



MCA COMPLAINT: ADJUDICATION COMMITTEE SUMMARY REPORT

Report on outcome of Complaints Received by The Marketing Code Authority

Date: 7 Sept, 2018
Director

Summary Prepared By: Executive

Complaint Reference: MCAC10

Complainant: Boehringer-Ingelheim South Africa

Respondent: AstraZeneca

Product: Forxiga (Dapagliflozin)

1. The facts as established by the Committee, or where it cannot be established:

Reference to clause in code	Briefly describe each alleged infringement (refer to all related promotional items) .	Code was infringed YES/No	If infringement is the finding, is the infringement still ongoing and needing to be dealt with
Old Code 26.1	Indication of Forxiga is T2D for glycaemic control as monotherapy or add-on therapy, with diet and exercise. Forxiga as a drug to address CV risk is not an approved indication, and hence off-label.	No	Distribution of hand-out ceased & withdrawn
Old Code 26.1	Branded materials (Forxiga) with clinical trial information that has not been evaluated by the MCC, further implying benefits beyond the approved indication of the drug. Furthermore, comparing a randomised controlled trial (EMPA-REG OUTCOME) to evidence from real world evidence (CVD-REAL) is misleading, with	No	Distribution of hand-out ceased & withdrawn

	statements that Forxiga has “no increase in the primary cardiovascular (CV) composite endpoints of cv death, stroke, myocardial infarction and hospitalisation for unstable angina” promoting off-label information. In addition, suggesting possible CV benefits on a broad population inferred because 87% of patients in CVD-REAL did not have known cardiovascular disease, is misleading.		
Old Code 26.1 26.4 26.5	Critical misinformation statement like “the only SGLT2 inhibitor with 4 years of proven efficacy” is misleading as information exists for other SGLT2i such as Empagliflozin.	No	Distribution of hand-out ceased & withdrawn

Remedies imposed on the Respondent to address the infringement:

No corrective action is to be imposed.

Sanction imposed by the Committee:

No sanctions are to be imposed in the circumstances.

Cost order for fees payable to the Respondent/Complainant:

There is no order as to costs.

Cost order for MCA costs:

There is no order as to costs.

2. Concluding remarks:

Nil

3. Rights:

Should the Complainant not be satisfied with the ruling of the Adjudicating Committee, the Complainant may lodge an appeal with the Executive Officer of the Marketing Code Authority which appeal must be lodged in writing within 5 days of receiving the findings of the Adjudication Committee. Such appeal may be on either procedural, substantive, interpretation or any other ground.



The full, committee-signed report, is on file with the MCA.

Val Beaumont

..... Date :.....
Executive Officer

For further information on the complaints processes of the Marketing Code Authority contact the Executive Officer, Val Beaumont, Val@marketingcode.co.za

Related Information for the record.

The Complainant lodged an appeal on the 28th September, 2018, but subsequently withdrew it on 12th October. The reason given was that further evidence necessitated the submission of a totally new complaint. The Appeal fee was refunded by the MCA.

It was noted on the closing correspondence (14th October) that a new complaint was to be submitted following the discovery of further possible breaches by the Respondent. MCA gave the advice that company-to-company dialogue was required for any new issues being raised.

VJB: January, 2020
