THERAPEUTIC GOODS ADMINISTRATION

Consultation: Therapeutic Goods Advertising Code

Proposed improvements include proposed framework for Schedule 3 medicine advertising

SUBMISSION
October 2017

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 fulfil 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 realise a fair return.

Submission Information & Company Overview

Organisation: Johnson & Johnson Pacific Pty Ltd
Type of Organisation: Proprietary Limited Company
Address: 45 Jones Street, Ultimo, NSW 2007
[redacted]

Johnson & Johnson Pacific Pty Ltd is a subsidiary of Johnson & Johnson, the world's most comprehensive and broadly-based healthcare company. 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 around the world. Our approximately 128,000 employees at more than 265 Johnson & Johnson operating companies work with partners in healthcare to touch the lives of over a billion people every day, throughout the world.

In Australia, we provide products and services including medical devices, diagnostics, pharmaceuticals and consumer healthcare products.

The Johnson & Johnson Family of Companies in Australia consists of:

- Johnson & Johnson Pacific Pty Limited – consumer health;
- Johnson & Johnson Medical Pty Limited – medical devices & related technology; and
- Janssen-Cilag Pty Limited – pharmaceuticals.

We employ approximately 1,600 Australians who bring innovative ideas, products and services to advance the health and well-being of the patients we serve. We recognise the impact of serious conditions on people's lives, and we aim to empower people through disease awareness, education and access to quality care.

Johnson & Johnson Pacific (JJP) is a provider of consumer health and wellbeing products, offering families more than 650 trusted solutions for their most common health and wellbeing needs. Many of our brands have earned consumers' trust over generations.

Johnson & Johnson Medical (JJM) produces a range of innovative products & solutions used by healthcare professionals in the fields of orthopaedics, neurological disease, vision care, diabetes, infection prevention, diagnostics, cardiovascular disease & aesthetics. We are the largest medical technology provider in Australia working across public and private sectors.

Janssen-Cilag is dedicated to addressing unmet medical needs in oncology, immunology, neuroscience, infectious diseases, vaccines cardiovascular and metabolic diseases. Janssen has a long-standing history in making a meaningful difference in global public health, dating back to Dr Paul Janssen's pioneering work in mental health and pain medications, as well as the development of more than 80 medicines.

Therapeutic Goods Advertising Code: Proposed improvements including proposed framework for Schedule 3 medicine advertising.

The Johnson & Johnson Family of Companies welcomes the opportunity to provide comment on the current consultation of the Therapeutic Goods Advertising Code. Johnson & Johnson Pacific (JJP) is primarily impacted by the proposed changes and responds on behalf of the Johnson & Johnson Family of Companies.

Globally and locally, Johnson & Johnson is an active participant in industry groups and takes a leadership role in support of patients and consumers.

JJP is a member of the Australian Self Medication Industry (ASMI) and ACCORD - the hygiene, cosmetic and specialty products industry. JJP has contributed and has endorsed the position of the industry bodies and their submissions to this consultation, unless specified in the submission below.

For the ease of review, we have maintained the numbering that has been used in the TGA's consultation document. Text from the TGA's consultation document (where relevant) has been included in this document boxed and in blue (with a page location reference).

4. Proposed Code Changes

4.1 Changes to support effective sanctions and enforcement of advertising requirements *{Page 9 of 19}*

In principle, JJP agrees it would be of mutually beneficial to sponsors, advertisers and regulatory decision makers to have clearer and more detailed objective requirements applying to advertisements about therapeutic goods directed to the general public and to healthcare professional.

It is important that any decision made by a Delegate of the Secretary will be subject to review under Regulation 48 of the Therapeutic Goods Regulations 1990. Further, it is important that no decision will be published or made available in the public domain until all avenues of review/appeal have been exhausted by the impacted parties. JJP believes that this practice would be in line with other non-legislative decisions made by the Delegate.

This consultation represents an opportunity to address some of the limitations that currently exist with the current complaints handling process. Some of these limitations include, but are not limited to, recommendations made by the Complaints Resolution Panel (CRP) not being subject to a merits review process and the publication of the panel's recommendations regardless of whether the complaint is referred to the TGA for resolution. There is also often

a void when a complaint is referred to the TGA with advertisers not knowing if the TGA agrees or disagrees with the determination of the CRP. . This creates unnecessary public awareness and concern, and is arguably not in the best interest of the consumer.

It is important to note that sponsors are not always the advertisers. Sanctions and penalties against sponsors in these instances may be unjustified.

Do stakeholders support minimising subjectivity in the interpretation of provisions in the new Code? *{Page 9 of 19}*

JJP strongly advocates for minimising subjectivity and ambiguity in the interpretation of provisions in the new Code. We believe this is critical as it would result in a reduction in the current significant number of advertisers or sponsor breaches of the code. Further, if there is subjectivity or ambiguity in the code or guidelines, taking appropriate action would be difficult for the regulator and would likely result in challenges to the Delegate's decision. Appropriate diligence in the drafting of the code and guidance will result in fewer merit review applications. It's also important to highlight that many advertisements are subjective. Often breaches may occur because of a view of the consumer take out of an overall advertisement, not because the data to support the claim is flawed. It's important that minimising subjectivity in this type of scenario is also taken into consideration when drafting the new code.

4.2 Changes to support effective sanctions and enforcement of advertising requirements

2. Advertisements must be truthful, balanced and not misleading. Claims about therapeutic goods must be consistent with the entry of the goods in the ARTG

Any representation (any written, pictorial or other descriptive matter) or claim (whether therapeutic or not) in the advertisement about therapeutic goods must be ***truthful, balanced, valid and must be consistent with the indications (medicine) or intended purpose*** *(medical device) accepted in relation to the ARTG.*

The intended purpose in a medical device inclusion can be very broad, as it may cover a range of medical devices in a grouped inclusion ('kind of medical device'). However, any representation made for a medical device must still be consistent with the intended purpose accepted in relation to the particular medical device's inclusion in the ARTG, and as detailed in its labelling and instructions for use. The Code may need to differentiate between medicines and medical devices in setting out these requirements. *{Page 10 of 19}*

JJP agrees in principle with this aspect of the code, however there is a need to ensure that the attributes or performance (such as rapid acting claims) of the therapeutic products are still permissible (on the proviso that they can be adequately substantiated) regardless of whether they are included in the ARTG. The ARTG includes high level indications whereas labels claims or advertising can be more specific. As long as the claims in the advertising is in line with the approved indications then we believe this will be sufficient.

When it comes to medical devices an appropriate level of flexibility needs to be accounted for in the interpretation of intended purpose. For instance, the intended use might be broader than the way a product is positioned or marketed, for example, if the intended purpose of a device is "*to be used in the treatment or management of some skin conditions*", however the device may be marketed as "for the treatment of acne" (arguably a skin condition). This use is not inconsistent with the intended purpose, but might not be immediately apparent.

There is also a need to ensure that non-therapeutic claims, for example, cosmetic claims remain permissible, without the need for additional regulatory action. There is a desperate need to avoid the issue that was experienced by the Complementary Medicine Industry over the past few years. In order to be able to make a claim relating to a non-therapeutic attribute of the medicine, for example, "*contains omega 3 sourced from shrimp originating from the Antarctic ocean*" the particular ono-therapeutic claim needed to be added to the "free field text" during a listing to allow this claim to be used in advertising.

JJP believes that it might not be the code that needs to be differentiated for medicines and medical devices but rather the guidance /guidelines with clear examples for each of the different types of therapeutic goods.

Advertisements must not contain any matter that is likely to ***lead a person to believe that they are suffering from a serious ailment or that harmful consequences*** *may result from a therapeutic good* ***not*** *being used* {page 10 of 19}

This might be an area where there could be further consideration. Valid arguments could be made for instances where this could be considered appropriate. For instance:

- Sunscreens for the prevention of skin cancer
- Folic acid supplements for the prevention of neural tube defects during pregnancy
- Nicotine replace therapy as a therapeutic option to help individuals quit smoking and reduce the risk of lung cancer
- Condoms for the prevention of sexually transmitted diseases

3. All Claims used in advertisements of therapeutic goods must be substantiated

Scientific information referred to in advertisements ***must be presented accurately, be educationally appropriate*** *and written in language that can be readily understood by the audience to whom it is directed. Details of the scientific information relied upon must be publicly accessible.* *{page 10 of 19}*

JJP agrees with the concept that all scientific information must be accurately presented and educationally appropriate.

If the data substantiating a claim is in the public domain, there should be no objections in providing this evidence to the general public if requested.

There may, however, be instances where this might not appropriate. For example, data on file may be commercially sensitive or studies that have not yet been published in a peer reviewed publication. In these instances, there is a heightened risk of an inadequately qualified individual making an assessment on the quality of the evidence, which could lead to unnecessary public awareness and consumer concern. This is not in the best interest of the general public and may also lead to damaging a brand's or company's reputation and irreparably compromise brand equity.

In the non-prescription medicine category, companies may choose to invest in clinical studies for many reasons, however the molecules or products generally have no IP protection. By providing unpublished clinical studies to the general public, this can compromise commercial gains that might be received from investing in a clinical study. This may ultimately result in a decrease in R&D investment and important work that advances our understanding of molecules or products involved in the study would cease.

We strongly support the position that all sponsors must hold the evidence to substantiate their claims, and sponsors should be required to provide this evidence to the TGA when requested. Within the TGA, the expectation from industry is there will be appropriate expertise in assessing evidence used to substantiate claims, such as clinical studies, consumer research or sales data, in addition to expertise in assessing the consumer understanding and outcomes.

Further, there are instances where claims have been approved on pack by the TGA during the registration of a product and these claims are supported by unpublished clinical studies. If a company has not yet published the study, and should a company choose not to make this study publicly available, under the current proposal, a claim that is approved on pack by the TGA cannot be used in advertising. We believe this would be inconsistent and confusing for the consumer.

*The advertisement must **identify the sponsor of the scientific study** and must also detail if the sponsor of that study has or had any direct or indirect commercial interest in the therapeutic good or the ingredients being promoted in the advertisement.* {Page 11 of 19}

JJP agrees in principle with this requirement, however there are some practical implications that need to be considered. When the body of evidence contains many studies, the likelihood is that the studies will have had multiple investigators and multiple sponsors. This requirement should be applied only where practical, with additional details held on file where required. There should be no objections to making this information publicly available when requested.

This requirement also covers comparative advertising of therapeutic goods. The advertising of therapeutic goods must not be disparaging, must be factual, fair, and already substantiated. It must refer to the source of any scientific information and must be reflective of the body of available scientific evidence. {Page 11 of 19}

JJP agrees in principle, however it must be taken into consideration that the concern is the judgement of the consumer take outs as opposed to the information being factual, fair and not disparaging. Further detail is required as to the most appropriate and qualified person for this. Unlike the science, the consumer takeout is subjective but robust peer reviewed market research may help provide objectivity.

*Certain **endorsements by health related bodies or organisations** would still be allowed, but subject to requirements to ensure they are not misleading and clearly disclose the relationship with the advertiser and basis for the endorsement.* {Page 11 of 19}

JJP seeks clarification on what is considered acceptable. For example, if a product has a seal on their product, would the use of this seal be excluded from advertising? Clarification on what endorsements are considered acceptable and where the use of these endorsements are considered appropriate. These might include, but are not limited to:

- The Nurses and Midwives association
- RAGCP
- Heart Foundation
- Cancer Council

JJP also seeks clarification on whether labels, such as “Chemist Own”, suggest endorsement by a chemist or pharmacist.

4. Advertisements of therapeutic goods must give adequate and appropriate information on the risks, cautions and side effects as well as provide a balance between promoting responsible self-treatment and encouraging consumers to seek timely professional help

An advertisement about therapeutic goods ***must not encourage, or be likely to encourage inappropriate or excessive use of the goods.*** *An advertisement must also not unduly glamorise products or prey on the vulnerability of particular consumers. In assessing compliance of an advertisement under this particular requirement, the following public interest criteria are to be applied:* {Page 11 of 19}

JJP makes the assumption that advertisements for the discounting of products are most likely to breach this aspect of the code. It is believed that significant discounting of goods result in excessive use. However, there is no direct or indirect proof that excessive purchase or poor purchase decision results in inappropriate use of excessive use or consumption.

JJP seeks better guidance on managing this issue and the view of the TGA in relation to excessive purchase in the Code. Consideration needs to be given to some therapeutic products that are "pantry stocked", for example , pain medication, vitamin and mineral supplements, condoms, sunscreens (usually when sold on discount), and others that are purchased under distress (for example, cold and flu). If a product is "Pantry stocked" it does not necessarily mean that the consumer is using excessive amounts of a therapeutic product.

To be able to prosecute on this clause, there needs to be an unequivocal demonstration that an advertisement has induced or resulted in, encouraging excessive consumption.

The adequate labelling of the products largely mitigates the risks associated with excessive use, and excessive purchase is not a factor in a consumer's behaviour when it comes to the use of therapeutic goods.

Advertisements must also ***not discourage consumers*** *from taking medicines prescribed by a healthcare professional. Subject to the media of publication or broadcast of the advertisement, mandatory statements, contraindications and warning statements must be included in advertisements such as "if symptoms persist consult your healthcare professional" or the warnings included in legislative instruments made under the Act for this purpose. (e.g. in the Medicines Advisory Statements Specification 2016). The nature of such statements, and their duration (for broadcast media), font size (in print media) or relative prominence (e.g. in outdoor marketing) may also be specified.* {Page 12 of 19}

JJP recommends better guidance in relation to the mandatories in advertising material. Subjectivity must be removed given the penalties that apply. This guidance might include the

font height of disclaimers and the duration for which they are required to remain on screen, however careful consideration must be given to all media (for example, digital, television) and the devices they are viewed on. This would be an area that needs broader consultation.

It is recommended this guidance is developed based on evidence or research that ensures the mandatories are viewed and understood by consumers. Advertisements are about brand promotion – all of the mandatories and more are included on the product label or instructions for use, which are read before purchase or before using the therapeutic product.

*In relation to **sponsorship advertisements**, it is proposed that a sponsorship advertisement must:*

- *clearly and primarily promote the team, individual, competition, event or activity being sponsored; and*
- *not contain a direct or implied claim or a sales message including any brand tag-line for a therapeutic product, other than product name, or in the case of a medical device, a purpose for use; and*
- *not imitate or use any part of a therapeutic product advertisement from any medium, or refer or link the advertisement from any medium.* *{Page 12 of 19}*

JJP seeks further clarification/examples on acceptable and unacceptable components in any future guidelines to be published.

It is also proposed that any disease awareness campaigns by sponsors of therapeutic goods, healthcare professionals, associations and other groups (e.g. Heart Foundation, Cancer Council) require that the campaign must be factual and balanced and support consumers in making informed health choices. Such campaigns must not identify a specific therapeutic good or sponsor either expressly or by implication. *{Page 12 of 19}*

JJP seeks further clarification and examples of this need to be provided, especially in relation to the scope of this statement. Presumably this will also apply to all therapeutic products, irrespective of classification. There are television advertisements/campaigns currently run by prescription pharmaceutical companies that are a disease awareness and treatment availability awareness (for example, smoking cessation, erectile dysfunction and neuropathic pain). This advertising informs consumers there are therapeutic options available for these conditions and offers advice to consumers speak to a health care professional. At the end of these advertisements, the sponsor name and address can be found.

If we understand the proposal correctly, under the current proposal, the sponsors will no longer be able to include their details on a disease awareness campaign.

There are no proposed changes to the requirements in relation to professional recommendations. {Page 12 of 19}

JJP respectfully suggests there is still some ambiguity in this part of the code, and seeks clarification and examples of what is acceptable. For example, HCP versus an organisation for example Nurses and Midwives Association.

Further, there are advertisements that mislead consumers into thinking that healthcare professionals are recommending a treatment, when they are not considered to be an HCP under the current legislation, for example, trichologists. JJP takes the view that the average consumer does not know whether these professionals are considered HCPs, and they should not be used to promote therapeutic options for particular conditions.

4.3 The Council recommendations

Amending the provisions dealing with "scientific information" to ensure that:

- *references to a specific research study in an advertisement must sufficiently identify the study as to allow consumers to access it; {Page 13 of 19}*

Often there are many references to support claims – a full list of references in an advertisement is impractical and provides no value to the consumer. Data on file should remain adequate, and a complete list of supporting studies provided upon request.

If the data is already in the public domain, then there will be no objections to providing evidence to the general public when requested.

Where the evidence is in the form of unpublished studies, these should be made available to regulators upon request and not necessarily directly to the general public. The biggest concern is the risk associated with individuals who are not adequately qualified to assess the quality of clinical or scientific studies, which could result in individuals drawing incorrect conclusions. This is discussed previously.

Testimonials and free samples

** Testimonials in advertisements to be subject to clearer more objective conditions.*
** Prohibiting offers of free samples of therapeutic goods as part of an advertisement. Exceptions would be sunscreens and class I medical devices (including for example condoms and dressings where the intended purpose does not require intervention by an appropriately qualified healthcare professional) but excluding IVDs. {Page 14 of 19}*

JJP believes that some additional therapeutic products should be exempt from restrictions on sampling, such as tampons, and other consumer devices where the intended purpose does not require intervention by an appropriately qualified healthcare professional.

It is also noted that condoms are not Class I devices, and the guidance should be corrected before being finalised.

4.4 Consultation comments

A number of comments were received in response to the 2016 advertising consultation regarding the proposal to redraft the Code. These comments included:

1. *Support for the **development of a new Code** to remove subjectivity by revising the interpretative provisions, particularly in light of the proposed enhanced sanctions and penalties, and consideration that it is important that any 'simplification' of the process for advertising regulation is not compromised by increased uncertainty around the implementation of the Code itself;*
2. *The Code should **clearly and unambiguously communicate requirements and include specific examples of compliant and non-compliant advertising**, and that the requirements should be consistently interpreted and applied, as well as being updated on a regular basis; and*
3. *There should be accompanying **guidelines** to assist with understanding of the requirements to enable compliance to the Code. {Page 14 of 19}*

JJP agrees with this aspect of the Code. Given the new range of penalties that can be applied, the Code needs to provide clear guidance and examples and less ambiguity, especially in relation to the type of studies required to support different types of claims and consumer take out. The guidance document should be a standalone document that can be updated as necessary to help "future proof" the Code.

Where there is uncertainty or ambiguity in the Code or guidance, all financial penalties should be suspended. Appropriate remedial action should then be taken to address these ambiguities in the code and/or guidance.

6. An Option for an Advertising framework for Schedule 3 (pharmacist only) medicines

6.2 Product Advertising Requirements

Product advertising requirements *{Page 16 of 19}*
Advertisements for Schedule 3 substances included in Appendix H will be subject to all general requirements as set out in the Code and the Act.
The following additional requirements are proposed for advertisements for medicines containing Schedule 3 substances:

*"**Your pharmacist must decide if this product is suitable for you**."*

JJP recommends softening the language such that is less directive and more likely to be acceptable to consumer. We recommend:
"Your pharmacist will help you decide if this product is suitable for you"

The above statement is to be included prominently in the advertisement. For print advertisement this statement should appear at the top of the advertisement, for broadcast media this should be the leading statement.

"Ask your pharmacist about side effects relevant to you"

JJP again recommends softening the language of this statement. We recommend:
"Ask your pharmacist if this product is right for you"

The above statement is to be included prominently in the advertisement. For print advertisement this statement should appear at the bottom of the advertisement, for broadcast media this should be the ending statement.

It is proposed that a single standard phrase is to be included at the top/beginning and bottom/end of an advertisement to facilitate consumer education and standardisation of messaging. More specific requirements around statements will be consulted upon at the time of public consultation on the draft advertising code.

Before this becomes a mandatory requirement, it is strongly suggested the TGA consults an expert or experts in the space of consumer perception and communications, and determines the best way to convey the desired message. JJP believes that covering an advertisement with disclaimers will be confusing and ineffective at achieving the desired outcome.

6.3 Substances unsuitable for inclusion in Appendix H

For some substances, it is acknowledged that direct-to-consumer (DTC) advertising would not be appropriate. It is a proposed that a working group, inclusive of a wide range of stakeholders would assess the existing list of substances included in Schedule 3. As a guide, the following categories may not be appropriate for DTC advertising:
** Injectable*
** Substance for use in emergency situations*
** Where safer analogues or therapeutically equivalent medicines are available*
** Where there is potential for inappropriate use, abuse or diversion*
** Where the substances form part of surgical procedure*
** Medicine for treatment of chronic condition that requires a doctor as part of the treatment* *{Page 16-17 of 19}*

JJP has limited S3 products, so there are no commercial considerations in the comments below.

If the intent is about making the consumer aware of the availability of medicines without the need for a prescription, we question the number of restrictions on this requirement. It is up to the manufacturers of these emergency treatments to decide to advertise directly to consumers, but it is important to raise consumer awareness on, for example:

- The availability of injectable adrenaline to prevent anaphylactic reactions
- The availability of salbutamol for asthmatics
- The availability of the emergency contraceptive.

Consumers are typically aware that they need these medications, but are not necessarily aware of their availability without a prescription. Greater public awareness of the availability of these medicines without a prescription is not likely to drive inappropriate or excessive use of these medications, and could potentially reduce some of the burden on the public health system.

6.4 Process for adding a substance to Appendix H

Stakeholders are asked to provide feedback on the proposed option for advertising of Pharmacist-only medicines containing Schedule 3 substances and inclusion in Appendix H.

In particular, we would appreciate feedback on

- *the specific requirements for advertisements containing Schedule 3 substances*
- *factors to be considered by the delegate*
- *restrictions on inclusion in Appendix H*
- *the proposed process* *{Page 17 of 19}*

JJP supports the S3 advertising model proposed by ASMI. The position should be that if an ingredient is included in Schedule 3, it will be place in Appendix H by default unless the ingredient is subject to one of the conditions listed above (for example, subject to abuse).

7. Next Steps

JJP is grateful for the opportunity to comment on the proposed changes to the Advertising Code. We see great value in being involved in further consultations on this matter.