

Summary Report: Outcomes of complaint MCA 23-02 received by the MCA

Case No: **MCA23-02** Appeal date: **7 March 2023** Report Date: **20 March 2024**

Complainant: Bayer (Pty) Ltd **Respondent:** Acino Pharma (Pty) Ltd

Product involved: Evra Contraceptive Patch

Committee Processes:

The MCA company-to-company complaint resolution process requirements had been complied with by the Complainant prior to submission of the complaint.

The matter was adjudicated upon by a duly constituted committee of three non-conflicted subject experts, acceptable to both the complainant and respondent and chaired by an attorney.

The Adjudication Committee processes were followed as required by the MCA Code.

The Respondent took the decision of the Adjudication Committee, issued on the 15th December 2023, on Appeal.

A separate independent Appeal Committee of three non-conflicted subject experts, acceptable to both parties, was duly constituted and chaired by an attorney.

The matter at hand:

The subject matter of the original complaint was a radio campaign flighted by the Appellant on Jacaranda FM from 6th June to the 11th June 2023, in terms of which a mother and daughter can be heard discussing inter alia the efficacy and convenience of a contraceptive patch, as compared to other forms of contraceptives ["the radio campaign"].

The Adjudicating Committee, having considered the submissions of both the Respondent and Appellant, ruled that:

- The radio campaign constituted advertising of a schedule 3 medicine;
- Information contained in the radio campaign was not factual and / or balanced;
- Given that the Appellant's contraceptive patch is the only contraceptive patch registered to be sold in South Africa, consumers will be made aware of this product when they follow the advice of the radio campaign and ask their doctor or nurse about "the contraceptive patch".
- The above factors were deemed to constitute a breach of sections 14.1, 14.4, 14.4 guideline 3, 14.5.2 and 4.4 of the MCA Code of Practice v15.
- Further, that the open-ended statements / claims made in the radio campaign, relating to the phrase that "the contraceptive patch is way more convenient than other forms of contraceptives" were not adequately substantiated, and hence in breach of sections 5.8.1.4, 5.8. 2.2, 5.8.2.4, 5.9.1, and f5.10.1.2 of the Code.

The Adjudicating Committee applied the following remedies and sanctions to the Respondent;

- The Respondent must sponsor an actual, balanced contraceptive awareness campaign, approved by the MCA, with equivalent public exposure to that of the advertisement complained about on Jacaranda FM.
- The MCA to consider further action as the respondent contravened the Medicines and Related Substances Act 101 of 1965;



- A fine of R 200 000 to be paid to the MCA; and
- Costs to be paid by the Appellant to the Respondent (previously the Complainant) in respect of the Respondent's own costs incurred in pursuing the complaint in question.

Appeal

The decision of the Adjudicating Committee was taken on appeal.

The Grounds for the Appeal.

- "the (Adjudication) Committee failed to proffer sufficient reasons (and in most instances any reasoning at all) for confirming that the Appellant had infringed all of the aspects of the Code, as contended by the Respondent";
- "the (Adjudicating) Committee erred in failing to take cognisance of the true nature and context of the disease awareness campaign in question (nor the fact that it was a disease awareness campaign, not an advertisement, in the first place)";
- "the (Adjudicating) Committee erred in undertaking an analysis of the aired aspect of the campaign in a piece meal fashion"
- "the (Adjudicating) Committee erred in accepting flimsy marketing-related data to refute clinical references upon which the Appellant relied in development of the aired aspect of its disease awareness campaign".

The Appeal Committee ruled as follows;

"the (Adjudication) Committee failed to proffer sufficient reasons (and in most instances any reasoning at all) for confirming that the Appellant had infringed all of the aspects of the Code, as contended by the Respondent";

The Appeal Committee acknowledged that the Adjudication Committee had not provided adequate reasoning to support the rulings made. The Appeal Committee therefore examined the findings of the Adjudication Committee and applied reasons to the findings, either confirming or overturning the findings with reasons.

The Appeal Committee found that the radio campaign constitutes advertising of a Schedule 3 medicine and confirms, with substantiation of each point, the decision of the Adjudicating Committee that the relevant sections of the Code complained about had indeed been breached by the Appellant.

"the (Adjudicating) Committee erred in failing to take cognisance of the true nature and context of the disease awareness campaign in question (nor the fact that it was a disease awareness campaign, not an advertisement, in the first place)";

The Appeal Committee found that, given;

- that the radio campaign was categorically not a disease awareness campaign because amongst other things, no disease is actually identified; and
- that the Appellant's product is the only product in the category of medicines that awareness is created for, and hence if a consumer follows the advice of the radio campaign, a doctor / nurse will necessarily advise the consumer about the Appellant's product;

The Committee concluded that the radio campaign cannot be considered anything else but an advertisement, notwithstanding that the product name is not mentioned and that the average lay consumer may not realise that they are being advertised to (until they actually consult their relevant health care provider).



This finding ties into the definition of "Advertisement" as per section 3 of the Code which includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the sale, use or supply of a health product.

"the (Adjudicating) Committee erred in undertaking an analysis of the aired aspect of the campaign in a piece meal fashion"

The Appeal Committee concluded, in respect of the Appellant's criticism of the manner in which the Appeal Committee had analysed the aired aspect of the campaign in a piecemeal fashion, that in the absence of any evidence of bias or other inappropriate conduct on behalf of the Adjudicating Committee, the Appeal Committee cannot justify any negative inferences being drawn against the Adjudicating Committee, purely on the basis of the format of the ruling and / or that such ruling encapsulated some of the same phraseology as the complaint.

"the (Adjudicating) Committee erred in accepting flimsy marketing-related data to refute clinical references upon which the Appellant relied in development of the aired aspect of its disease awareness campaign".

The claims made in the radio campaign:

"...more and more women like me are choosing a contraceptive patch.," and "And I'm all for it (the contraceptive patch) because a once-a-week patch is way more convenient, I'm a busy woman."

The Appeal Committee found that the claims made were marketing claims rather than clinical claims, that the marketing data submitted did not support these claims and that should the relevant claims on the other hand be regarded as clinical claims, the data provided in support thereof, did not meet the threshold duly required of it.

Appeal Dismissed

The Appeal Committee ruled that the appeal be dismissed.

Sanctions and remedies applied to the Appellant by the Appeal Committee

The Appeal Committee noted;

- that this was the first recorded incident of the Appellant breaching the Code, and
- that the tone and manner of communication of the Appellant was an aggravating factor in considering sanctions.

Taking account of the rulings, the Appeal Committee imposed the following sanctions and remedies on the Appellant:

1. A fine of R100 000.00 (One hundred thousand rand) to be paid to the MCA within 7 days of the ruling being issued (i.e. a reduction in the original fine as issued by the Adjudication Committee).
2. The Appellant need not put out any type of corrective advertisement / radio campaign as referred to in the Adjudicating Committee's decision on account that it may actually draw more attention to the advertising campaign that has since been ruled against.
3. The Appellant need not pay the costs of the Respondent as regards either the adjudication or the appeal
4. The Appellant was warned to abide by both the letter and spirit of the Code.



5. The Appellant was ordered to ensure that all employees are required to become duly Code certified and maintain such Code certification within three months of this ruling.

The Respondent has complied with all the sanctions and remedies imposed by the Committee.

Learnings and comments from the MCA Executive Officer

- The holder of a health product registration licence, the applicant, is responsible for ensuring compliance of the product with the information submitted in the registration application and with the relevant legislation. Moreover, this responsibility rests with the Responsible Pharmacist (in the case of medicines) and the Authorised person (in the case of a medical device company not registered with the Pharmacy Council).
- Advertising of S3 products to the public is a breach of the Medicines Act and the MCA Code of Practice.
- Certification of all customer facing staff at least once in two years is compulsory for Code compliance.
- The disguising of promotional activities is considered to be a breach of the Code.
- In determining whether conduct constitutes "advertising", both the substance and form of the conduct must be born in mind.

Given that the sanctions have been complied with by the Respondent, this matter is now closed.

The rulings will form MCA precedent.

Signed:

Date:

Executive Officer: Val Beaumont

M.Pharm (Ind Pharmacy), M.SC Med (Bioethics and Health Law), FPS