GMiA Generic Medicines Industry Association Pty Ltd

ABN 19 096 009 540

PO Box 222
Pymble BC
NSW 2073

Generic Medicines Industry Association

Submission to ACCC concerning

Medicines Australia Limited - Revocation & Substitution - A91316 - A91320

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For further details
Please contact
Kate Lynch, CEO
kate.lynch@gmia.com.au

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2. Executive Summary

This submission is made on behalf of the members of the Generic Medicines Industry Association ("GMiA"). The members of GMiA agree to be bound by the GMiA Code of Practice ("**GMiA Code**").

The members of Medicines Australia Limited ("**MA**") agree to be bound by the Medicines Australia Code of Conduct ("**MA Code**") and participate in the development of the MA Code. The members of MA include some but not all pharmaceutical companies in Australia. However, all companies that make prescription medicines available in Australia (including GMiA members) are required to market and promote those medicines in compliance with the MA Code, as a condition of the marketing authorisation issued by the Therapeutic Goods Administration. The result is that the marketing and promotional activities of all pharmaceutical companies (including GMiA members) are, in effect, regulated by the members of MA.

Suppliers of generic medicines are directly impacted by changes to the MA Code.

The amendments to section 2.6 of the MA Code proposed in edition 17 of the MA Code introduce a total prohibition on the provision of brand name reminders to healthcare professionals ("**HCP"**). An HCP is defined under the MA Code to include doctors and pharmacists. GMiA submits that the ACCC reject this proposed amendment to the MA Code or, alternatively, the prohibition not apply to the generic medicines market.

A total prohibition on the provision of brand name reminders to HCPs removes an important element of competition in the generic medicines market.

In Australia, the regulatory system for pharmaceutical products ensures that generic medicines are bioequivalent (i.e. has the same quality, safety and efficacy characteristics) to the originator medicine they compete with. In addition, prescription medicines cannot be advertised or sold directly to the public so there is little ability for a supplier of a generic medicine to differentiate its product. The key competitive mechanism available to a supplier to differentiate a generic medicine is to offer discounts to pharmacists. Brand name reminders ("**BNR**") are not used to induce prescribing, rather, they are regularly used by GMiA members to remind a pharmacist that there are substitutable (and often lower cost) generic medicines available. The expensive methods of promotion utilised by MA members are often not affordable in respect of generic medicines as they cannot be covered within the narrower cost margins for these medicines. However, a BNR is a low cost means by which a pharmacist can be reminded that there are substitutable products available. Therefore, removing the capacity of a company to provide a BNR will have the effect of reducing competition.

The promotional activities of the members of GMiA are targeted at encouraging pharmacists to consider dispensing an alternative brand of a bioequivalent medicine. The choice of which brand of competing bioequivalent medicines to dispense has little or no impact on the health outcome for a patient and, in fact, a decision to dispense an alternative cheaper brand drives savings of hundreds of millions of dollars for the government, the Pharmaceutical Benefits Scheme ("**PBS**") and the public.

This is in stark contrast to the focus of MA members; promotional activities in respect of medicines where only one brand of the medicine is available ("**originator medicine**"). The promotional activities of MA members are targeted at influencing the choice of medicine prescribed by a doctor and this has a direct impact on the health outcome of the patient. Promotional activity by members of MA may also have the potential to result in the over use of medicines by doctors that can cause a blow out of PBS costs.

3. Generic Medicines Industry Association

The GMiA was established in 2001 to represent the interests of suppliers of generic medicines in Australia.

GMiA seeks to develop good relationships with all constituencies involved in the continued delivery of pharmaceutical care to the Australian community and to contribute to the long-term sustainability of the PBS through support of the principles of the National Medicines Policy.

Members of GMiA:

- supply greater than 90% of generic medicines
- employ 2,500 Australians; more than half in manufacturing and R&D roles representing functions that generate strong economic multiplier benefits (GMiA survey 2011)
- export $585 million in value of pharmaceuticals [per annum] which represents approximately 15% of current pharmaceutical export market by value (GMiA survey 2011)
- invest $50 million in R&D in Australia [per annum] (GMiA survey 2011)

The guiding principles of the Members of GMiA are:

1. To support the long term sustainability of the PBS by ensuring the timely and cost effective provision of generic medicines to consumers.
2. To support the quality use of medicines ("**QUM**") in partnership with other stakeholders.
3. To support the development of policies that facilitate timely access to generic medicines for all Australians.
4. To support the development of policies that promote the continued viability of a local manufacturing base for generic medicines (for domestic and export markets).
5. To encourage a high level of awareness and general knowledge of the safety, efficacy and appropriate interchangeability of generic medicines amongst HCPs, government and consumers.
6. To support balanced intellectual property rights in the pharmaceutical sector that enable timely, cost effective access to generic medicines.
7. To enhance the accountability of members by establishing a complaints handling mechanism that is both readily accessible and transparent.
8. To reduce actual and potential conflicts of interest between members and healthcare professionals responsible for prescribing and dispensing prescription medicines by establishing an educational event reporting procedure with independent review.

4. The regulatory framework for prescription medicines

The principal piece of legislation regulating the manufacture, promotion and supply of prescription medicines in Australia is the *Therapeutic Goods Act 1989* (Cth) ("**TG Act**"). The TG Act is administered by the Therapeutic Goods Administration ("**TGA**") which is part of the Commonwealth Department of Health and Ageing.

The TG Act requires that prescription medicines imported into, supplied in or exported from Australia be included in the Australian Register of Therapeutic Goods ("**ARTG**") Applications for inclusion in the ARTG are made to the TGA and must include data supporting the quality, safety and efficacy of the medicine for its intended use. The TGA approves medicines based on an assessment of risks against benefits. If a prescription medicine is approved for inclusion in the ARTG, the TGA issues a marketing approval letter to the applicant ("**sponsor**") and the medicine is then included in the ARTG.

The promotion of prescription medicines to healthcare professionals is controlled by a combination of statutory measures administered by the TGA and self-regulation through codes of practice such as the MA Code and the GMiA Code. The TG Act prohibits the promotion of prescription medicines to consumers but allows promotion to HCPs provided that the promotion only refers to the approved uses of medicine included in the ARTG. As a condition of the marketing authorisation issued by the TGA, a sponsor is required to market and promote the prescription medicine in compliance with the MA Code.

The *National Health Act 1953* (Cth) ("NH Act") established the PBS. When a medicine is "listed" under the PBS, the government subsidises the cost of that medicine for one or more of its approved uses. A medicine cannot be "listed" unless it is included in the ARTG. Once "listed" the medicine can be supplied to a consumer at a fixed statutory price by an approved pharmacist on presentation of a prescription written by a medical practitioner. The pharmacist is then reimbursed by the government at a fixed rate specific to each medicine.

5. GMiA Code of Practice

Members of GMiA administer and comply with their own Code of Practice that has been authorised by the Australian Competition and Consumer Commission on 3 November 2010 (authorisation numbers A91218 and A91219) ("**GMiA Code**").

A copy of the GMiA Code can be found on the GMiA website at http://www.gmia.com.au/code-of-practice.html

The GMiA Code is a principles based code. It is intended to provide GMiA members and the public, in a single document, guidance on the different legislation, regulation and guidelines with which sponsors of generic medicines listed on the ARTG must comply.

A primary objective of the GMiA Code is to:

> *Formalise the commitment of the Members to a system of best practice self-regulation and ethical supply of Products to the Australian community, in compliance with applicable laws and standards.*

The GMiA Code reflects the unique characteristics of the market for the supply of generic prescription medicines. For a generic medicine to be included in the ARTG, the sponsor must provide scientific data demonstrating the bioequivalence of the generic medicine to the originator medicine. This means that the relevant generic medicine must have the same active pharmaceutical ingredient as the reference product and the same amount of medicine is made available in the body to give the same therapeutic effect (and side effects).

The unique features of the generic prescription medicines market include:

- There is typically a lengthy market experience and a strong knowledge of a medicine by the time bioequivalent generic medicines enter the market, which can be 15- 20 years after the originator medicine was first launched. Accordingly, doctors' prescribing habits regarding a generic prescription medicine are usually well formed; and pharmacists are usually well informed as to the medicine's approved uses and effectiveness.
- Marketing of generic prescription medicines typically seeks to influence behaviour at the point of dispensing not at the point of prescribing. The decision to switch a patient from one brand to a more affordable brand of a prescription medicine is unlikely to create any change to the health outcomes for the patient, and drives savings of hundreds of millions of dollars for the government, the PBS and the public.
- Members of GMiA may supply prescription medicines and non-prescription medicines. At the time a prescription medicine is subject to competition from generic medicines, it may have been rescheduled as non-prescription medicine.

6. Comparison of GMiA and MA operating principles

Australia's National Medicines Policy ("**NMP**") has the overall aim of ensuring that a medicine's use promotes both optimal health outcomes and economic benefits for Australians and Australia.

The NMP seeks to achieve this aim through four central objectives. As a key partner in the NMP, the pharmaceutical industry must play its role in supporting these objectives:

1. Timely access to the medicines that Australians need, at a cost individuals & the community can afford;
2. Medicines meeting appropriate standards of quality, safety and efficacy;
3. Quality use of medicines; and
4. Maintaining a responsible and viable medicines industry.

Consequently, the promotion of medicines by pharmaceutical companies must be undertaken within this framework.

While all of these objectives are relevant to the members of GMiA, generic medicines have a particular and important role in ensuring that Australians have timely access to affordable medicines, and that the PBS remains sustainable.

The main focus of the promotional activities of GMiA members is to highlight how selection of generic medicines can contribute to a reduction in the cost of medicine, increase affordability and achieve the same health outcome. In contrast, the main focus of the promotional activities of MA members is to promote the comparative safety and efficacy of a new medicine within the existing treatment pathway, to maximize health outcomes. Therefore, for a GMiA member, the target audience and competitive environment is very different to MA members.

Different considerations of MA members and GMiA members when promoting prescription medicines

Characteristic	**GMiA member**	**MA member**
Decision influence point	Decision to dispense a brand of medicine (cost & affordability)	Decision to prescribe an individual medicine (comparative safety & efficacy)
Primary Customer	Pharmacist	Medical Practitioner
Promotional Focus	The company & its product range	An individual medicine (therapeutic claim)
Product classification	Prescription, OTC and unscheduled medicines	Prescription medicines
Competitive environment	Multi-brand competitive market determined by price	Exclusive market guaranteed by patent
Consumer involvement in product selection	Decides which brand	No involvement in brand selection

- For each generic medicine sold, GMiA members have multiple competitors selling a product that is equivalent in quality, safety and efficacy. There is no product exclusivity guaranteed by patent.
- For each originator medicine sold, MA members typically have no direct competitors. Typically, they have exclusivity guaranteed by patent.
- The primary goal of a GMiA member is to inform the pharmacist of the availability of alternative brands of a prescription medicine that can be dispensed, after the decision to prescribe a particular prescription medicine has been made by the prescriber.
- The primary goal of a MA member is to encourage a prescriber to prescribe its patent protected medicine rather than an alternative medicine for a particular illness or condition.
- The primary selling point for a GMiA member is the price of their brand of medicine, in comparison to other brands of the medicine.
- The primary selling point for a MA member is the safety and efficacy of its medicine, in comparison to other therapeutic choices.
- The consumer has very little involvement in a medical practitioner's decision to prescribe a particular medicine.
- The consumer may choose which brand of medicine the pharmacist dispenses where there are alternative brands of a medicine available.

7. Public detriment arising from total prohibition on the provision of brand name reminders

GMiA notes the comments of the Australian Competition Tribunal on the meaning of the term public detriment:

> *Sections 90(6) and 90(7) of the TP Act require consideration of the risk of "detriment to the public", a concept extending to "... any impairment to the community generally, any harm or damage to the aims pursued by the society including as one of its principal elements the achievement of the goal of economic efficiency...": Re 7-Eleven Stores Pty Ltd (1994) 16 ATPR 41-357 at 42,683….*[1]

GMiA submits that there is public detriment arising from the proposed amendment to section 2.6 of the MA Code to introduce a total prohibition on the provision of brand name reminders to HCPs.

Brand reminders are not an inducement to prescribe, rather they are a standard method of advertising and promotion to keep brand awareness of medicines top of mind. These are generally low cost items that are used as part of practicing medicine. By being able to maintain product awareness of older and/or cheaper products, the prescriber is more likely to consider less expensive alternatives as part of their decision making process.

A new medicine released on the market in Australia is often supported by significant financial resources to promote that medicine, including journal advertising at up to $12,000 per page, educational seminars (including a sit down meal) and funding HCPs to participate in international conferences to hear from key opinion leaders nominated by the promoter of the new product. If this promotion is not able to be balanced with information or awareness of competing substitutable medicines, an HCP is more likely to switch to prescribing a new medicine.

These expensive methods of promotion are often not affordable in respect of substitutable generic medicines as they cannot be covered within the cost margins for the medicines. However, a BNR is a low cost means by which an HCP can be reminded that there are competing substitutable products available. Therefore, removing the capacity of a company to provide a BNR will have the effect of reducing competition.

Whether the intent of removing BNRs is or is not intended to reduce competition, it will in fact reduce competition. The removal of BNRs will reduce or remove a barrier to prescribing new medications, through ongoing awareness of existing less expensive medicines which are still effective and well tolerated.

[1] *Re Medicines Australia Inc* [2007] ACompT 4 (27 June 2007) – paragraph 108 - http://www.austlii.edu.au/cgi-bin/sinodisp/au/cases/cth/ACompT/2007/4.html

We therefore submit that the amendment to MA Code to introduce a total prohibition on the provision of brand name reminders to HCPs be rejected or, alternatively, the prohibition not apply to the generic medicines market.

8. Co-regulation system

GMiA supports the co-regulation system in the pharmaceutical industry as established by self-regulating Codes of Practice such the GMiA Code and the MA Code.

GMiA submits that the system of co-regulation established by such Codes deliver significant public benefits.

The added enforcement provided by self-regulating industry codes in relation to the TGA and the TG Act is a public benefit. As stated by the Australian Competition Tribunal:

> *A voluntary industry code may provide an additional informal low cost complaint and enforcement mechanism covering both the conduct formally addressed by the statutory system and analogous or related conduct which the statutory system does not reach because of legal boundaries or resource limitations. Even if the voluntary enforcement mechanism has gaps and deficiencies the additional coverage it provides may be identified as a public benefit by reason of its capacity to lessen the detriment associated with conduct within the letter or policy of the statutory theme. The relationship between statutory regulation and complementary voluntary codes in such cases is sometimes referred to as "co-regulation".*[2]
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> *..there are transaction costs associated with the investigations and other administrative and judicial processes necessary for the enforcement of statutory regulation. Those costs and limits on the resources available to government agencies limit the extent of enforcement coverage.*[3]

[2] *Ibid*., para. 119.
[3] *Ibid*., para. 342.