

Johnson & Johnson

Family of Companies

*Johnson & Johnson
Family of Companies in Australia*

Submission to the
Therapeutic Goods Administration
– Regulatory Reforms to Advertising
Arrangements

August 2010

Our Credo

We believe our first responsibility is to the doctors, nurses and patients,
to mothers and fathers and all others who use our products and services.

In meeting their needs everything we do must be of high quality.

We must constantly strive to reduce our costs
in order to maintain reasonable prices.

Customers' orders must be serviced promptly and accurately.

Our suppliers and distributors must have an opportunity
to make a fair profit.

We are responsible to our employees,
the men and women who work with us throughout the world.

Everyone must be considered as an individual.

We must respect their dignity and recognise their merit.

They must have a sense of security in their jobs.

Compensation must be fair and adequate,
and working conditions clean, orderly and safe.

We must be mindful of ways to help our employees fulfill
their family responsibilities.

Employees must feel free to make suggestions and complaints.

There must be equal opportunity for employment, development
and advancement for those qualified.

We must provide competent management,
and their actions must be just and ethical.

We are responsible to the communities in which we live and work
and to the world community as well.

We must be good citizens – support good works and charities
and bear our fair share of taxes.

We must encourage civic improvements and better health and education.

We must maintain in good order
the property we are privileged to use,
protecting the environment and natural resources.

Our final responsibility is to our stockholders.

Business must make a sound profit.

We must experiment with new ideas.

Research must be carried on, innovative programs developed
and mistakes paid for.

New equipment must be purchased, new facilities provided
and new products launched.

Reserves must be created to provide for adverse times.

When we operate according to these principles,
the stockholders should realize a fair return.

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1. Executive Summary

Organisation: The Johnson & Johnson Family of Companies in Australia

Type of Organisation: Group of Proprietary Limited Companies

Address: 1 – 5 Khartoum Road, Macquarie Park NSW 2113

Contacts: Peter Vicary
Director, Government Affairs & Policy
Johnson & Johnson Medical
Ph: +61 2 9815 3913
Fax: +61 2 9805 0335
Email: pvicary@its.jnj.com

Or

Tim James
Senior Manager, Corporate & Government Affairs
Janssen-Cilag Australia
Ph: +61 2 9815 3495
Fax: +61 2 8875 3200
Email: tjames@its.jnj.com

Summary of Recommendations

Recommendation 4.1

Penalty processes put in place by the TGA and CRP must act as effective deterrents to drive self-regulation and compliance with the Therapeutic Goods Advertising Code

Recommendation 4.2

Sanctions for offending advertisers should be shaped around business-impacting penalties, which reflect both the severity and serial nature of transgressions

Recommendation 4.3

In order to act in the best interest of the public, the complaints resolution process must be swift and result in timely remediation of advertising found in breach

Recommendation 4.4

Sanctions imposed by TGAC must be enforced and enforcements made visible to complainants

Recommendation 4.5

The TGA should publish on its website information relating to products that have been removed from the ARTG for advertising offences

Recommendation 4.6

In order for this measure to act as an effective deterrent, the TGA must ensure that information is visible to the public and has the potential to impact purchasing behaviour

Recommendation 4.7

The TGA should have the right to refuse to list products that are substantially similar to those that have been previously cancelled unless, and until, the relevant remedial action has been taken

Recommendation 4.8

The TGA should not create provisions for seeking civil penalties for advertising breaches

Recommendation 4.9

The TGA must ensure that any conceived reforms are proportionate to the gravity and consequence of the transgression committed

Recommendation 4.10

The TGA should advise any consumers seeking to take legal action against an advertiser to consult the Trade Practices Act of 1974 (soon to be replaced by the Competition and Consumer Act 2010) and Duty of Care under Common Law

Recommendation 4.11

The TGA must not put in place any measures that could conceivably result in unfair advantage for advertisers with greater access to expert and financial resources

Recommendation 4.12

The TGA should make adherence to an industry code of conduct compulsory for all advertisers of therapeutic goods, regardless of industry membership status

Recommendation 4.13

The various industry codes should be appended to the TGAC to create a single, overarching and enforceable code for advertising of therapeutic goods

Recommendation 5.1

The CRP should maintain its current composition of members representing the therapeutic goods and advertising industries

Recommendation 5.2

The CRP should improve transparency of process by instituting an online tracking system whereby advertisers may monitor the status of their complaints

Recommendation 5.3

The CRP should provide a complete report of the Panel's meeting minutes to both the complainant and the advertiser in question

Recommendation 5.4

Censure rulings against an advertisement should apply to all related advertisers, as opposed to just the organisation or advertiser that has been brought before the CRP

Recommendation 5.5

Censure rulings made on specific types of claims should be made public and deemed categorically impermissible

Recommendation 5.6

The complaints resolution process should include an avenue for appeals

Recommendation 6.1

The TGA CRP should consider complaints about all forms of advertising

Recommendation 6.2

Revisions to the TGAC should result in a single code for advertising of therapeutic goods, which includes advertising of complementary medicines to consumers as well as advertising to HCPs

Recommendation 6.3

The TGA should put measures in place that effectively eliminate the need for pre-approval of advertising

Recommendation 6.4

The TGAC should be amended to include a principles-based code covering advertising directed to HCPs

Recommendation 6.5

The TGA should implement a team of experts to act as case workers, advising advertisers on compliance and avoidance of penalties and sanctions

Declaration of Interest:

The arrangements for the advertising of therapeutic goods have a direct impact on the business conducted by companies in the Johnson & Johnson Family of Companies in Australia.

2. The Johnson & Johnson Family of Companies

Worldwide

Caring for the world one person at a time inspires and unites the people of Johnson & Johnson.

We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people.

Employees of the Johnson & Johnson Family of Companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

Our Family of Companies comprises:

- The world's premier consumer health company
- The world's largest and most diverse medical devices and diagnostics company
- The world's third-largest biologics company
- And the world's sixth-largest pharmaceuticals company.

We have more than 250 operating companies in 60 countries employing 114,000 people.

In 2007 we invested US\$7.68 billion in research.

Our worldwide headquarters is in New Brunswick, New Jersey, USA.

In Australia

Johnson & Johnson Pty Ltd became an Australian corporate entity in 1931.

Today there are more than 1,500 J&J employees in Australia and New Zealand and annual turnover of more than AUD\$1.1 billion.

There are six health and medical care focused operating companies in Australia: Johnson & Johnson Medical; Janssen-Cilag; Johnson & Johnson Pacific; Tasmanian Alkaloids; and Ortho-Clinical Diagnostics.

In 2005, Access Economics reported that during 2004, Johnson & Johnson in Australia accounted directly for gross value added of \$327 million and GDP of \$366 million.

In addition, the flow-on from inputs of domestically produced goods and services into Johnson & Johnson activities indirectly contributed additional gross value added of \$253 million, GDP of \$259 million and the employment of 2,772 FTE.

Combining the direct and indirect contributions, in 2004 Johnson & Johnson contributed gross value added of \$580 million, GDP of \$624 million and employment of 4,085 FTE to Australia.

We now outline the lines of business and companies within the Johnson & Johnson Family of Companies in Australia.

Pharmaceuticals

Janssen-Cilag Australia

Janssen-Cilag Pty Ltd (JCA) is a research-based company that markets pharmaceuticals for a range of conditions including those in mental health, neurology, haematology, gastroenterology, virology, and pain management. One of its key focus areas is biotechnology, which represents the promise of entirely new and highly targeted therapies for a range of diseases. At the same time, innovative genomics tools are already beginning to revolutionise and advance the discovery of pharmaceutical medicines.

Tasmanian Alkaloids

Tasmanian Alkaloids Pty Ltd is an advanced agricultural production and research & development company. It extracts alkaloids (morphine and thebaine) from poppies. Some of this product is converted to active pharmaceuticals (codeine phosphate and buprenorphine) with around 99% of the product exported.

In 1995, Tasmanian Alkaloids initiated a project to develop a high-thebaine poppy. In sampling the alkaloid content of thousands of plants, one plant was found to have a high content of thebaine and no morphine, and the first commercial crop of these unique poppies was harvested in 1998. The new plant revolutionised thebaine production and today it has up to 80% of the worldwide market for Oxycodone raw materials.

Tasmanian Alkaloids is presently the largest manufacturer of active pharmaceutical ingredients in Australia and the largest exporter of codeine and thebaine in the world.

Medical Devices & Diagnostics

Johnson & Johnson Medical

Johnson & Johnson Medical Pty Ltd (JJM) is a major provider to the Australian healthcare system through both the supply of products and the development and implementation of support services for the medical community. Each year, JJM reinvests more than ten per cent of its sales in Australia to provide training and assistance to local doctors. It is focused on a broad range of medical products through a number of separate groups: Ethicon women's health and urology; wound closure and wound management; advanced sterilisation; Ethicon Endo-Surgery minimally invasive technology, laparoscopic instruments and mechanical staplers; Cordis cardiology, endovascular, electrophysiology and neuro-radiology; and DePuy Australia, a leading developer of state-of-the-art technologies for joint reconstruction which markets a range of orthopaedic products.

JJM also supports clinical research programs in Australia across all of its business franchises; from involvement in global programs and first-in-human studies of new innovative technologies, to support for original research ideas from Australian clinicians and specialists. JJM is particularly proud to have a long track-record of partnering with Australian surgeons to bring new and innovative devices to the global marketplace.

Ortho-Clinical Diagnostics

Ortho-Clinical Diagnostics (OCD) and Veridex LLC supply professional in vitro diagnostic instrumentation and related supplies to hospital laboratories, private pathology laboratories, and blood donor centres. Products include reagents used for determining patient blood groups and the compatibility of blood units prior to blood transfusions, screening of blood for infectious agents (e.g. Hepatitis C), and reagents and instrumentation used for clinical chemistry, endocrinology, serology and oncology blood testing.

Consumer Healthcare

Johnson & Johnson Pacific

Johnson & Johnson Pacific Pty Ltd (JJP) is the largest over-the-counter supplier to retail pharmacy in Australia and in the top thirty suppliers of manufactured goods to grocery supermarkets. JJP is committed to providing the best service, programs and advice to consumers, healthcare professionals and the community, and is dedicated to bringing to market innovative healthcare solutions.

JJP's broad product range spans the baby, beauty, oral care, smoking cessation, upper respiratory, gastro intestinal, eye care and general medicine categories. Among our brands are Johnson's Baby® , Band-Aid® Brand Adhesive Bandages, Listerine® Antiseptic Mouthwash, Reach® toothbrushes, Codral® cold and flu preparations, Sudafed® decongestants, Imodium® Anti-diarrheal and Benadryl® cough suppressants.

3. Johnson & Johnson and the advertising of therapeutic goods

Our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality.

Our Credo

As supported by Our Credo, Johnson & Johnson believes its first responsibility is to the doctors, nurses, patients and all others who use our products and services. We take our responsibility to these individuals seriously, recognising that their well-being rests in our hands.

In valuing this approach, we are committed to delivering quality in everything we do – from the robust practices that go into developing, testing and validating our products, to the self-imposed discipline that we put into communicating how those products should be selected and used.

As such, companies in the Johnson & Johnson Family of Companies are faithful in abiding by the arrangements for the advertising of therapeutic goods and by the codes of ethical practice that guide the industries in which we operate.

We recognise the importance of these arrangements in ensuring the accurate conveyance of information to consumers, and in promoting the safe and effective use of products. However, we believe there is scope to improve the efficiency, consistency and effectiveness of advertising arrangements.

We therefore commend the Government's proposal to improve the processes which regulate the advertising of therapeutic goods in Australia. We believe this will not only improve process, reduce costs and eliminate unnecessary regulatory burdens, but also support the welfare of those who use these goods.

In this submission we respond to the series of questions posed in the corresponding consultation document and articulate our recommendations for an optimised system that promotes effective self-regulation of the industry, as well as compliance with a non-exclusive code of conduct.

We have noted and broadly support the submission made by the Australian Self-Medication Industry (ASMI), of which Johnson & Johnson is a member.

4. Effective sanctioning and public recourse

4.1 Imposing effective deterrents to reduce regulatory burdens and improve self-regulation

Issue

According to the Consultation Paper on reforms to the regulation of therapeutic goods advertising, concerns have been raised by some opponents of the current advertising framework that the system is not working as well as it might. The paper reflects the perception that the sanctions currently available to the Complaints Resolution Panel (CRP) and the Therapeutic Goods Association (TGA) do not provide sufficient deterrence against breaches of the Therapeutic Goods Advertising Code (TGAC).

The TGA proposes a number of revised sanction and penalty arrangements, with the requirement that they are:

“...both a real deterrent against transgression and ensure the effective remediation of advertisements that are found to be in breach.”

Johnson & Johnson Family of Companies Position

The Johnson & Johnson Family of Companies supports the proposition of a timely, equitable and meaningful penalty process, which results in more effective self-regulation and compliance with the TGAC.

Business-impacting penalties

In order to act as compelling deterrents, sanctions must be shaped around business-impacting penalties, which reflect both the severity and serial nature of transgressions committed by individual advertisers. Appropriate penalties include fines for damages resulting from erroneous claims, removing goods from the Australian Register of Therapeutic Goods (ARTG), denying inclusion of goods on the ARTG and publishing the details of all penalties issued on the TGA and TGACRP websites.

Timely remediation of advertising breaches

Another effective deterrent available to the TGA is the promise of timely resolutions and immediate removal of advertising that is found in breach. At present, the complaints resolution process does not enable expedient determinations on Code breaches or swift remediation of advertising. Consequently, advertisements with erroneous claims have the potential to remain live for an entire advertising cycle (frequently spanning several months) as it can, and often does, take many months for a complaint to be heard by the CRP.

Case in Point: Complaint 2010/02/013

Complaint lodged on 08/02/2010. Determination not received until 26/07/2010, a period of 5 months. As of August 27th, the Determination had not been published on the CRP website.

Additionally, the CRP's approach to communication does not assist with resolving breaches in a timely manner. Complaints and determinations are communicated to advertisers and complainants via facsimile, as the Secretariat of the CRP has indicated, on a number of occasions, this cannot be done via email. Also, determinations are frequently not published on the TGACRP website until many months after a Panel meeting.

This prolonged process can have the unintended consequence of encouraging non-compliance with the TGAC. Advertisers who are aware that questionable or fallacious claims are not likely to be resolved or remediated for several months or more may determine that the eventual obsolescence of their advertisements gives them little incentive to comply. As this is not in the best interests of the public, the Johnson & Johnson Family of Companies advocates for a more rapid resolution and remediation process.

Enforcement of sanctions

In order to act as compelling deterrents, sanctions imposed by the TGAC arising from a complaint must be enforceable. At present where an advertiser chooses not to comply with a sanction imposed by the TGAC the only recourse that the TGAC has available is to make a recommendation to the Secretary that the inclusion of the goods on the ARTG be cancelled. Any subsequent action, or not, arising from this recommendation is not visible to the complainant. Also, as the sanctions are not enforceable, an advertiser making false and misleading claims can choose not to comply with the imposed sanctions, particularly where complying with such sanctions would be costly.

Case in Point: Complaint 2009/07/005

The Panel requested that Pureste Pty Ltd, amongst other things, arrange for publication of a retraction in Woman's Day, Who Weekly and New Idea magazines and also on the website, www.pureste.com.au. The retraction was never published in the specified magazines and it certainly was not published on the aforementioned website for the required 120 days. As Pureste Pty Ltd chose not to comply, the Panel made a recommendation to the Secretary that the inclusion of the goods on the Register be cancelled. On follow up the Secretary advised that any actions with respect to the Pureste product are subject to the usual rules of confidentiality and procedural fairness and, as such, will not be disclosed. The Secretary also advised that where products are suspended or cancelled from the ARTG by TGA then these decisions are made public via the Commonwealth Gazette.

Improved self-regulation

Through the imposition of business-impacting penalties and the promise of swift action to remediate advertisements in breach, the TGA can expect a marked improvement in self-regulation across the industry and, consequently, a reduction in the expenditure of TGA and CRP resources to pre-approve advertising and hear complaints.

The Johnson & Johnson Family of Companies ardently advocates for heightened self-regulation of therapeutic goods and supports measures that contribute to this end.

Recommendation 4.1

Penalty processes put in place by the TGA and CRP must act as effective deterrents to drive self-regulation and compliance with the TGAC

Recommendation 4.2

Sanctions for offending advertisers should be shaped around business-impacting penalties, which reflect both the severity and serial nature of transgressions

Recommendation 4.3

In order to act in the best interest of the public, the complaints resolution process must be swift and result in timely remediation of advertising found in breach

Recommendation 4.4

Sanctions imposed by the TGAC must be enforced and enforcements made visible to complainants

4.2 Use of the TGA website to publish information related to products removed from the ARTG for advertising offences

Issue

Concerns have been raised by some opponents of the current advertising framework that the system is not working to protect consumers as well as it might.

There is a perception that the complaints handling process is not as transparent as it could be and that the sanctions available to CRP and the TGA do not provide sufficient deterrence.

A proposal has been put forward to utilise the TGA website to publish information related to products removed from the ARTG for advertising offenses.

The Johnson & Johnson Family of Companies agree with this proposal, in principle. If seeking to introduce reforms that serve the interests of consumers, the TGA would be advised to make information relating to products removed from the ARTG for advertising offences public and freely available. This will enable consumers to make more informed selection of therapeutic goods.

However, it should not be assumed that this will serve the dual purpose of acting as a deterrent against future transgressions by offending advertisers. At present, this type of sanction is not considered an effective deterrent, for the following reasons:

- consumers seldom utilise the TGA website to obtain information relating to advertising offenses
- this sanction is very infrequently applied to offending advertisers
- the gravity of this consequence is not unilaterally agreed; rather the weight of the sanction is interpreted by the advertiser in question, based upon the values they hold.

Johnson & Johnson Family of Companies Position

In order for the TGA to accomplish its aim of protecting consumers, it must ensure that the publication of information relating to products removed from the ARTG for advertising offences serves as a true deterrent against future transgressions.

For this to be true, the information available through the TGA website must be shown to be of interest to consumers and there must be evidence that it is being accessed and utilised to inform purchasing behaviour. If no evidence can be found to support this, the proposal should be abandoned in favour of sanctions that serve as more effective deterrents.

Recommendation 4.5

The TGA should publish on its website information relating to products that have been removed from the ARTG for advertising offences

Recommendation 4.6

In order for this measure to act as an effective deterrent, the TGA must ensure that information is visible to the public and has the potential to impact purchasing behaviour

4.3 Empowering the TGA with the right to deny inclusion on the ARTG products that are similar to those removed from the register following advertising breaches

Issue

At present, advertisers that have been found in significant breach of the TGAC may eventually have their product removed from the ARTG. As discussed previously, this does not act as an effective deterrent for various reasons, nor does it serve as an effective punishment for offenders. This is due to the fact that, for every product that is removed from the ARTG, advertisers presently have the ability to apply to have a similar product included on the ARTG under a slightly different name and description. In doing this, advertisers are able to continue promoting their products with only minor interruptions.

Some advertisers have also demonstrated use of this type of tactic to avoid taking remedial action, as ordered by the TGA, to rectify specific transgressions.

Proposed Solution

The TGA is now proposing to assert a right of refusal in listing on the ARTG products that are substantially similar to those that have been previously cancelled unless, and until, the relevant remedial action has been undertaken.

The Johnson & Johnson Family of Companies agrees with this proposal as an effective deterrent against habitual breach of the Advertising Code. Any actions that will prevent routine advertising offenders from actively competing in the therapeutic goods marketplace will encourage improved self-regulation and better serve the interests of consumers.

Recommendation 4.7

The TGA should have the right to refuse to list products that are substantially similar to those that have been previously cancelled unless, and until, the relevant remedial action has been undertaken

4.4 Introduction of civil penalties for breaches of advertising arrangements

Issue

According to the Consultation Paper on reforms to the regulation of therapeutic advertising, concerns have been raised by some opponents of the current advertising framework that the system is not working to protect consumers as well as it might. These opponents have raised the point that there are currently no provisions for seeking civil penalties or enforceable undertakings for breaches of the advertising provisions. The proposal suggests that the sanctions regime under the legislation could be strengthened to include civil penalty contravention provisions and court-imposed remedial action for advertising breaches.

Johnson & Johnson Family of Companies Position

The Johnson & Johnson Family of Companies believes that there is currently no call for the TGA to create provisions for seeking civil penalties for advertising breaches.

No evidence of harm

Whilst the Johnson & Johnson Family of Companies advocates for any action that would serve as an effective deterrent and encourage self-regulation in the industry, the suggestion that civil penalties should be enforced to 'protect consumers' implies that breaches of the advertising provisions have directly resulted in consumer harm. Contrary to this, there is presently no evidence to show that consumers are being, or have been, caused harm as a direct consequence of the advertising of therapeutic goods. Therefore, the TGA would be advised to ensure that any conceived reforms are proportionate to the gravity and consequence of the transgression committed.

Existing legal mechanisms in place to protect consumers

Should any civil complaint be brought against an advertiser for breaching the TGAC, consumers will find they are adequately protected under the Trade Practices Act of 1974 (soon to be replaced by the Competition and Consumer Act 2010) and Duty of Care under Common Law.

Under these legal mechanisms, advertisers are compelled to provide accurate and truthful information about their products to the public and to ensure that their actions do not knowingly cause harm to individuals. The Trade Practices Act of 1974 provides grounds for the ACCC and for individuals to take action against corporations that fail to act against these responsibilities. Similarly, Duty of Care under Common Law ensures that any action taken by an advertiser, which results in harm to an individual, gives rise to an action in tort.

Unequal access to resources in litigation proceedings

For any organisation or individual, the ability to defend one's self in a court of law requires significant resources, both financial and expert. The introduction of civil penalties would result in unfair advantage given to those advertisers that have access to greater resources.

This fact could encourage some competitors, particularly those that are large and resource-rich, to use the civil complaints system as a weapon against smaller, less-enabled organisations. The time, expertise and investment required to mount a defence could result in both commercial disadvantage and exhaustion of financial resources for these smaller competitors.

As the TGA has an obligation to ensure the continuity of a fair and active commercial environment, the Johnson & Johnson Family of Companies advises against the imposition of civil penalties for breaches of the advertising regime.

Recommendation 4.8

The TGA should not create provisions for seeking civil penalties for advertising breaches

Recommendation 4.9

The TGA must ensure that any conceived reforms are proportionate to the gravity and consequence of the transgression committed

Recommendation 4.10

The TGA should advise any consumers seeking to take legal action against an advertiser to consult the Trade Practices Act of 1974 (soon to be replaced by the Competition and Consumer Act 2010) and Duty of Care under Common Law

Recommendation 4.11

The TGA must not put in place any measures that could conceivably result in unfair advantage for advertisers with greater access to expert and financial resources

4.5 Adherence to industry association codes of conduct

Issue

At present, the manufacturers of prescription, non-prescription products and devices each have their own industry association (Medicines Australia (MA), Australian Self-Medication Industry (ASMI) and Medical Technology Association of Australia (MTAA)), and each has their own code of conduct. The relevant code applies to members of the association, but does not extend to non-members.

The implication of this is that industry members are held to higher standards of conduct and bound to remediate all advertising that is found in breach of the relevant code, whilst non-members may disregard codes of conduct as well as any orders to remediate advertising. This failure to comply with industry mandates carries no consequences for non-members and there is no authority that member advertisers can appeal to in such cases.

Further, non-members may presently lodge complaints against member organisations as a competitive tactic, with the full knowledge that they, themselves are not held to the same standards of compliance.

Industry members are also frequently at a disadvantage with respect to non-members. For example, member companies are required to provide the data substantiating a claim being made to any consumer or competitor company that requests it. Often this data is commercial-in-confidence, yet it is still provided as it is a requirement of membership. In

contrast, competitor companies that are non-members are under no obligation to provide data to substantiate any claims being made.

Johnson & Johnson Family of Companies Position

The Johnson & Johnson Family of Companies advocates for the TGA to make adherence to a code of conduct compulsory for all advertisers of therapeutic goods, regardless of industry membership status.

One way of achieving this would be to amend the TGAC by appending the various industry codes (Medicines Australia (MA), Australian Self-Medication Industry (ASMI) and Medical Technology Association of Australia (MTAA)). Although we would envisage each industry body maintaining ownership for the development and amendment of their respective codes, we believe this action would deliver a single overarching code for advertising of therapeutic goods to consumers as well as HCPs.

This would help ensure that codes of conduct become universally enforceable and that sanctions placed on offending advertisers are meaningful and carry enforceable consequences. It would also act as a further measure to encourage self-regulation within the industry and better protect the interests of consumers.

Recommendation 4.12

The TGA should make adherence to an industry code of conduct compulsory for all advertisers of therapeutic goods, regardless of industry membership status

Recommendation 4.13

The various industry codes should be appended to the TGAC to create a single, overarching and enforceable code for advertising of therapeutic goods

5. Improvements to the complaints resolution process

5.1 Reconstitution of the CRP as an independent body

Issue

Currently the CRP is made up of nominees from industry associations, professional organisations, peak consumer organisations and the TGA, and has an independent chair. For some this raises a perception that, due to the affiliations these members have with the therapeutic goods and advertising industries, conflicts of interest impose bias on the Panel.

A proposal has been put forward to form an independent complaints resolution body devoid of any members of the therapeutic goods and advertising industries.

Johnson & Johnson Family of Companies Position

The Johnson & Johnson Family of Companies does not agree with this proposal. It is the Company's assertion that industry representation is essential for the following reasons:

- Members of the therapeutic goods industry possess the technical expertise necessary to evaluate the medical and scientific accuracy of claims

- Members of the therapeutic goods and advertising industries possess a unique understanding of the complexities (as they relate to regulatory restrictions and scientific accuracy) around the advertising of therapeutic goods
- Members of the therapeutic goods and advertising industries possess an understanding of the competitive nature of the therapeutic goods industry. This provides them with an enhanced ability to evaluate questionable advertising activities, which challenge the codes of conduct, and create unfair advantage

It is the Company's understanding that the members of the CRP are already appointed in such a way as to avoid conflict of interest.

Recommendation 5.1

The CRP should maintain its current composition of members representing the therapeutic goods and advertising industries

5.2 Transparency in the complaints resolution process

Issue

At present, there is little transparency in how cases brought to the CRP progress through the system. Advertisers have no way of tracking the status of a complaint and learning where it sits in the queue.

This lack of transparency leads to the perception of an unfair system as some complaints appear to progress to resolution faster than others.

There is also a lack of clarity around how complaints come to be resolved. Advertisers are not provided with information pertaining to how determinations are reached by the CRP (for instance, as the result of a blind majority vote, by way of a unanimous vote, or by final ruling from the panel Chairperson, etc?).

The absence of understanding around this process may contribute to a perception that unfavourable rulings are not well or clearly founded.

Johnson & Johnson Family of Companies Position

The TGA and CRP would be advised to institute measures that provide further transparency around the processing and resolution of complaints.

Tracking and monitoring of complaints

It is recommended that, to improve transparency in the complaints resolution process, the CRP institute an online tracking system, which would allow advertisers and complainants to monitor the status of individual complaints. This would assure advertisers and complainants that no one organisation is able to enjoy an unfair advantage and a uniform approach applies to the progression of all complaints.

This action would also reduce the burden on the CRP to respond to inquiries from advertisers and complainants who are seeking information about the status of their individual complaints.

Clarity around CRP determinations

Further to this, upon determination of a complaint, the CRP should provide both the complainant and the advertiser in question with a complete report of the Panel's meeting minutes. This will serve to provide more clarity around the Panel's rationale for its determination and also provide evidence of the Panel's fair approach to case evaluation. In doing so, this could address aforementioned concerns around the constitution of the CRP.

Recommendation 5.2

The CRP should improve transparency of process by instituting an online tracking system whereby advertisers may monitor the status of their complaints

Recommendation 5.3

The CRP should provide a complete report of the Panel's meeting minutes to both the complainant and the advertiser in question

5.3 Consistency in the complaints resolution process

Issue

Under the current system, complaints brought before the CRP pertain to specific claims made by individual advertisers. If, in reviewing the available data, the CRP finds that there is insufficient evidence for the advertiser to make such claims, then the advertiser in question is obliged to remove said claims from promotional materials and packaging. However, as this ruling only applies to the individual advertiser in question, other industry competitors may continue to make substantially similar claims until such time that they themselves are brought before the CRP and the claims once again evaluated.

Johnson & Johnson Family of Companies Position

Rulings made by the CRP are not universal and therefore, are not collectively enforced. The individual basis on which claims are evaluated and determinations made creates an unfair advantage for competitors, duplicates work for the CRP and is not in the best interests of the public.

The Johnson & Johnson Family of Companies believes that determinations on specific types of claims should be made to apply to all advertisers in a related industry. At such a time that a decision is made against a particular claim or set of claims, the TGA should regularly publish this information to advise all advertisers that these claims have been deemed categorically impermissible.

In doing so, the TGA will:

- Create a more equitable process and prevent unfair advantage for competitors who are not obligated to abide by a ruling made against a fellow advertiser
- Level the playing field and thus eliminate the incentive for aggressive advertisers to use the CRP as a tool by which to gain advantage against competitors

- Eliminate the necessity for the CRP to re-evaluate the permissibility of substantially similar claims for different advertisers, thus reducing the regulatory burden and optimising TGA and CRP resources
- Protect the public interest in ensuring that fallacious claims are categorically removed by all advertisers, as opposed to just those brought before the CRP.

Recommendation 5.4

Censure rulings against an advertisement should apply to all related advertisers, as opposed to just the organisation or advertiser that has been brought before the CRP

Recommendation 5.5

Censure rulings made on specific types of claims should be made public and deemed categorically impermissible

5.4 Opportunity to appeal determinations made by the CRP

Issue

Determinations made by the CRP are considered final and absolute. As a result, advertisers and complainants currently have no recourse to appeal if they feel they have grounds to petition a ruling delivered against them.

Johnson & Johnson Family of Companies Position

The complaints resolution process should include an avenue for appeals for advertisers and complainants who believe that there is cause for their case to be re-evaluated.

Recommendation 5.6

The complaints resolution process should include an avenue for appeals

6. Reducing regulatory burdens

6.1 Complaints resolution for all forms of advertising

Issue

The TGA CRP presently manages complaints made about print, radio, television and internet advertisements for therapeutic goods including prescription and non-prescription medicines and medical devices. The TGA CRP does not possess responsibility for resolving complaints relating to in-store materials or promotional materials intended solely for healthcare professionals (HCPs). The primary consequence of this is inconsistency between advertisements developed for the same products in different mediums.

Johnson & Johnson Family of Companies Position

The Johnson & Johnson Family of Companies believes the TGA CRP should hear complaints and appeals relating to advertisements for therapeutic goods in any media, regardless of the environment in which they appear and their intended audience.

In line with this, the CRP's remit should be extended to include evaluation of complaints made against advertisements for complementary medicines, as well as advertisements to healthcare professionals (HCPs). See section 6.2.

Recommendation 6.1

The TGA CRP should consider complaints about all forms of advertising

Recommendation 6.2

Revisions to the TGAC should result in a single code for advertising of therapeutic goods, which includes advertising of complementary medicines to consumers as well as advertising to HCPs

6.2 Pre-approval by the TGA for all forms of advertising

Issue

The TGA currently requires pre-approval of advertisements for non-prescription medicines intended for print, radio and television. Advertisements intended for the internet or in-store promotional materials are not subject to the same pre-approval processes. Again, this enables inconsistency between advertisements developed for the same products in different mediums.

Johnson & Johnson Family of Companies Position

The Johnson & Johnson Family of Companies believes that effective measures should be put in place to eliminate the need for pre-approval of advertising by the TGA.

Amendments to the TGAC

As stated in Section 6.1, the Johnson & Johnson Family of Companies suggests expanding the TGAC to apply to advertising of complementary medicines, as well as advertising for all therapeutic goods directed to HCPs (see Section 3 1 (b) of the TGAC). This would create a level playing field for all companies advertising to HCPs, harmonise advertisements intended for different audiences (consumer and professional), and require compliance with the TGAC.

Effective sanctions to eliminate pre-approval and improve self-regulation

As stated in Section 4.1, the Johnson & Johnson Family of Companies supports the proposition of a timely, equitable and meaningful penalty process, which results in more effective self-regulation and compliance with the TGAC.

The Company advocates for revisions to the current process, which will:

- Make adherence to industry codes of conduct mandatory
- Remove opportunities for advertisers to utilise the complaints resolution process as a competitive tool
- Hasten resolution and remediation of advertising breaches, and
- Impose business-impacting penalties that reflect the severity and serial nature of offenses.

In introducing measures against these imperatives, the TGA will, in effect create an environment in which all advertisers are incentivised to regulate their own activities in line with the TGA and industry codes.

Optimised use of TGA resources

Given the regulatory burden that would be eased in implementing these new measures, the TGA would be advised to channel its available resources toward the creation of an advisory process (as executed through a team of case workers) intended to guide advertisers in the avoidance of practices that could be found in breach.

Access to a team of experts, specialising in the various aspects of the Code, would further enable self-regulation by advertisers and support the CRP's ability to impose and enforce sanctions as offenders would be unable to claim ignorance.

Recommendation 6.3

The TGA should put measures in place that effectively eliminate the need for pre-approval of advertising

Recommendation 6.4

The TGAC should be amended to include a principles-based code covering advertising directed to HCPs

Recommendation 6.5

The TGA should implement a team of experts to act as case workers, advising advertisers on compliance and avoidance of penalties and sanctions

7. Conclusion

The Johnson & Johnson Family of Companies in Australia supports the proposed efforts to optimise the current arrangements for the advertising of therapeutic goods. The Company believes that a more transparent, timely and equitable process will result in more effective self-regulation and compliance with the Therapeutic Goods Advertising Code for all makers of therapeutic goods (irrespective of industry group membership).

Enabling this would be a CRP process for:

- Hearing complaints and appeals relating to advertisements in any media, executed against agreed and meaningful timeframes
- Translating proven breaches into business-impacting penalties that are enforced. In severe or repeat cases, where a product has been removed from the ARTG, this should be published on the TGA website as a point of public record.

An additional and final point is the recommendation for the TGAC to include advertising of complementary medicines under its remit and to be amended to include the various industry codes. This would create a consistent and unified code, where all advertising, regardless of intended audience, is obligated to comply with the TGAC.

In implementing the aforementioned changes, the Johnson & Johnson Family of Companies believes that the TGA will be able to accomplish its aim of improving efficiency,

effectiveness, transparency and consistency of the system, whilst reducing the regulatory burden and allowing a responsible, active and competitive environment to proceed.

We are deeply committed to working with the government and stakeholders to enable these changes and to support the provision of quality, accurate information about therapeutic goods to all Australians.

In this spirit, we thank the TGA for the chance to make this submission and we are pleased to commend these ideas and recommendations for consideration and would welcome the opportunity to expand on these ideas and recommendations should the opportunity arise.

We would be pleased to assist and work with the TGA and the Government to:

- (a) amplify and/or clarify these submissions;
- (b) attend hearings to speak to these submissions;
- (c) provide expert advice in relation to these submissions; and
- (d) otherwise contribute to the further development and implementation of an effective regulatory system relating to advertising.