



FAMILY OF COMPANIES

***THERAPEUTIC GOODS ADMINISTRATION***

**THE REGULATORY FRAMEWORK FOR  
ADVERTISING THERAPEUTIC GOODS**

**SUBMISSION**

**December 2016**

## **Contents**

Our Credo	3
Submission Information & Company Overview	4
Comments on the consultation document	5

## **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 Pty Ltd  
**Type of Organisation:** Proprietary Limited Company  
**Address:** 45 Jones Street Ultimo NSW 2007  
**Email and phone contact:** [REDACTED]

Johnson & Johnson Pty Ltd is a subsidiary of Johnson & Johnson, the world's most comprehensive and broadly based healthcare company. 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 brands;
- Johnson & Johnson Medical Pty Limited – medical devices and related technology; and
- Janssen-Cilag Pty Limited – pharmaceuticals.

We employ approximately 1,500 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. Our research and development focuses on identifying medical needs and harnessing the best science, whether from our own laboratories or through strategic relationships and collaborations.

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

**Janssen** is dedicated to addressing unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and 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.

## Comments on the consultation document

### Overall Comments

We support the Government’s endorsement to move to a more self-regulatory framework for the advertising of therapeutic products. In order for a self-regulatory system to be successful, we believe it needs to be supported by a swift acting and effective complaint body. This body needs to be made up of members who have the appropriate expertise including (but not limited to):

- advertising healthcare products and solutions,
- emerging advertising trends
- evaluating scientific data, peer reviewed publications and clinical trials

It is also critical that the committee member(s) that are deemed to be the consumer representatives genuinely represent the interests of consumers and are qualified to accurately represent “the reasonable consumer”.

If self-regulation is found to be problematic for a specific advertiser, we suggest that a provision to require mandatory pre-approval for a stipulated period could be used to bring that advertiser into compliance.

We are of the opinion that the current advertising framework for Therapeutic Goods (The TGAC) is now out of date and requires revision to incorporate more specific considerations of advertising medicines using emerging types of digital media and devices. We would also support the regular (every 2-3 years) update to the TGAC, allowing the code to cater for emerging trends and techniques of advertising as well as the development of an accompanying guideline.

### 4.1 Moving forward

At the time of product listing, sponsors and manufacturers of complementary medicines may not have developed promotional claims and won’t be able to submit any proposed promotional claims for assessment. Additionally, new promotional claims may be developed after the product is listed. Further consideration will need to be given to whether these new claims will be assessed and how the process will look in terms of getting the new claims assessed.

### 5. Sanctions and penalties

We support the Governments proposal to increase the regulator’s enforcement powers with respect to advertising. This proposal however must include a process for a merits and judicial review of any decision made by the committee or delegate (i.e. all decisions should be subject to operation of section 60 of the Act). There should be no publication of any decision until such time that the timeframes for the review process referenced above have been expired.

We believe that sanctions and penalties should not be issued for advertisements that are highly subjective in nature as they are matters that cannot be 100% confirmed e.g. there is uncertainty around likely consumer take out. Sanctions and penalties should only be issued where there is clear objective evidence of a breach of the advertising requirements e.g. advertising that puts the

consumer's health at risk or claims that are not scientifically substantiated.

### 5.1 Civil penalty provisions

We support the Government's proposal to include civil penalties as part of the sanctions package, however this should be reserved for breaches that endanger public health and safety or for obstinate and repeat offenders. The issuing of such sanctions must go through the appropriate process and be subject to operation of section 60 of the Act.

### 5.2 Infringement notices

We note that infringement notices will only be used where there is a clear objective evidence of a breach of the advertising requirements. We propose that 'objective evidence' be clearly defined to ensure decisions that are subjective won't result in infringement notices being issued.

### 5.3 Injunctions

We support the proposal for the TGA to have the power to apply for an injunction relating to advertising. The injunction should only apply to advertisements of therapeutic goods that pose risks to public health and safety, or if the advertisement contains false or misleading representations that contravene the requirements relating to quality use of medicines or medical devices.

We suggest that all costs relating to the injunction should be paid by the advertiser that has been found to be in breach.

### 5.4 Substantiation and warning notice powers

We have no objection to the TGA being given the discretionary power to publish public warning notices in relation to advertising claims as long as the claims are likely to cause or result in harm or injury.

### 5.5 Transparency

We agree the TGA should publish information on their website if a matter is referred to the Secretary to take action and the advertiser did not provide an appropriate response. However, this information should only be published if the complaints handling process (including any potential legal proceedings) has been closed out. This needs to apply to both advertisements that have been found in breach of the TGAC as well as those referred to the TGA having found to comply with the TGAC.

We also propose that full meeting minutes (from the complaints review committee, including the committee representatives) and a copy of the outcome report (if the assessment of the complaint included an evaluation of clinical or other scientific data) should be made available to the advertiser. This will allow advertisers to have greater transparency of the decisions made from the committee.

that reviewed the information provided during the complaints handling process.

**6.3 Future Options: Model 1 – Commonwealth agency**

Consideration should be given to how this model will be funded and whether the TGA would also assess complaints for non-therapeutic products making therapeutic advertising claims. Additionally, the individuals who assess the complaints need to have both technical expertise and a good understanding of the regulatory framework and are adequately qualified to represent the reasonable consumer.

**6.3 Future Options : Model 2 – Independent non-government authority**

If an independent authority will be handling the complaints process, the individuals within the group must have the right expertise. We suggest that rotating industry members could be included in the independent authority, as long as there is no conflict of interest.

Careful consideration must be given to this option, as it is effectively no different to the existing CRP.

**6.3 Future Options : Model 3 – Hybrid government and non-government authorities**

Consideration should be given to how complaints for advertisements that both contain non-therapeutic and therapeutic advertising claims would be assessed. If the TGA only assesses the therapeutic advertising claims and an external agency assesses the non-therapeutic advertising claims, we have concerns that the timeframe for the outcome of the complaint could be overly long.

**7.1 The Therapeutic Goods Advertising Code**

In addition to the considerations listed in the consultation document, the following points should also be considered:

- The Code should be clear so that it is less open to interpretation. Definitions should be aligned with Industry prior to publication of the code (for instance – “Internet marketing” is not a term that is used in Industry)
- The Code should be updated and maintained on a regular basis – this will help incorporate advertising requirements for advertising material that use emerging types of digital media and devices
- The Code should continue to be written in plain English
- The Code should have an accompanying guideline
- There is currently no information as to how large mandatory statements and disclaimers should be or how long they should appear in the advertisement for. This should factor in advertisements that are provided via social media and mobile apps. This information could be provided in the accompanying guideline
- Examples of what is considered ‘prominent’ should also be provided. This information could be provided in the accompanying guideline
- Examples of what is considered to be ‘implied’ endorsement should be given. This

information could be provided in the accompanying guideline

- Examples of what is considered as scientific information should be given. A criterion should also be included so that advertisers are clear of the requirements when using scientific evidence. This information could be provided in the accompanying guideline.

## **7.2 Future provision of expert advice**

The committee and expert advisers who will provide the TGA advice on matters relating to advertising should have the appropriate expertise, be completely independent and be up to date with the different advertising channels available. In order to be quorum, the committee should also include members who truly represent the consumers. We also suggest that industry members could be included in the committees, as long as there is no conflict of interest.