medicines. The self-monitoring of a product, once registered, is only possible because of the rigorous requirements of registration – and because registration (and therefore profits) can be cancelled.

No independent body is checking the quality of complementary and alternative medicines in South Africa.

The producers and sellers of complementary and alternative medicines in South Africa are certainly not voluntarily submitting information on the quality of their products to any independent body.

This means that none of the (unregistered) complementary or alternative medicines available on the shelves of your leading (and non-leading) pharmacies, health shops or supermarkets have been independently assessed in terms of their contents (what's on the label is in the product), possible contaminants (bacterial or toxic heavy metals), spiked substances (e.g. Viagra), prohibited substances (e.g. dangerous herbal products) or scheduled substances (e.g. dehydroepiandrosterone — DHEA). (Sorry to disillusion you, Mike.)

If it is not known exactly what's in every batch of a medicine/product, logically you can't know whether it's safe or effective. And if the original medicine/product has not initially been rigorously and independently assessed for quality (and safety and efficacy), self-monitoring has no validity or reliability.

So, please, should you be feeling a little short (fat, bald, small, libido-deficient, aged), don't hesitate to buy my product(s). You and your healthcare professionals will be astounded at the results. I will make a fortune, and will have joined a cohort of unscrupulous, predatory, and soulless sellers of scam products in South Africa.

Disclaimer: Please note that any resemblance between "Taller-brand" and "HeightoMAX", or any other globally available commercial height increase product, is purely coincidental.

Comment from Jackie Dring, a pharmacist with many years experience in the regulatory field

When considering the current status of Complementary and Alternate Medicines (CAMs) regulation in SA, there is a school of thought held by some people in the pharmaceutical industry that because there are no regulations that read specifically to complementary medicines, that these medicines are not regulated.

This is not true.

All medicines, irrespective of their registration status, are subject to the conditions of the Medicines and Controlled Substances Act 101/1965 and its regulations, whether an application has or has not been submitted to the Medicines Control Council.

Section 1(3) of the Act reads "In determining whether or not the registration or availability of a medicine is in the public interest, regard shall be had only to the safety, quality and therapeutic efficacy thereof in relation to its effect on the health of man or any animal, as the case may be."

Interpreted to the current environment, CAMs available in SA are required in terms of Act 101/1965 to be subject to substantiation and justification by both the MCC and marketer (seller) in relation to safety, quality and therapeutic efficacy.

The MCC has included a statement on its website homepage which indicates that all medicines including complementary medicines are subject to all aspects of the Medicines Act, which includes submitting them for registration. (See www.mccza.com).

It is the statutory mandate of the MCC to regulate all medicines, registered or not, and no specific additional regulations are necessarily required to control complementary medicines. By implication, section 1(3) also implies that it is Council's responsibility to ensure that substantive evidence has been submitted by an applicant to prove safety, quality and efficacy as well as suitability for intended use. (*Note:* What Section 1(3) also implies is that no one apart from Council

can make this decision!)

It is also important to note that the MCC has the authority to stop any medicine/product from being sold if it is deemed an "undesirable" product, be it registered or not. This is very much dependent upon the Council being notified of possibly undesirable products by the Inspectorate, or the public or even pharmacists and others in the medical profession.

Dr Roy Jobson highlights the following points:

Natural "nutritional or dietary supplement"

Comment: Despite this description these products still fall into the definition of a medicine, depending on what medicinal claims are made or "purported".

· Submission to the MCC

Comment: The abbreviated application consists of:

- i. Administrative information (Applicant, product, manufacturer/packer and release responsibility details)
- ii. A copy of the label and package insert
- iii. A list of other countries in which the product is sold
- iv. A breakdown of the unit formulation. (Evaluation of safety, quality and efficacy cannot be assessed on this information alone).

An MBR20.8 is issued by the MCC to confirm receipt of the abbreviated application. This form simply acknowledges that the MCC/MRA has taken receipt of the abbreviated application. The footnote stipulates that it does not permit the use of the MCC's/MRA's name for trading purposes and failure to provide correct information may lead to prosecution in terms of Act 101/1965. The MBR20.8 does not; in anyway, grant product registration status.

Nappi Codes

Comment: This is industry driven and is required to be submitted to the Directorate: Pharmaceutical Economic Evalua-

tion, National Department of Health, by a manufacturer or importer, as part of the information to be published before taking an increase in the Single Exit Price. NAPPI codes are used by the medical aid industry as a guide to which products will be paid for by the medical aid.

• "Get a pharmacist and/or medic to substantiate the claim"

Comment: The ASA Code, 4.1. Section II requires that "advertisers shall hold documentary evidence to support all claims that are capable of objective substantiation and that such evidence shall emanate from or be evaluated by an independent and credible expert in the field to which the claims relate. The substantiation must relate to the composite product and not only to individual ingredients. The ASA has to accept the evidence of the independent credible expert and rule on it." The credibility and independence of the expert can be contentious.

• The use of "obfuscatory" phrases for claims

Comment: Claims for CAMs are, currently, usually based upon literature and anecdotal evidence – very different from scientifically proven clinical studies required for registered medicines.

"Science" based evidence used for promotion

Comment: Pharmacists and health professionals have a responsibility to educate the public at the point of sale, that CAMs with their related claims have not been evaluated by the MCC. Unfortunately, this creates a huge conflict of interest. Is there a pharmacist who will not recommend/sell a medicine stocked in their pharmacy?

Use of salespersons and advertorials

Comment: Advertising is regulated by the ASA Code of Advertising practice and any person has the right to complain to the ASA if advertising contains misleading or unsubstantiated claims. The ASA, upon receipt of a complaint, may consult with the MCC to clarify the admissibility of advertising claims. BUT as most members of the public (consumers) would not recognise misleading or unsubstantiated claims this route of ensuring that dubious medicines are not sold to a gullible

public is not effective. Pharmacists are far better able to recognise misleading and unsubstantiated claims, yet many advertise and display such products in their pharmacies and never make a comment or complaint to ASA.

· Distribution outlets and systems

Comment: Schedule 0 medicines are permitted to be sold in an open shop but not all CAMs are automatically Schedule 0. Some contain scheduled substances which require prescriptions and yet are sold over the counter by pharmacists and also on the Internet simply because the product is not registered and therefore not scheduled as it should be, and is promoted by the marketer so as to imply that no registration is needed. Examples include glucosamine (S3), silymarin (S3) and DHEA (S5).

Do pharmacists know their schedules, what should be registered and sold on prescription only, pay attention to the contents of 'open shop' products? If they did, and complained about the promotion and sale of products which should not be freely available, the state of the CAM industry would be in a far better state than it is today.

The pharmacist is the custodian of quality medicines and has a responsibility to ensure the public receive effective, safe and quality medicines. Our obligations to ensure quality CAMs are no less than that required of registered medicines.

As indicated above, the majority of CAMs have not been independently checked for quality in South Africa. For a registered medicine, the pharmacist can rest assured that quality, safety and efficacy of the medicine has been assessed by independent evaluators appointed by the MCC, but for a CAM there is no assurance of this. Does the manufacturing site have a valid GMP certificate, has the product been assayed, does it contain the ingredients and the quantities as stated on the label, is the product stable?

The CAMs market has exploded over the past 10 years and the pharmacist is bombarded with meeting consumer demands for advertisement driven products.

The pharmacist (healthcare practitioner) selling CAMs is responsible for pointing out to the consumer the possible deficiencies with respect to CAMs. The public needs to be told that CAMs are not registered or evaluated by the MCC, and claims are (in general) not supported by scientific evidence, at best anecdotal and vaguely circumstantial evidence is provided to support claims of efficacy.

When selling a CAM, the pharmacist (healthcare practitioner) should consider the following:

- Is the CAM registered with the MCC? (Only MCC can register products.)
- If not, are the claims valid/true? What is the quality of evidence provided?
- Are the label-claimed ingredients present in therapeutic concentrations?
- Can the combination of active ingredients support the claims made?
- Is the product from a reputable source/manufacturer?
- Are the marketer's details on the packaging and can they be contacted for product verification; complaints and / or reporting of possible side effects?

Not all CAMs lack quality, efficacy and safety – some are manufactured using excellent GMP, are safe and efficacious and the marketer has documentation to substantiate them. BUT at present there is no way of distinguishing between the 'good' and the 'bad' unless the medicine has been evaluated by the MCC and been registered. And with the backlog at the MCC in registration of prescription medicines, this is unlikely to happen in the near future.

The proposed Regulations to the Code of Marketing Practice relating to complementary medicines, published in July 2004, have not yet been re-published for public comment. Until such time as these regulations are finally written into law, there will probably be no independent evaluation of the efficacy, quality and safety of CAMs, and unless any complaints about the advertising of CAMs are assessed by healthcare scientists, the situation is unlikely to change.