Case No: MCAC06/2016

Date: 14 MARCH 2016.

In the matter between:
MUNDIPHARMA (PTY) LTD **Complainant**
INOVA PHARMACEUTICALS (PTY) LTD **Respondent**

3 Panelists (1 legal)

1. Details of Complaint.

The complaint relates to website and point of sale (POS) advertising of a schedule 2 medicine.
The complaint is in respect of the advertising of Metrogel V, a schedule 2 medicine which the complainant alleges is in contravention of regulation 45 of the Medicines and Related Substances Act 101 of 1965 (the "Act") and the Code of Marketing Practice ("the Code"). The complaint is specifically in regard to the following:

(a) Material used in its advertising and/or promotion, more specifically the in-pharmacy promotional material which includes a signing pad and patient leaflets, the use of which the complainant alleges is in contravention of regulation 45 of (the Act) and the Code (sections cited in the complaint being 4, 7.3, 20.9, 22.1).
(b) Alleged misleading claims used in its promotional material and the product website www.myvaginalgel.co.za.

2. Committee's findings:

2.1 The committee considered the complaint against the applicable sections of the Code namely:

2.1.1. Part B of the Code, more specifically
2.1.1.1. 25.2
2.1.1.2. 25.12
2.1.1.3. 25.20
2.1.2. Part A of the Code
2.1.2.1. 22 (internet-based promotion is not specifically catered for under Part B of the code)

2.2. The Committee is of the view that the MCA needs to clarify note 3, clause 24 of the Guideline document i.e. advertising of schedule 2 health products. It is the concern of the committee that this guideline, which encourages "point of sale promotion" of schedule 2 products may be in contravention of regulation 45 unless further directives are provided in order to keep it aligned with regulation 45.

2.3 The leaflet

The committee was unsure of the context in which such a leaflet is used. Since the leaflet contains both diagnosis-related information and the product name, the committee's view was that the acceptability or unacceptability of the leaflet depends on its use. The respondent is required to provide additional information on its intended use and the decision of whether it is compliant with the regulations and the code will be tested in light of this additional information.

2.4 The website

It is the view of the committee that the website, save for the use of the claim discussed in 2.5 below, is compliant with the Code. However, in light of the concerns expressed below, the website should be revised to remove the claim made in 5.5 above until such time that the claim can be substantiated

2.5 The claim

The claim that "Metrogel V is the gynecologists' preferred treatment" is defended by the respondent with the supply of the Impact Rx data. The committee found this data wanting in the following respects, i.e. that the data was not verifiable and that it was difficult to ascertain exactly on what basis the data was extracted.

Without an independent verification process and until such time that the MCA and the complainant have been able to validate the data upon which the claim is based, the committee suggest that the respondent refrain from making this claim and from using the data to substantiate such a claim.

3. Penalty / corrective action ordered and why that would be an APPROPRIATE sanction:

All the clauses of the code stated in the original complaint relate to part A (promotion to professionals) of the Code and were not applicable to the actual complaint which related to the POS and website advertising (Consumer advertising). The Committee therefore considered the Code in totality when making its findings.

The sanctions and recommendations of the committee are summarized as follows:

3.1. The Leaflet – withdraw or permit depending on respondent's explanation of the context of its use.

3.2. The pad – withdraw, as it contravenes what is deemed permissible in POS advertising whether the narrow or the wider interpretation of the objective of POS advertising is applied.

3.3. The Website – may be permitted to continue provided the issues in respect of the reference to the claim are adequately addressed or removed.

3.4. The claim – the respondent must refrain from using this claim until such time as the basis for this claim can be substantiated on verifiable data by an independent source, as has been discussed in the full judgment.

4. **Conclusion:**

The respondent is requested to provide the MCA with additional information as detailed above. Until such time, the offending advertisements and/or claims must be withdrawn.

The MCA needs to urgently issue guidance in respect of POS advertising to ensure conformance with regulation 45.

MCA COMPLAINT: THE APPEAL COMMITTEE SUMMARY REPORT

Case No: MCAC06 2016 **Date of Appeal:** 16th November 2016 **Date Report:** 5th December 2016

Appeal 1:
Complainant (Company Name): MundiPharma Pty (Ltd)

Respondent (Company Name): iNova Pharmaceuticals

Product/s: Metrogel V

Appeal 2:
Complainant (Company Name): iNova Pharmaceuticals

Respondent (Company Name): Mundipharma (Pty) Ltd

Product/s: Metrogel V

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1. **Appeal Committee:** Committee duly constituted by the Executive Officer in terms of the Code

2. **Findings:**

Complaints: Committee has determined there are infringements (list):
Two appeals against the Adjudicating Committee findings as per the two tables below:

Appeal 1 (Mundipharma Appeal)

	Reference to Adjudicating Committee findings	Finding of the Adjudicating Committee Appealed Against	Allow/dismiss the appeal (54.2.1/2)	Substitute any finding (54.2.3)
1	3.1 & 5.1	Decision to not admit supplementary information	**Dismiss**	
2	5.2 and 7	The referral of the subject of the complaint in terms of Regulation 45, the Code and the Guideline to the CTAC committee.	**Dismiss**	
3	5.3, 6.1 and 7	The lack of decision on the acceptability of the leaflet	**Allow**	

4	5.5, 6.4 and 7	The claim regarding the product being a preferred product: absence of a decision.	**Allow**	
5	5.6 and 6.3	The decision that, save for the claim of preferred product, that the website complies and that it should be revised to remove the claim until such time that the claim can be substantiated	**Allow**	
6	6.4 and 7	Refrain from using claim until verified.	**Allow**	

Appeal 2 (iNova Appeal)

	Reference to Adjudicating Committee findings	**Finding of the Adjudicating Committee Appealed Against**	**Allow/dismiss the appeal (54.2.1/2)**	**Substitute any finding (54.2.3)**
1	Initial Complaint	Cites contravention of Regulation 45 of Act 101	**Dismiss**	
2	5.3	The lack of decision on the acceptability of the leaflet	**Allow**	
3	5.4	Non-compliance of the signing pad and a requirement to remove it from the pharmacy vicinity	**Dismiss**	
4	5.5	The claim regarding the product being a preferred product: absence of a decision	**Allow**	

3. Sanction/Remedies

Remedial Action Required:

Mundipharma: None

iNova: To cease all use of the infringing materials until such time that said use is in full compliance with the Code. This is appropriate in the circumstances to give effect to the provisions of the Code and to underline the intent of a self-regulatory industry.

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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