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28 June 1995

OUR REFERENCE

YOUR REFERENCE

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BY FACSIMILE: 06 264 2803

Mr Michael Kiley
Trade Practices Commission
Benjamin Offices
Chan Street
BELCONNEN ACT 2617

Dear Mr Kiley

Application No A90549 - Authorisation of the Proprietary Medicines Association of Australia Inc Code of Practice

Further to our telephone conversation of 16 June, we respond to your queries in relation to clauses 7.3 and 9.2.7 as follows.

Clause 7.3

The proposed clause 7.3 provides that consumer product information should not contain any direct/indirect form of advertising for the product to which the information relates. The reason why the PMAA has incorporated this provision into the Code is because of the statutory function of CPI as information to the consumer about the product. By definition, it is not directed towards the pharmacist or health professional but towards the consumer. Its primary purpose is to be used as a counselling tool, used by the pharmacist when discussing the safe and effective use of the medicine with the consumer. It is important to provide balanced information so that the consumer can easily understand how to achieve best use of the medicine. The involvement of advertising messages in the context of detailed information conveyed at the time of the pharmacist's intervention would not be appropriate.

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Mr Michael Kiley
28 June 1995

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Schedule 12 of the the Therapeutic Goods Regulations providing for patient information documents sets out 10 categories of information that must be included in CPI (including what the product is used for and how it works, advice before using the product, how to use the product properly, unwanted effects, in case of overdose).

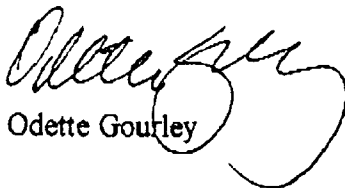
Clause 9.2.7

The Therapeutic Goods Administration had agreed that the requirements for the provision of CPI in relation to Schedule 3 products be a self-regulatory process. This amendment providing for automatic referral by the executive director of complaints concerning breaches of the proposed clause 7.3 underpins this self-regulatory process. There is a distinction between the executive director's obligation to automatically refer a breach of clause 7.3 to the Complaints Panel and the discretion to refer a complaint regarding advertising/promotion to the Complaints Panel because:

- a breach of 7.3 will be easily ascertainable; other breaches of the Code of Practice may be more subjective;
- the PMAA views such a breach as serious and that automatic referral is necessary; and
- as the PMAA is the sole self-regulatory organisation in relation to CPI, it is distinct from advertising where the Advertising Standards Council and/or the Media Council of Australia may be independently approached.

Please contact me if you have any further questions.

Yours sincerely


Odette Gourley