



Summary Report on outcomes of complaint received by the MCA

Case No: MCA23-01 **Adjudication date:** 7 March 2023 **Report Date:** 16 March 2023

Complainant: Galderma Laboratories

Respondent: MC Pharma (Pty) Ltd

Product involved: Retin-A marketed by Rite Aid Healthcare, an S3 product

Independent Adjudication Committee:

The matter was adjudicated upon by a duly constituted committee of three non-conflicted subject experts, approved by both the complainant and respondent.

Processes were followed as required by MCA Code v15.

The matter at hand:

- Promotion of Retin-A by Rite Aid Healthcare (Schedule 3) direct to the public.
- Promotion of indications not approved in the product information.
- Promotional material referencing not compliant with MCA Code requirements.

Prior company-to-company complaint resolution process requirements had been complied with by the Complainant.

The committee determined, based on the details submitted in the complaint pack, that the Code had been infringed as follows;

- that Section 5.1 (5.1.1, 5.1.2, 5.1.4), Section 5.6(5.6.3, 5.6.4) and 14.4 of the MCA Code have been infringed as well as the Medicines Act, in respect of promoting a higher than schedule 2 medicine to the public;
- that the magazine articles appearing in Rooi Rose and Woman and Home are inappropriately promotional and furthermore promote Retin – A in a manner that is not in accordance with the registered Prescribing Information. This constitutes the promotion of “off-label” use of the product;
- that the Respondent as Marketing Authorisation Holder (MAH) is ultimately responsible for and liable for infringements of the Medicines Act and MCA Code notwithstanding that the material was placed by a third party; and
- that in the company-to company complaint process, the Complainant had communicated concern about the ethical and legal compliance of the material in question to the Respondent. The Respondent seemingly

acknowledged prior infringements but did not take sufficient steps to avoid further infringements. Respondent did not comply with its legal and ethical obligations as MAH.

Sanctions

Taking account of the rulings, the Committee imposed the following sanctions and remedies on the Respondent:

1. A fine of R25000.00 (Twenty-five thousand rand) to be paid to the MCA by the 1st May, 2023 unless an appeal is lodged and subject to the outcome of the appeal.
2. Remedies imposed on the Respondent to address the infringement:
 - o Corrective statement to be issued by the Respondent noting infringement for direct-to-consumer promotion of an S3 medicines and off label promotion by the Respondent.
 - o The Respondent's corrective statements to appear in the magazines Women and Home and Rooi Rose and be of similar prominence to the infringing articles.
 - o Corrective statement by the Respondent to be approved by the MCA prior to it being issued.
 - o Refund of complaint fee, payable to the Complainant.

Appeal

Neither party exercised their right to appeal the Committee's findings or the sanctions.

Compliance with sanctions

The Respondent complied fully with all the sanctions imposed by the Committee.

Learnings and comments from the MCA Executive Officer

- The holder of a health product registration licence, the *applicant*, is responsible for ensuring compliance of the product with the information submitted in the registration application and with the relevant legislation. Moreover, this responsibility rests with the Responsible Pharmacist (in the case of medicines) and the Authorised person (in the case of a medical device company not registered with the Pharmacy Council).
- Where a third party has the right to market a registered product, the license holder remains responsible for ensuring that the advertising and promotion of that product is ethically and legally compliant.
- Editorial, whoever the author is, including HCPs, should not make claims or promote a product beyond what has been approved in the registered product information.



- SOPs and checks and balances by the MAH/applicant are advised where authority is delegated to a third party for the marketing of health products.

Given that the sanctions have been complied with, this matter is now closed.

Val Beaumont.

Updated by V Beaumont 23/10/20

Executive officer: Val Beaumont
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