THE ADJUDICATION PANEL OF THE MARKETING CODE AUTHORITY OF SOUTH AFRICA

Case No: MCAC07 2016

Date: 20 May 2016

In the matter between:

GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD **Complainant**

MERCK (PTY) LTD **Respondent**

3 Committee members (1 legal)

Date Consideration of material:
11 May 2016

Date of ruling being finalized:
20 May 2016

SUMMARY

1. OVERVIEW:

1.1. The Complainant alleged that the Respondent had infringed the aforementioned clauses of the Code by making unsubstantiated and misleading claims in the website, social media, point of sale and television advertising of Illiadin®, an over the counter nasal decongestant spray.

1.3. The claims that the Complainant challenged, with regard to their legal and scientific validity are:

1.3.1. "Illiadin® not only unblocks a nose fast, but cuts the duration of a cold by up to 2 days";
1.3.2. "Help him get over his 'man flu'".

1.4. The Claimant also alleged that there was a serious safety risk associated with the claims since a consumer, parent or caregiver of a child, as well as a pharmacist could use, administer or dispense Illiadin® acting on the unsubstantiated and misleading claims, which could lead to the condition worsening or adverse events as set out in the Package Insert being experienced.

1.5 In accordance with the provisions of clause 48.1, the Parties had attempted to resolve the matter in an amicable fashion by way of a series of written correspondence. of the Code prior to approaching Marketing Code Authority ("the MCA") for adjudication.

1.6 The Adjudication Committee considered the matter, by evaluating all material in relation to the following clauses of the Code that the Claimant alleged the Respondent had infringed:

1.6.1. **PART A**

Clause 5.2 All advertising and/or promotional material must be based on the current approved South African package insert

Clause 7.4 Exaggerated or misleading claims
Promotional material must encourage the rational use of a health product by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a health product. Claims should not imply that an active ingredient or health product has some special merit, quality or property unless this can be substantiated.

1.6.2 **PART B**
Clause 25

Clause 25.2 Advertisements must be consistent with the requirements of the Medicines Act and other applicable legislation and in line with the approved package insert.

Clause 25.3 Advertisements shall not mislead or disparage either directly or by implication. Information, claims and comparisons must be accurate, balanced, fair, objective, unambiguous and supportable and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. The use of medical terminology is acceptable provided that this does not confuse or mislead the consumer.

Clause 25.4 Advertising and/or promotion shall not be misleading as to the nature of the product, its ingredients or indication(s). It shall not contain any exaggerated claims either direct or implied as to the benefits that can be obtained from use of the health product.

Clause 26

Clause 26.1 All advertising and/or promotion must be consistent with the provisions of the Medicines Act i.e. all advertising and/or promotion must give the information necessary for the correct use of a product as approved by the medicines regulatory authority and may not deviate from, be in conflict with or go beyond the evidence submitted in the application for registration with regard to its safety, quality and

efficacy in respect of what has been approved by the medicines regulatory authority and incorporated in the approved package insert.

1.7 The Adjudication Committee evaluated the safety risks associated with the claims, as raised by the Claimant.

3. CONCLUSION:

3.1. The Adjudication Committee found that the Respondent had committed an infringement of the provisions of the following clauses of the Code, for the reasons set out below:

PART A: Clause 5.2 and Clause 7.4 – the advertising campaign is aimed at Healthcare Professionals
PART B: Clause 25 and Clause 26 – the advertising campaign is aimed at the general public.

3.2 The Adjudication Committee found that whilst there are indeed safety concerns that may arise from the incorrect use of those Illiadin® products, those adverse events could also be experienced with the correct use of those Illiadin® products.
Moreover, the more serious/severe of the concerns lie with the incorrect administration of those Illiadin® products to infants, since the adverse events that they would experience are severe.
The Adjudication Committee found that it was unlikely that a parent or caregiver would administer those products to an infant due to the fact that the products are not available in an open shop; a Pharmacist would have to dispense the products and would have the skills and expertise to dispense the products accordingly.

3.3 The Adjudication Committee drew the conclusion that the Respondent delayed in its responses to the Claimants correspondence in an effort to prolong the advertising campaign.
Moreover, the Respondent has been aware of the Complainants complaints since 16 February and has done nothing to nuance statements or change words that are misleading. At the time of adjudication of this matter, the Respondent has also not shown an attempt to draw a clearer differentiation between the Oxymetazoline adult and paediatric formulations and Illiadin® saline, as per its undertaking contained in its letter dated 2 March 2016.
The Adjudication Committee found that, by virtue of the abovementioned conduct, the Respondent acted disingenuously in order to prolong the advertising campaign for as long a time as possible.

4. PENALTY / CORRECTIVE ACTION ORDERED:

4.1 The Respondent is directed to forthwith cease and withdraw all adverting in all formats, including but not limited to website, social media, point of sale and television advertising, containing the misleading claims.

4.2. The Respondent is ordered to pay for the Claimants costs and expenses, including any legal fees on an attorney and own client basis, and including the lodging and adjudication fees associated with this complaint.

4.3. No other order is made.

5. APPEAL RIGHTS:

Any aggrieved party has, under clause 55 of the Code the right to appeal the ruling to the MCA office in writing within 5 working days from the date of the finding, and that such appeal can be on any procedural, substantive, interpretation or other ground.

MCA APPEAL IN RESPECT OF THE FINDINGS OF COMPLAINT NUMBER : 007

MCA appeal in respect of complaint number MCA 007

Date of complaint: 20th May 2016 Date of appeal: 5th July, 2016

1 APPELLANT

Merck (Pty) Ltd

2 RESPONDENT:

Glaxosmithkline South Africa (Pty) Ltd

3 PRODUCT

Illiadin product range.

4 APPEAL COMMITTEE

A Committee of 3 was duly Constituted by the Executive Officer in terms of the Code.

5 SUMMARY OF COMPLAINT

Original Complaint: Unsubstantiated and misleading claims for Iliadin drops made on the website, social media, point of sale and television advertising.

The Adjudication committee ruled that:

3.1 the Respondent had committed an infringement of the provisions of the following clauses of the code:

- PART A: Clause 5.2 and Clause 7.4 – the advertising campaign is aimed at Healthcare Professionals
- PART B: Clause 25 and Clause 26 – the advertising campaign is aimed at the general public

3.2 the Adjudication Committee found that whilst there are indeed safety concerns that may arise from the incorrect use of those Illiadin products, those adverse events could also be experienced with the correct use of those Illiadin products.

3.3 the Adjudication Committee ruiled that the Respondent delayed in its responses to the Claimants correspondence in an effort to prolong the advertising campaign. Moreover, the respondent has been aware of the Complainants complaints since 16 February, 2016 and had done nothing to nuance statements or change words that were misleading.

The grounds for the Appellant's appeal were as follows:

- The Pre – adjudication processes;
- Ruling by the Adjudication Committee on processes and timelines;
- Differentiation between oxymetazoline containing products and saline;
- The use of the word "cold";
- The use of the phrase "man flu";
- The sanctions imposed by the Adjudication Committee.

The appellant challenged the grants for the complaint and has questioned in its Notice of appeal, *inter alia"* the procedural fairness of the ruling handed down by the Adjudication Committee.

6 APPEAL COMMITTEE RULING

The Appeal Committee dismissed the appeal and ruled as follows:

In respect of process, timelines and differentiation between products:

The Appeal Committee upheld the finding of the Adjudication Committee that the Appellant had taken no meaningful action since 16 February 2016 to nuance statements or change words which were misleading and further had shown no attempt to comply with undertaking for corrective action made on 2 March 2016.

In respect of the use of the world "*cold*":

The Appeal Committee agreed with the findings of the Adjudication Committee and reiterated that such claims were indeed exaggerated, misleading and inaccurate and infringed upon various sections of the code's.

In respect of the use of the phrase "*man flu*":

The Appeal Committee confirmed and upheld the finding of the Adjudication Committee that the Appellant's claims in respect of "man flu" are exaggerated, misleading and inaccurate and go beyond the information contained in the package insert, infringing sections of the code.

In respect of safety concerns:

The Appeal Committee found that a serious safety concern existed to all consumers as a result of the Appellants deviation from what is approved in respect of the Iliadin product range per the package insert together with its disregard for a directive issued by the Medicines Control Council.

Corrective Actions:

- the appeal was dismissed;
- save for the issue relating to health and safety concerns, the Adjudicating committee's ruling was upheld;
- the removal of all promotional material and activities using the claims through all channels were to be removed and discontinued with immediate effect, being a time period of no more than 24 hours from date of receipt of the ruling;
- the patient safety concern was referred to the Medicines Control Council for further investigation and determination into the appellants use of claims which go beyond the approved package insert together with the promotion of Iliadin products to children under the age of 2, with no contraindications contained within the package inserts and patient information leaflets;

7 FINES OR COST ORDERS

The Appeal Committee ruled that the Appellant should pay the costs of the respondent occasioned and associated with this appeal on the scale as between attorney and client.

The MCA obtained a legal opinion in respect of the payment of attorney and client costs which lead to a resolution by the MCA Board that attorney and client costs should not be the subject of cost orders in respect of code enforcement measures.

Following correspondence between both parties, the offending material was confirmed withdrawn from the market and the cost order was set aside by the Respondent.

Prepared by the Executive Officer from Complaint and Appeal Committee Reports