

**MCAC 05 2014**

***BOEHRINGER- INGELHEIM PHARMACEUTICALS (PTY) LTD***

***AGAINST SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD***

**Adjudication**

30<sup>th</sup> April 2014

**Committee Members:**

3 MCA Panelists (1 Legal)

In this matter, the complainant, Ingelheim alleged that the respondent, Servier was in breach of the Marketing Code and the Medicines and Related Substances Act (Act 101, 1965) by promoting off-label claims and inadequately substantiating some of the claims in the promotional material.

1. The Complainant has taken issue with the use of the statement **“With proven mortality benefits for the combination of perindopril/amlodipine”** by the Respondent in the launch promotional material for the product COVERAM®. The Complainant argues that since this is not included in the latest approved package insert for COVERAM®, it is in contravention of clauses A4.2 and A5.2.5 of the Code.
2. The Respondent is of the view that the information available in the package insert must be viewed as distinctly different from information that relates to the effects of product use within the registered indications, nullifying the applicability of clauses A4.2 and A5.2.5 of the Code. The Respondent also argues that the results of the ASCOT BPLA1 study adequately support the use of this statement.
3. The Complainant disputes the relevance and applicability of the ASCOT BPLA to support the statement in 1 above.
4. The Complainant further states that the use of the statement **“Introducing the only RAASi/CCB combination with proven mortality benefits”** by the Respondent in the launch promotional material for the product COVERAM® is in contravention of clause A7.2 of the Code as it has not been adequately substantiated, and as in 2.1 above the **“proven mortality benefits”** are not included in the latest approved package insert.
5. The Respondent provided a table of all-cause mortality and cardiovascular mortality in outcomes trials of RAS inhibitor/CCB regimens in patients with hypertension which in their view substantiates this claim.

6. The Complainant complains that the following statement contained in the launch promotional material for the product COVERAM® is in contravention of clause A7.2 of the Code as it has not been adequately substantiated:  
**5mg perindopril arginine is equivalent to 4mg perindopril terbutylamine**  
**10mg perindopril arginine is equivalent to 8mg perindopril terbutylamine**
7. The Respondent is of the view that since the bioequivalence data between perindopril arginine and perindopril terbutylamine was submitted to the Medicines Control Council (“MCC”), and was the basis of the approval of the perindopril arginine salt in 2005, there is no need to reference, nullifying any contravention of clause A7.2 of the Code.

Upon careful consideration of the matter the panel has made the following ruling:

1. Contravention of clauses A4.2 and A5.2.5 of the Marketing Code:
  - a. The statement “with proven mortality benefits for the combination of perindopril/amlodipine” does not contravene the marketing Code as it is consistent with the most recently approved package insert.
2. Contravention of clauses A7.2 of the Marketing Code:
  - a. The statement “introducing the only RAASi/CCB combination with proven mortality benefits” has not been substantiated.
  - b. All current promotional material that contains this statement must no longer be circulated or used.
  - c. The respondent must not be found guilty of a similar transgression of clause A7.2 within the next two years.
3. Contravention of clauses A7.2 of the Marketing Code
  - a. The statement of equivalence between the two perindopril salts is inferred, but not substantiated.
  - b. All current promotional material that does not contain substantiation must no longer be circulated or used.
  - c. The substantiation must be implemented with immediate effect for all future promotional material where a statement of equivalence between the perindopril salts is made.
  - d. The respondent must not be found guilty of a similar transgression of clause A7.2 within the next two years
4. In terms of Clause 57.5.7 of the Marketing Code, Servier is to pay Ingelheim 50% of the lodging and adjudication fees incurred by Ingelheim within 30 days of receipt of the adjudication report.
5. No additional fine will be levied provided these rulings are complied with.

## **Appeal**

18<sup>th</sup> May 2014

## **Committee Members:**

3 MCA Panelists (1 Legal)

## **The Scientific Claim**

The Appeal Committee agrees with the finding of the Adjudicating Committee and uphold their decision. The Appeal must fail.

## **Sanction**

The Appeal Committee is satisfied with the finding of the Adjudicating Committee (“that all current promotional material that contains the erroneous statement must no longer be circulated or used”). Further to this the Appeal Committee substitutes the finding of the Adjudicating Committee by ordering the Respondent to provide such evidence to the Executive Officer of the MCA within 60 (sixty) days from the date of this Ruling.

## **Costs**

There is no order as to costs.