Quality of pharmaceutical print advertising in South Africa – assessment of reproductive health advertisements 2001–2005

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Abstract

Background: Pharmaceutical advertising, in a variety of forms, has been shown to influence prescribing behaviour. Regulatory systems have therefore been concerned with the quality of advertising and compliance with either imposed or self-regulatory codes of practice. Although the South African Medicines Act provides for an enforceable code of practice, the draft version published in 2004 has yet to be put into effect. This study aimed to assess the quality of pharmaceutical advertisements for reproductive health products, published in South African medical publications over the period 2001 to 2005. Compliance with the draft code of practice was considered, as well as the usefulness of the code itself.

Methods: Half-page and larger print advertisements for reproductive health medicines were sought from two South African peer-reviewed and four non-peer-reviewed medical publications. Advertisements published in three consecutive months in 2001 to 2005 were selected. This period represented the period prior to legislation being developed and the period during which the code of practice was developed and published for comment. Details from each advertisement were captured independently by two reviewers using a pre-determined, pre-tested 60-question questionnaire. Differences were resolved by consensus. The questionnaire was pre-tested and adapted before being applied. Questions sought to identify characteristics of the advertisement that were indicative of quality relating to claims and evidence used in support of the claims, as well as adherence to the draft code of practice. The number of claims made in each advertisement was identified, and for each claim the evidence provided in the form of references was assessed.

Results: A total of 136 reproductive health product advertisements were retrieved from 105 medical publications. Only 63 advertisements were unique. On average each medical publication selected contained 1.3 reproductive health product advertisements. All but three advertisements were for registered orthodox medicines. A total of 191 'claims' could be discerned in advertisements placed in medical publications (average 3.0 'claims' per advertisement). Only 7/103 (6.8%) references cited in unique advertisements in medical publications could be retrieved in abstract form from Medline, and only 1/7 (14.3%) of these references could be retrieved in free full-text format. In total, 14/103 (13.6%) of the references cited in advertisements placed in medical publications were listed as "data on file". Compliance with the relevant general regulation was easier to judge, and seen more often, than was the case in respect of the more subjective elements included in the draft code of practice.

Conclusions: The quality of advertisements for reproductive health products placed in medical publications appears to fall short of at least some of the requirements of both existing and draft regulatory instruments. This may potentially have deleterious consequences for both prescriber and consumer behaviour. The draft code of practice is, however, often difficult to apply in an objective and consistent manner, and may be open to interpretation and therefore variable standards of quality.

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Introduction

The potential influence of commercial sources of information on medicines, such as printed advertisements, on the prescribing behaviour of health professionals has long been a source of concern.[1] Control over the content and quality of pharmaceutical advertising is therefore considered to be a key element of medicines regulatory practice. In South Africa, the National Drug Policy, approved by the Cabinet in 1996, committed to the following stance: "The objective is to ensure that advertising and marketing of drugs shall be in keeping with the National Drug Policy, and in compliance with national regulations, as well as with voluntary industry standards. All promotion-making claims shall be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They shall not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks. Promotional material shall not be designed to disguise its real nature."[2] This was codified in the Medicines Act, Section 18C, which reads as follows: "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."[3] Following the withdrawal of the court action blocking the promulgation of the 1997 Amendment Act which introduced this section, this envisaged code of practice was co-developed by the pharmaceutical industry and representatives of the regulatory authority. It was published

as part of a draft set of General Regulations to the Medicines Act in May 2004.[4] Although comment was invited and received, these regulations were never issued in final form. The code of practice therefore remains in draft form only and unenforced. General Regulation No. 45, covering the advertisement of medicines, was brought into effect in 2003, and remains the only extant regulatory instrument in this area.[5]

The code of practice, which deals with the marketing of medicines in South Africa, is divided into five parts. The five parts deal with marketing to health care professionals; marketing to the general public; marketing of complementary medicines to healthcare professionals; marketing of complementary medicines to the general public; and the authority of the code. Part 1A of the code, with particular reference to clauses 1 to 5, was relevant to this study in that it dealt with the marketing of medicines to healthcare professionals with specific reference to registration; prescribing information and other obligatory information; abbreviated advertisements; journal advertisements; and information, claims and comparisons.

The extent to which the requirements of the code are already adhered to, or whether there has been movement towards compliance over time, has not been assessed in South Africa. No assessments of the quality of print or other forms of advertisements for medicines in South Africa have been published. This study aims to assess the quality of pharmaceutical advertisements for reproductive health products, published in South African medical publications over the period 2001 to 2005. Compliance with the draft code of practice was considered, as was the usefulness of the code itself. Reproductive health was chosen as an exemplar based on the wide range of possible products, the applicability to both male and female medical care and the likelihood that new product advertisements would appear in the period under review. No single pharmacological category has been selected in other studies, making comparison on this basis impossible.

Methods

Half-page and larger print advertisements for reproductive health medicines were sought from a range of South African peer-reviewed *(South African Medical Journal, South African Family Practice)* and non-peer-reviewed *(CME, Medical Chronicle, Modern Medicine, Update)* medical publications. Advertisements published in January, February and March of the years 2001 to 2005 were selected. This period represented the period prior to legislation being developed (in particular the Medicines and Related Substances Control Amendment Act, No. 90 of 1997) and the period during which the code of practice was developed and published for comment. Where a publication from a particular month could not be sourced, the issue from the next available month in the same year was used. Advertisements for both complementary and orthodox medicines were sought, covering areas such as fertility, contraception, pregnancy, menstruation, menopause and sexual dysfunction.

Details from each advertisement were captured independently by two reviewers using a pre-determined questionnaire. Both reviewers are pharmacists with postgraduate training in pharmacology. One (AS) has extensive experience in the marketing of pharmaceutical products, while the other (AG) is experienced in the field of drug policy and rational medicines use. Differences were resolved by consensus. The questionnaire (which is attached) was pre-tested and adapted before being applied. The questionnaire comprised 60 questions, of which three were specific to consumer publications. Questions sought to identify characteristics of the advertisements that were indicative of quality relating to claims and evidence used in support of the claims, as well as adherence to the draft code of practice. The number of claims made in each advertisement was identified, and for each claim the evidence provided in the form of references was assessed. References cited were searched for in Medline (PubMed) and, if possible, retrieved in free full-text format.

Results

A total of 136 reproductive health product advertisements were retrieved from 105 medical publications. There was evidence of substantial use of the same advertisement across different publications. Only 63 advertisements from medical publications were unique. On average each medical publication selected contained 1.3 reproductive health products. The sources of these advertisements over time are shown in Table I. All but three advertisements were for registered orthodox medicines. All three advertisements for unregistered complementary medicines appeared in non-peer-reviewed medical publications.

Table I: Source of advertisements over time

Year of publication	2001	2002	2003	2004	2005	Total
Medical publications (total)	34	12	24	32	34	136
Medical publications (unique)	14	8	14	13	14	63

A total of 191 'claims' could be discerned in 63 unique advertisements placed in medical publications, with an average of 3.0 'claims' per advertisement. 'Claims' were deemed to be statements relating to efficacy, safety, tolerability or quality. Examples are statements such as "enhancing quality of life" in relation to an advertisement for a hormone therapy preparation or "release the crush of osteoporosis".

The number of references cited in each advertisement in a medical publication ranged from 0 to 12. Only 7/103 (6.8%) references cited in unique advertisements in medical publications could be retrieved in abstract form from Medline (PubMed). Only 1/7 (14.3%) of these references could be retrieved in free full-text format. In total, 14/103 (13.6%) of the references cited in advertisements placed in medical publications were listed as "data on file".

The placement of advertisements in close proximity (on either the opposite page, same page or overleaf) to an article or advertorial on a related subject was identified in 24/63 (38.1%) advertisements.

Compliance with selected elements of the relevant general regulation dealing with advertising (General Regulation 45, issued in terms of the Medicines and Related Substances Act, No. 101 of 1965) and the draft code of practice is shown in Table II. For unique advertisements placed in medical publications, high levels of compliance with the objective and well-established standards related to inclusion of the approved (generic) and proprietary (trade) names, quantitative list of active ingredients, scheduling status, registration details and details of the licence holder (manufacturer) were shown. Although the number of unique advertisements retrieved from consumer publications was low, the level of compliance with these requirements (which related more directly to the existing General Regulation 45) was far lower. In the case of the three advertisements for unregistered complementary medicines, compliance with some of these requirements was not possible.

Table II: Compliance with existing and proposed standards

Quality standard	Medical publications (n = 63 unique advertisements)	
	n	%
Name of medicine (proprietary and approved name) included	57	90.5
Quantitative list of ingredients (using approved names)	56	88.9
At least one indication consistent with the approved package insert	49	77.8
Statement of information relating to dosage and method of use, relevant to indications quoted in the advertisement, and consistent with the package insert	10	15.9
Statement of information relating to side effects, precautions and contraindications, relevant to indications quoted in the advertisement, and consistent with the package insert	7	11.1
Scheduling status and pharmacological classification	57	90.5
Registration number, name and address of registered licence-holder or part of business responsible for sale and supply	52	82.5
Placement of approved name of medicine or list of active ingredients (using approved names) immediately adjacent (before/after/above/below) to the most prominent display of the proprietary name in at least 6-point Helvetica bold	16	25.4
Relevance of the artwork (charts/graphs/tables) to the claims and comparisons made	nd	-
Artwork presented in a clear (labelled adequately), fair (not giving visually misleading impression of the data shown), balanced (complete information supplied) manner	nd	-
Logo and trade dress subordinate in size, concentration of colours and visual impact to the proprietary (trade) name of the medicine	29	46.0
Relevance of the illustration to the indication	10	15.9
Relevance of the target market to the indication	21	33.3

nd – could not be determined

Elements included in the draft code of practice were more likely to be difficult to assess or ambiguous. Only 10/63 (15.9%) unique advertisements placed in medical publications included both recommended dosages and methods of use. Side effects and special precautions were mentioned in 7/63 (11.1%) of such advertisements. Compliance with the requirements in regard to the placement and size of the proprietary name was seen in only 16/63 (25.4%) of such advertisements.

Judgment of the relevance of the artwork to the indication or of the supposed target market to the indication is highly subjective. Although low levels of compliance were adjudged, these findings could be challenged. Levels of compliance were therefore indicated as "not determined".

Discussion

Print advertisements remain an important part of the marketing efforts of pharmaceutical manufacturers, especially in countries that do not provide for legal advertising of prescription medicines to the general public. In South Africa, an exception to the general regulation prohibiting the advertising of prescription medicines to the public allows the advertiser to announce the price of a particular pack size and strength of a product. Advertising of the indication for which a prescription medicine is registered, without mentioning the name of the medicine, but including elements of the "trade dress", such as a logo or colour associated with the product, is not specifically proscribed. Print advertisements in publications intended for the professional audience can, however, contain far more details, provided they comply with the minimum requirements of the general regulations. Such advertisements can be considered to be complementary to the efforts of sales representatives and industry-associated educational events. The publications in which these advertisements appear and the pharmaceutical manufacturers have been described as "uneasy bedfellows", as the journals are heavily dependent on advertising for revenue, but can exert little influence over the quality of such advertising.[6]

The volume of print advertising for pharmaceutical products is immense, and this study therefore chose to focus on a single area in which a range of products was expected to be advertised. Similar studies have focused on different clinical areas, such as antihypertensive medicines, lipid-lowering agents and medicines for rheumatology.[7,8,9] Each of these studies used a cross-sectional design. Although this study set out to cover a specific time period, the extensive re-use of the same or similar advertisements in different years precluded the use of any time series analyses.

As only 7/103 (6.8%) references cited in unique advertisements in medical publications could be retrieved in abstract form from Medline, the quality of these references was not assessed. Greving et al have recently shown the references cited in advertisements for antihypertensive agents in a Dutch medical journal to be of questionable relevance.[7] In 35% of the unique advertisements assessed, the claims made were not supported by the evidence presented. A cross-sectional analysis of advertisements in six 'popular' Australian medical publications showed that only 45% of the claims made were supported by "compelling evidence" (defined as a randomised clinical trial or better).[10] A more recent study of advertisements in reputable rheumatology journals showed that only 6.4% of the 190 referenced claims in 84 unique advertisements were "well supported" by the literature cited.[9] These results were broadly in concert with those from older studies, also conducted in North America.[11]

A particular problem is faced by any reader of advertisements when the reference cited is in the form of "data on file". In this study, 14/103 (13.6%) of the references cited in advertisements placed in medical publications were in this format. Such references cannot be retrieved without contacting the manufacturer. Lexchin and Holbrook assessed the quality of references cited in advertisements placed in the most widely-read peer-reviewed Canadian medical journal. Of the 87 references requested from advertisers, 10 (11.5%) were listed as "data on file", and only six were supplied. The methodological quality of such studies cannot be assessed without access to the original material. In the study of advertisements for rheumatology products, 54.6% of those references considered to be poor support for the claims made, the source was listed as "data on file".[9] An analysis of 438 unique advertisements appearing in the 1999 issues of 10 American medical journals (nine of which were peer-reviewed) showed that 28% of the 721 references cited were listed as "data on file".[12,13]

Similar problems have also been detected in other marketing media used to bring medicine-related information to the attention of prescribers. An analysis of the advertisements included in Australian prescribing software showed that compliance with the requirements for included information was far from universal.[14] Only 11% provided a substantiating reference. Printed brochures are another common form of marketing aid provided to prescribers. Such brochures may highlight the results

of a single study. An American analysis found that 75.0% of 20 such brochures contained claims supported by the original study.[15] A more wide-ranging study, based on 175 different brochures collected from 45 Pakistani general practitioners' offices showed that 44.4% of the 559 references cited were not traceable in PubMed.[16] Of those that were traceable, 63.5% made "justifiable" claims. Only 1.4% were cited as "data on file".

Citation of "evidence" is not the only way in which a marketing message can be conveyed. Ferner has argued that advertisers are "increasingly using symbols to circumvent logical argument when trying to persuade people … to make choices that are not strictly rational".[17] Graphical representations of data or the subtle juxtaposition of advertising and non-advertising material may serve this purpose. In this study, a considerable proportion of advertisements in both medical and consumer publications were placed in close proximity to an article or advertorial on a related subject. This practice requires the active involvement of both parties. While acknowledging that the current business model for most medical journals is reliant on advertising revenue, it has been suggested that acceptance of such revenue sources "compromise[s] the objectivity of journals".[18]

The greatest difficulty was experienced when attempting to apply the elements of the draft code of practice that deal with the subtleties of image and symbol. Item 5.8 of the draft code states that: "All artwork, including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made". Graphs are commonly utilised in medical brochures that attempt to convey scientific evidence. Cardarelli et al showed that 95% of 20 such brochures include at least one graph.[15] A study specifically addressing this issue showed that 36% of 74 graphs in 64 unique advertisements could be considered to include numerical distortions.[19] Examples included improperly scaled or split axes, 3-dimensional elements that improperly compared volume instead of other properties such as length, and improper baselines. While assessing compliance with the 'letter' of a code is somewhat easier, compliance with the 'spirit' of the code must, of necessity, be highly subjective.

A key element of Section 18C of the Medicines Act is the requirement that the code of practice be "enforceable". Reliance on industry self-regulatory codes has long been criticised.[20,21] Shapiro has argued that "[o]ur best hope of counteracting the power and influence of the drug industry lies in regulation by government agencies, whose interest is the protection of the public".[22] Even if such regulation were in force, health professionals would still need to be empowered to assess all marketing materials critically.[23] Although this study was limited in the type of advertisements sought, the publications searched and the elements assessed, the results obtained mirrored those from a wide variety of settings. The need for effective regulation of the quality of pharmaceutical advertising, of various types, would seem to be established. Although a trend towards more consumer-directed advertisements was shown, as well as advertisements for unregistered complementary medicines, whether this represents an attempt to escape the more stringent control of the envisaged code cannot be stated with any certainty. It does, however, point to the need for effective regulation of all forms of advertisements and products.

Conclusions

The quality of advertisements for reproductive health products placed in medical publications appears to fall short of at least some requirements of both existing and draft regulatory instruments. This may potentially have deleterious consequences for prescriber behaviour.[24] The draft code of practice is, however, often difficult to apply in an objective and consistent manner, and may be open to interpretation and therefore variable standards of quality.

References

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QUESTIONNAIRE:			
A.	**GENERAL INFORMATION**		
1.	**Month of publication:**	☐ January ☐ February ☐ March	
2.	**Year of publication:**	☐ 2001 ☐ 2002 ☐ 2003 ☐ 2004 ☐ 2005	
2.1.1.	Name of publication:	☐ SAMJ ☐ SAFP ☐ CME	
		Medical Chronicle ☐ Modern Medicine	
2.2.	Which of the following categories does the publication fit:		
2.2.1.	Peer reviewed	☐ Yes	☐ No
2.2.2.	Not peer reviewed	☐ Yes	☐ No
3.	**Is the ad positioned in proximity (opposite page, same page, overleaf) to an article or advertorial on a related subject or condition:**	☐ Yes	☐ No
4.	**Does the ad contain a reference:**	☐ Yes	☐ No
4.1.1.	If yes how many references:		
4.1.2.	How many of these references are retrievable from Pubmed:		
B.	**TECHNICAL CONTENT**		
1.	**How many claims have been made in the ad?:**		
2.	**How many claims have been referenced?:**		
3.	**What medical condition information is supplied in the ad:**		
3.1.	Condition name:	☐ Yes	☐ No
3.2.	Misconceptions:	☐ Yes	☐ No
3.3.	Prevalence:	☐ Yes	☐ No
3.4.	Symptoms:	☐ Yes	☐ No
3.5.	Typical patient profile:	☐ Yes	☐ No
4.	**What treatment information is supplied in the ad:**		
4.1.	Competing treatments:	☐ Yes	☐ No
4.2.	Mechanism of action:	☐ Yes	☐ No
4.3.	Success rate:	☐ Yes	☐ No
4.4.	Supportive behaviours:	☐ Yes	☐ No
4.5.	Time to onset of action:	☐ Yes	☐ No
4.6.	Treatment duration:	☐ Yes	☐ No
4.7.	Class of drug:	☐ Yes	☐ No
4.8.	Dosage:	☐ Yes	☐ No
5.	**Does the ad contain any of the following:**		
5.1.	Inadequate indications:	☐ Yes	☐ No
	(e.g. "Tranquility with simplicity", "Light up your patients day")		
5.2.	Approved/reliable:	☐ Yes	☐ No
	(e.g. "You can trust it. Prescribe it", "The drug most used by doctors")		
5.3.	Standard or reference medication:	☐ Yes	☐ No
	(e.g. "World leader in X", "first choice", "WHO reference drug")		
5.4.	Approved by a responsible agency:	☐ Yes	☐ No
	(e.g. "Approved by the MCC")		
5.5.	Absence of interactions:	☐ Yes	☐ No
	(e.g. "Does not have drug interactions")		
5.6.	The most prescribed one:	☐ Yes	☐ No
	(e.g. "The most prescribed antidepressant")		
5.7.	Quick relief:	☐ Yes	☐ No
	(e.g. "Rapid onset of action", "immediate relief")		
5.8.	Suggestion of a wide spectrum:	☐ Yes	☐ No
	(e.g. "for all types of anxiety", "wide solution")		
5.9.	Physiological action:	☐ Yes	☐ No
	(e.g. "The right physiological answer")		
5.10.	Certainty of efficacy:	☐ Yes	☐ No
	(e.g. "Will work each time, every time")		
5.11.	Pharmacokinetics:	☐ Yes	☐ No
	(e.g. "Superior pharmacokinetics for a better life")		
6.	**How would the advertising slogan be classified?**		
6.1.	Claims of efficacy:	☐ Yes	☐ No
	(e.g. With improvement of outcomes)		
6.2.	Claims of safety:	☐ Yes	☐ No
	(e.g. Reduction in adverse effects)		
6.3.	Claims of convenience:	☐ Yes	☐ No
	(e.g. Ease of administration, improvement of dose)		
6.4.	Claims of cost:	☐ Yes	☐ No
	(e.g. Low price, better cost effectiveness ratio).		
6.5.	Claims of prevalence:	☐ Yes	☐ No
6.6.	None of the above:	☐ Yes	☐ No
6.7.	Unsure:	☐ Yes	☐ No

Complete for each claim made within the advert.

7.	**How would you classify the claim:**		
7.1.	Unambiguous clinic outcomes:	☐ Yes	☐ No
	(e.g. When compared with DRUG X, DRUG Y delivers faster symptom relief. End points e.g. mortality, infarcts, and readmissions)		
7.2.	Vague clinical outcomes:	☐ Yes	☐ No
	(e.g. DRUG X is the new, effective 20mg pill with a low incidence of discontinuation due to skin irritation. Surrogate end points e.g. decrease in arterial pressure, lipid concentrations)		
7.3.	Emotive or immeasurable outcome:	☐ Yes	☐ No
	(e.g. DRUG X is one of a kind or DRUG X is a source of healing power)		
7.4.	Non clinical outcome:	☐ Yes	☐ No
	(e.g. Using DRUG X resulted in a 30% increase in arterial luminal diameter in post-mortem dissections. I.e. drug plasma t1/2 or biochemical marker. Pathophysiological endpoints e.g. regression of atheroma plaques, changes in arterial diameter.)		
7.5.	None of the above:	☐ Yes	☐ No

Points 8 - 9 are to be complete for each reference.

8.	**What is the level of evidence used to support the claim?**		
8.1.	Is the claim supported by level 1 evidence:	☐ Yes	☐ No
	(i.e. Meta-analysis or systematic review)		
8.2.	Is the claim supported by level 2 evidence:	☐ Yes	☐ No
	(i.e. Randomized controlled trial)		
8.3.	Is the claim supported by level 3 evidence:	☐ Yes	☐ No
	(e.g. Other study e.g. cohort)		
8.4.	Is the claim supported by level 4 evidence:	☐ Yes	☐ No
	(e.g. Expert opinion, data on file, conference proceedings)		
9.	**What are the financial sources of the study being described?**		
	The study is funded by:		
9.1.	Pharmaceutical industry:	☐ Yes	☐ No
9.2.	Nonprofit organization:	☐ Yes	☐ No
9.3.	Mixed financing:	☐ Yes	☐ No
9.4.	Government:	☐ Yes	☐ No
9.5.	Not stated:	☐ Yes	☐ No
9.6.	Unsure:	☐ Yes	☐ No

Points 10 - 17 are only to be completed for adverts where references corresponded to Level 1 or 2 evidence. Complete for each Level 1 and 2 evidence.

10.	Was the study described as randomized:	☐ Yes	☐ No
	(i.e. This includes words such as randomly, random and randomization)		
11.	Was the method used to generate the sequence of randomization described and appropriate:	☐ Yes	☐ No
	(i.e. Table of random numbers, computer generated)		
12.	Was the study described as double blind:	☐ Yes	☐ No
13.	Was the method of double blinding described and appropriate:	☐ Yes	☐ No
	(e.g. Identical placebo, active placebo, dummy)		
14.	Was there a description of withdrawals and drop-outs:	☐ Yes	☐ No

15.	Was the method used to generate the sequence of randomization was described and was inappropriate: (e.g. Patients were allocated alternatively, or according to date of birth, hospital number)	☐ Yes	☐ No
16.	Was the study described as double blind but the method of blinding was inappropriate: (e.g. Comparison tablet vs. injection with no double dummy)	☐ Yes	☐ No
17.	Quality of the quantitative data quoted:		
17.1.	Was the p value given:	☐ Yes	☐ No
17.2.	Were Confidence Intervals given:	☐ Yes	☐ No
17.3.	Was the number needed to treat explicitly stated, if pertinent:	☐ Yes	☐ No
17.4.	Power mentioned, if pertinent:	☐ Yes	☐ No
C.	**COMPLIANCE WITH THE CODE OF MARKETING PRACTICE:**		
	All adverts to be reviewed.		
1.	**Does the following information appear in the ad:**		
1.1.	Name of the medicine: (i.e. both proprietary and approved name)	☐ Yes	☐ No
1.2.	Quantitative list of the active ingredients using approved name:	☐ Yes	☐ No
1.3.	At least one indication consistent with the package insert:	☐ Yes	☐ No
1.4.	Statement of information relating to dosage and method of use relevant to the indications quoted in the ad and consistent with the package insert:	☐ Yes	☐ No
1.5.	Statement of information relating to side effects, precautions and contra indications relevant to the indications quoted in the ad and consistent with the package insert:		
1.6.	Any warnings issued by the MCC and required to be included in the ad:	☐ Yes	☐ No
1.7.	Scheduling status and pharmacological classification:	☐ Yes	☐ No
1.8.	Registration number and name and address of registered license holder or name and address of the part of the business responsible for its sale and supply:	☐ Yes	☐ No
2.	**Does the approved name of the medicine or list of active ingredients using approved names appear immediately adjacent (before, after, above or below) to the most prominent display of the proprietary name in bold type of size 6 point Helvetica typeface in black on white or in type of such size that the approved name or list of active ingredients occupies a total area of no less than that taken up by the proprietary name:**	☐ Yes	☐ No
3.	**Is all the information, claims or comparisons within the ad:**		
3.1.	Accurate: (e.g. Valid comparisons are made e.g. based on therapeutic equivalent dose required for the same indication. Economic evaluations are clinically appropriate. Correct and truthful information is given)	☐ Yes ☐ No ☐ Unsure	
3.2.	Balanced: (i.e. Appropriately highlights side effects and contraindications. It must not raise unfounded hopes of successful treatment or be misleading with respect to safety)	☐ Yes ☐ No ☐ Unsure	
3.3.	Fair: (i.e. Presents a reasonable balance between information relating to efficacy and side effects and contraindications.)	☐ Yes ☐ No ☐ Unsure	
3.4.	Objective: (i.e. If a medicine is described as better than or stronger than or suchlike it must show criteria for comparison. Information is provided in an unbiased manner.)	☐ Yes ☐ No ☐ Unsure	
3.5.	Unambiguous: (Clear and unmistakable information is supplied)	☐ Yes ☐ No ☐ Unsure	
3.6.	Based on the latest evidence:	☐ Yes ☐ No ☐ Unsure	
3.7.	Reflects the evidence: (i.e. Does not misrepresents conclusions of clinical trials)	☐ Yes ☐ No ☐ Unsure	
3.8.	Not misleading: (i.e. Not a deceptive use of data. E.g. Data from in-vitro studies, studies in humans and animals are relevant to the clinical setting. There is a sound statistical basis for information. If no significance is reached it is not represented to look at such.)	☐ Yes ☐ No ☐ Unsure	

4.	**Is a comparison made in the ad:**	☐ Yes	☐ No
	If yes:		
4.1.	Are medicines for the same purpose are compared:	☐ Yes	☐ No
4.2.	Are one or more area of comparison made:	☐ Yes	☐ No
4.3.	Is there any confusion between the medicine advertised and that of the competitor with respect to trademark, proprietary name or other distinguishing feature:	☐ Yes	☐ No
4.4.	Is the trademarks, proprietary name, other distinguishing feature, medicine, services, activities or circumstances of a competitor discredited or denigrated.:	☐ Yes	☐ No
4.5.	Is an unfair advantage being taken of the reputation of a trademark, proprietary name or other distinguishing marks of the competitor:	☐ Yes	☐ No
4.6.	Is the medicine being presented as an imitation or replica of the goods bearing the competitor's trademark or trade name:	☐ Yes	☐ No
5.	**Does the ad contain references:**	☐ Yes	☐ No
	If yes:		
5.1.	Are clear and complete references provided:	☐ Yes	☐ No
5.2.	Can the information, comparisons and claims be substantiated:	☐ Yes	☐ No
6.	Is the artwork (illustrations, graphs, tables, logo and trade dress) relevant to the claims and comparisons being made:	☐ Yes	☐ No
7.	Is the artwork (illustrations, graphs, tables, logo and trade dress) presented in a clear (labeled adequately),fair (not giving visually misleading impression as to the data shown), balanced manner (complete information supplied) relating to the issue that they are dealing with:	☐ Yes ☐ No ☐ Unsure	
8.	Is the logo and trade dress subordinate in size, concentration of colours and visual impact to the trade name of the medicine:	☐ Yes	☐ No
9.	Is the artwork (illustrations, graphs, tables, logo and trade dress) relevant to the indication:	☐ Yes	☐ No
10.	Is it relevant to the target audience relating to the indication: (i.e. Promotes use of the drug in appropriate populations)	☐ Yes	☐ No
11.	Are the words proven safe/ safety or demonstrated safe/ safety used without qualification:	☐ Yes	☐ No
12.	Are there claims of no side effects, toxic hazards or risk of addiction:	☐ Yes	☐ No
13.	Does the ad contain the words 'the best', 'the strongest', 'the widest' etc implying that it is in effect the best:	☐ Yes	☐ No
14.	Does the ad contain the words 'the' and 'unique' other than to define a clearly defined special feature:	☐ Yes	☐ No
15.	Does the ad contain the word 'new' unless the product has been available for less than 12 months on the market:	☐ Yes	☐ No
16.	Does the ad contain a proprietary name of another company's product:	☐ Yes	☐ No
16.1.	If yes – has consent been given:	☐ Yes	☐ No
17.	Does the ad disparage the medicines, products and activities of other pharmaceutical companies:	☐ Yes	☐ No
18.	Does the ad disparage the scientific and clinical opinion of health care professions:	☐ Yes	☐ No
19.	Does the ad resemble advertorial matter:	☐ Yes	☐ No
20.	If yes – does it clearly state that it is advertorial or a sponsored feature:	☐ Yes	☐ No