MCA COMPLAINT: ADJUDICATION COMMITTEE SUMMARY REPORT

Case No: MCA 21-01 Date of Adjudication Report 29th October 2021

Complainant (Company Name): GSK Consumer

Respondent (Company Name): Adcock Ingram Healthcare

Product: Panado tablets, Reg No. B/2.8.858;
Panado capsules, Reg No. S/2.8/57; and
Panado effervescent tablets Reg No. V/2.7/219

Committee: Duly constituted adjudicating committee of the MCA

Clarification of processes
Report is final – no clarification or correspondence allowed. If parties are not satisfied with decisions, penalties, rulings or decisions of the adjudicating committee, they have 7 days to appeal in writing.

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
1	5.1	The promotion of the health product shall comply with the terms of registration, and be consistent with the particulars listed in the registered product documentation. Indications, which have not been approved may not be promoted and may not deviate from, be in conflict with or go beyond the evidence submitted in the application for registration.	No	N/A
2	5.1		No	N/A

		As above		
3	5.8.5.1	An Advertisement for a self-medication must not refer, either expressly, or by implication, to products used in, or assisting in, the treatment of serious forms of disease, conditions, ailments or defects unless prior approval is given by the Regulatory Authority.	No	N/A
4	5.8.5.3	Advertising and/or Promotion shall not claim guarantees about a Health Product's effects, safety or quality.	Yes	No

Remedies imposed on the Respondent to address the infringement:

The Respondent is to ensure that all packaging material bearing the phrase "proven safety" / "proven safety profile" be removed from circulation by no later than 15 December 2021, being three months from the date of the adjudication panel having received the complaint. In this regard, it is acknowledged that the Respondent had already commenced such removal upon its receipt of the complaint.

Sanction/Remedies imposed by the Committee (Delete what is not relevant)

Fine: **N/A** - (Payable to the MCA)

Cost order for fees: **N/A** - Payable to the Respondent/Complainant

Cost order for MCA costs: **N/A** - Payable to the MCA

If no appeal is submitted within 7 days, a summarised version of the findings of the adjudication process shall be published on the MCA website including a summary of the violation and the penalty imposed.

The MCA does not envisage cost orders for legal and other third party costs.

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2. **Concluding remarks: (Does any action need to be taken with respect to the code or guideline/action regarding code certification/**

Include instructions to respondent in respect of deadlines and notification for complying with sanctions and recommendations.

The Code should expressly provide for the packaging and promotional material of Schedule 0 and 1 products to be able to stipulate clinically appropriate and verified examples of the sort of uses the product is registered for, even if such specific examples of use had not been stipulated in the registration dossier, the Package Insert and / or the Product Information Leaflet. This allowance is important from the perspective of public guidance and safety.

The above recommendation is specific to Schedule 0 and 1 products, because schedule 2 and higher products necessitate the involvement of a pharmacist / pharmacist-assistant or doctor, as the case may be, and hence questions / misconceptions about the product can be clarified. Schedule 0 and 1 products may be sold without any such intervention, hence information which is of genuine value to guide lay consumers is justified.

It does bare mentioning though that the Complainant promotes several of its own products in the exact same manner as that which it complains about the Respondent doing. Whilst this ruling clarifies that the conduct in question should be seen as lawful and a justifiable extension of the broad scope of the conditions for which the product is registered, each such case must still be assessed on its own merits and in context.

3. **Rights:**

To Appeal

Either party to a complaint has the right to appeal the ruling e to the Executive Officer in writing within 7 days of receiving the findings of the Adjudication Committee. Such appeal can be on any procedural, substantive, interpretation or other ground.

To report it to regulatory authority:

The MCA has the right to refer to a regulatory body prior to the final internal resolution or to any relevant authority should it deem the matter to warrant such referral.

It is noted that no appeal was lodged in respect of the Adjudication Committee's ruling.

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

Val Beaumont.

29th October 2021

…….. *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