

# MCA CODE ENFORCEMENT

SUMMARY REPORT: Case No MCA 19-01A

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## 1. Case details

Complaint:	19 <sup>th</sup> October 2020
Adjudicating Committee Report:	3rd February, 2020
Appeal:	27 <sup>th</sup> February, 2020
Appeal Committee Report:	15th May, 2020
Non-Compliance Committee Report	28 <sup>th</sup> July 2020
Summary Report:	5 <sup>th</sup> August, 2020
Complainant/Appellee:	Adcock Ingram Critical Care (Pty) Ltd (AICC)
Respondent/Appellant:	Fresenius Kabi (Pty) Ltd (FK)
Product:	Container material for IV fluids

## 2. Complaint

The complaint was lodged following an unresolved company-to-company process. The complaint related to the respondent's marketing campaign, which related to PVC free IV bags and included a comparison of IV container materials of competitive products. The promotional material included a 'wheel' a promotional bag, a conference stand, a banner and a 'one-pager'. The complaint was extensive and alleged numerous provisions of the Marketing Code being transgressed.

### 3. Adjudicating Committee's Ruling

The Adjudicating Committee dealt with the complaints and infringements of the Marketing Code in detail, including raising a number of procedural matters, further set out below. The Committee substantially upheld the complaint and found that all items except the promotional bag infringed the Code and that the claims made were not substantiated. The Adjudicating Committee also found aggravating circumstances and imposed a fine of R150 000 on the respondent. In addition, the remaining material had to be withdrawn from the market, a corrective statement had to be sent to all conference participants and stakeholders and the MCA was tasked with sending a letter of reprimand to the respondent.

### 4. Appeal

The appellant challenged the Adjudicating Committee's ruling, amongst others, on the following basis:

- the process adopted and, in particular, the timelines imposed by the MCA were unnecessarily strict, formalistic and flawed;
- the marketing and advertising material presented at the conference in question did not infringe the Code. It stated, amongst others, that there was an irrefutable international move away from DEHP and that there was growing global recognition of the harmful effects that DEHP exposure could have on both humans and the environment;
- the alleged transgression of the Code was not clear in all respects.

The appellee's response included, amongst others, that

- the appellant infringed the Code as ruled by the Adjudicating Committee and that the appeal was frivolous, vexatious and revealed no grounds of appeal that related to the Marketing Code;
- the appellant did not address any substance i.e. indicating how it complied with the Code and why the Adjudicating Committee erred, but largely relied on

innuendo, assumptions and a rehash of known materials, presented as irrefutable scientific evidence.

## 5. Appeal Committee's Ruling

### 4.1 Code Infringements

The Appeal Committee found that the following provisions of the Code were transgressed by one or more components of the promotional material:

- (a) Section 5.7.1.1.1: Comparisons, which discredit or denigrate a competitor's Health Products, (...) etc.
- (b) Section 5.7.1.1.3: Comparisons with competitor products and activities that are misleading or disparaging.
- (c) Section 5.7.1.5: Points of comparison must be factual and reflect the body of scientific evidence.
- (d) Section 5.7.1.6: Comparisons shall not imply that the Health Products with which comparisons are being made are harmful or ineffectual.
- (e) Section 5.7.2: Accuracy balance and fairness guided by Note 6, which requires that where a clinical or scientific issue exists that has not been resolved in favour of one generally accepted viewpoint, particular care must be taken to ensure that the issue is treated in a fair and balanced manner in Promotional Material.
- (f) Section 5.7.2.2: Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous, based on an up-to-date evaluation of all the evidence and reflect that evidence.
- (g) Section 5.8: Substantiation guided by Notes 1 and 2, which require that only evidence deemed by the Code to be acceptable should be used and that advertisers must hold the evidence for all claims made in advertising. Evidence to support a claim must be

factual, unambiguous, not vague or emotive, or immeasurable, and must be able to be substantiated and stand up to scrutiny. Extreme caution must be exercised when presenting such data.

- (h) Section 5.8.1: All information, claims or comparisons must be capable of substantiation.
- (i) Section 5.8.4: All references must be listed in the advertisement or promotional material.
- (j) Section 5.11.1.1: Health products and activities of other companies shall not be disparaged in any way including the safety, quality, efficacy, effectiveness, and performance.

## 4.2 Ruling

The Appeal Committee upheld the ruling of the Adjudicating Committee and found that:

1. procedurally the correct process was followed;
2. the initial complaint was relevant as it related to the manner in which the data used by the appellant was presented in its marketing material and not the fact that data was available to support the claims; and
3. the intent of the appellant's promotional campaign contravened the Code.

Ruling and sanction:

1. The material/activity had to be immediately withdrawn from the market;
2. The respondent had to issue a corrective statement in accordance with the format prescribed by the Committee, which the MCA had to publish on its website;
3. A letter of reprimand had to be addressed to the appellant by the MCA.
4. A fine of R150 000 payable within 30 business days was imposed
5. A summarised version of the findings of the appeal process had to be published on the MCA website including a summary of the violation and the penalty imposed.

## 6. Procedural Matters

The Adjudicating Committee commented that the way in which the complaint had been articulated was unnecessarily complex and convoluted. It resulted in an exceptionally long and arduous ruling having to be drafted. It also raised a number of general and / or procedural matters of note, namely;

- the fact that several promotional methods referred to in the complaint have ceased, and would not recommence, did not diminish the jurisdiction of the Committee to adjudicate upon the conduct concerned.
- Outcomes from animal studies could not be extrapolated or correlated, and specifically non-primate animal studies, to human outcomes. If no primate/human studies have been conducted, then the company concerned was duty bound to refer to such evidence in terms, which were not categorical, and furthermore explain that the relevant findings of such studies were preliminary and/or indicative in so far as they were linked to or associated with human outcomes.
- the fact that the respondent did not refer to the complainant and/or any of its brands by name did not, in and of itself, mean that the respondent's claims were not disparaging of the complainant and others. Disparagement h be determined by the terminology actually used and the impression likely to have been created by the use of such terminology.

In addition, the Appeal Committee noted that the language and tone of the appellant was inappropriate and unprofessional and was not conducive to the adjudication process.

## 7. Compliance with Ruling

- The Respondent confirmed that the material which was the subject of the complaint was no longer in use
- The Respondent paid the fine of R150000 to the MCA
- A letter of reprimand was sent to the Respondent

## 8. Point of non-compliance

Fresenius Kabi issued a corrective statement which did not fully comply with the Committee ruling in that a paragraph 2 of the statement was omitted.

The Executive Officer raised a Non-Compliance complaint in terms of S16 of the Code.

4. The Respondent argued for the omission of paragraph 2 of the statement on the basis of the findings of the Appeal Committee that “the initial complaint was relevant as it related to the manner in which the data used by the appellant was presented in its marketing material and not the fact that data was available to support the claims; and that the intent of the appellant's promotional campaign contravened the Code.

A second Appeal Committee was appointed to decide on the matter of the Non-Compliance.

### Evaluation of the Complaint by Appeal Committee

1. In the evaluation of the complaint and in making its determination, the Appeal Committee was mindful of its powers as set out in clause 16 of the Marketing Code, particularly clause 16.22.10 thereof.
2. The Appeal Committee took into consideration the reasons for the finding of both the Adjudicating Committee and the Appeal Committee, the sanctions imposed by both committees, as well as, and importantly, the purpose and spirit of the Marketing Code itself and the objectives of the Marketing Code Authority (which are set out in its Constitution).

In this regard the Appeal Committee found that both the Adjudicating Committee and the Appeal Committee acted reasonably and fairly when evaluating the matter and that the sanctions that they imposed were, in most respects, appropriate, when one considers the spirit of the Marketing Code.

In as much as the Marketing Code Authority ought to enforce the provisions of the Marketing Code by ensuring that the sanctions of an Adjudicating Committee or Appeal Committee authority are adhered to, it should not act to persecute the party against whom the sanction has been imposed

3. The Appeal Committee also took into consideration the Respondent's conduct in its compliance with the sanctions. The Respondent complied in all respects with the corrective actions, save for just the one aspect of remedy C (the completeness of the corrective statement), and paid the penalty of R150,000. Appeal Committee is of the opinion that the respondent is not acting disingenuously and is making a concerted attempt to comply with the rulings in as far as is reasonable as far as they are reasonable

It is noteworthy, though, that the respondent failed to raise the contents of its response to the Non—Compliance Complaint during the initial Appeal, however it is not for this Appeal Committee to speculate on the reasons therefore

4. In considering the corrective statement as recommended by the Appeal Committee, this Appeal Committee found that the insertion or omission of paragraph 2 therefore did not take the statement any further if inserted, nor did it detract from its impetus if omitted.
5. There was no evidence, angle, or persuasion in any other supporting documents under consideration when evaluating this matter that was overwhelming enough to warrant insertion of paragraph 2
6. The Appeal Committee is of the view that paragraph 2 is unnecessary and will go beyond what is reasonably necessary if there is a demand for the insertion of paragraph 2 in the corrective statement.

#### Sanctions/Remedies

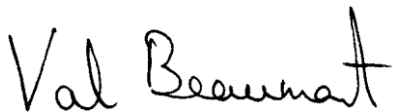
1. The Respondent was directed to forthwith furnish the Marketing Code Authority with its amended corrective statement for publication on the Marketing Code Authority's website together with the rulings.
2. No other order was made.

The Corrective Statement follows at the end of this summary.

#### Comments by the Executive Officer on process:

All processes in this matter were protracted beyond normal allowable timelines for a number of reasons, including;

- the complaint and appeal documentation had to be returned to the parties for non-compliance with MCA submission requirements;
- the adjudication process fell over the annual shut down and key staff within the companies were not available to supply information;
- the Adjudicating Committee requested additional information from both parties;
- parties requested extensions, most of which were granted;
- the appeal process coincided with the national Covid-19 lockdown;
- the lockdown created challenges in identifying and appointing non-conflicted legal panel representatives to chair the Appeal Committee



M.Pharm (Industrial Pharmacy)

Executive Officer

Date 4<sup>th</sup> August, 2020

For further information on the complaints processes of the Marketing Code Authority contact the Executive Officer, Val Beaumont, [Val@marketingcode.co.za](mailto:Val@marketingcode.co.za).

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