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Advertising Consultation

Recalls and Advertising Section

Office of Product Review

Therapeutic Goods Administration

PO Box 100

WODEN ACT 2606

Submission by Blackmores on the Consultation Regulation Impact Statement: Regulating the advertising of the advertising of therapeutic goods to the general public, version 4.6 May 2013

Introduction

In May 2013, the TGA released the *Consultation Regulation Impact Statement – Regulating the advertising of therapeutic goods to the general public*. The purpose of the Impact Statement is to help inform the Australian Government in decision making on proposed regulatory reforms to improve the management of public health risks in relation to the advertising of therapeutic goods to the general public.

Blackmores has been advocating advertising reform for over 10 years and we welcome the consultation paper.

Blackmores is Australia's leading natural health brand and the most trusted name in natural health. We have been pioneers in natural healthcare for more than 80 years, breaking boundaries and seeking new ways to improve people's health.

Blackmores employs 749 people and has annual sales of over $300 million.

The document titled: *Consultation Regulation Impact Statement – Regulating the advertising of therapeutic goods to the general public*, has been presented as a Regulation Impact Statement; however it contains multiple proposals, and multiple options for each proposal, some of which are do not appear to be clearly defined or thoughtfully considered. It has been difficult for us to respond with a defined impact statement. We will be better placed to provide a realistic impact assessment when presented with clearly defined and realistic proposals for advertising reform.

Due to our interest in specific areas of this consultation, our submission addresses 6 of the 8 proposals put forward in the impact statement.

Proposal 1: Alternatives to the pre-approval scheme

Several options to the current scheme for approving advertisements in specified media prior to publication exist:

Option 1: Status quo - maintain the current system.

Option 2: Extend the current system to:

a) include pre-approval for medical devices

b) cover subscription broadcasting ('narrowcasting') (pay-TV).

Option 3: Limit the current pre-approvals scheme to cover only "higher risk" categories of advertisements.

Option 4: Retain pre-approvals (modified or not as per option 2 or 3) and:

(a) maintain the current pre-approval delegations to industry associations, such as ASMI and CHC (with an appropriate medical devices industry group if option 2(a) is endorsed); or

(b) appoint an independent statutory office holder to undertake pre-approval function; or

(c) TGA to undertake the pre-approval function.

Option 5: Remove the pre-publication approval scheme.

Blackmores supports option 4 (b): Retain pre-approvals and (b) appoint an independent statutory office holder to undertake pre-approval function, with modifications.

Blackmores supports the retention of mandatory pre-approval for 'above-the-line' advertising for listed complementary medicines. Pre-approval of advertising for complementary medicines improves confidence of consumers and regulators that advertising material directed to consumers is appropriate.

A factor that has substantial significance to our business is the need to establish one approval office for all types of media for complementary medicines to ensure consistent decision making in the pre-approvals process. Whether the approvals body is the TGA, an industry association or a new statutory body is of relatively little significance so long as the process is clear, consistent, timely and cost effective.

We also support, in principle, a modified version of option 3, whereby advertisements deemed 'non-high risk' could be approved by the sponsor using a delegated authority.

We require certainty as a business that pre-approval is a worthwhile process that when undertaken correctly, adds value to the practice of marketing complementary medicines to consumers. The issues with the current system which have been identified within this consultation create a lack of certainty for our business and impact consumer confidence. Currently pre-approvals do not offer any protection when a complaint is made against an advertisement, which is unacceptable. The validity of the pre-approval process should be improved by aligning the office and procedures with the complaints handling body (see proposal 2 comments regarding competencies required for this body).

We support the office that performs the preapproval function being either the Complementary Healthcare Council (CHC), or an independent statutory office. The CHC as the peak industry body for complementary medicines can play a critical role in the setup, support and ongoing governance of the statutory body for preapprovals and complaints handling. There is an argument that the industry association's involvement in this process has the potential to generate a perception of bias, we genuinely do not believe this to be a real issue for consumer confidence in the pre-approvals or complaint handling process. However in order to address the potential for perception of bias, a clearly defined, cohesive and transparent process that can be published and readily accessed by consumers would help educate and address this perception.

The scope of the pre-approval needs clear definition. The pre-approval should not be an assessment of indications listed or registered on the ARTG. It is an assessment of the marketing claims and the overall presentation of the advertisement submitted. The approval officers should be sufficiently qualified to interpret and review evidence supplied to support marketing claims, plus receive training to assess an advertisement's impact on a reasonable consumer. This defined scope should also tie into other areas of reform currently underway, to educate and assist both the pre-approvals officers and sponsors to understand and identify the differences between indications and marketing claims, thereby eliminating the practice of sponsors including marketing claims on the ARTG to assist with approval of these in advertising.

If the validity of ARTG indications is in question during a pre-approval or during the complaints process, this should be handled separately/ deferred to the TGA, as this is not within the jurisdiction of the advertising process and should be dealt with by the regulator who has the personnel and expertise deal with matters of indications and supporting evidence.

Option 3 – 'higher risk' approvals provides opportunities for advertisers to build in-house knowledge and expertise – assisted by the pre-approvals office and expert advisory committee, to perform their own assessments of low risk advertising material without using the pre-approvals office, perhaps using a delegated authority if necessary. This would improve timeliness and reduce costs associated with external pre-approvals.

Higher risk could be determined as certain categories of products or products advertised for specific health conditions or advertisements in particular media formats. Or it could be attributed to specific advertisers – for example if an advertiser has a track record or recent history of complaints this could be used to place them in the high risk category for a defined period of time. Further clarification of higher risk approvals and the criteria used to determine the classification is required in order to comment more thoroughly.

Proposal 2: The complaints handling process

A number of options can be considered to address the concerns raised about the timeliness and inconsistencies associated with the current complaints handling mechanisms for advertising of therapeutic goods to the general public.

Option 1: Status quo - maintain the current system.

Option 2: All complaints about advertising of therapeutic goods to the general public to be handled by a single body, either:

a. the TGA; or

b. an independent statutory office holder.

Blackmores supports option 2: All complaints about advertising of therapeutic goods to the general public to be handled by a single body, (b) an independent statutory office holder, with modifications.

A factor that has substantial significance to our business is the establishment of one committee for all complementary medicine advertising complaints. A single committee would enhance consistency in decision making for determinations, reduce duplication of complaints to multiple bodies for multimedia campaigns, and enhance speed and effectiveness in finalising complaints.

It is essential that this is a correctly constituted committee, with the appropriate level and breadth of complementary medicine expertise on the panel to assess advertising complaints.

As with advertising pre-approvals, the identity of the single body is less important than the expertise of the individuals and the clarity, efficiency and consistency of the process. An option to streamline and improve the complaints process is to enable management by the industry association. Complaints about complementary medicines in all media should be directed to the Complementary Healthcare Council (CHC). The composition of the complaints committee needs to support the National Medicines Policy (e.g. appropriate balance of people to protect the viability of industry while ensuring public choice and product affordability are maintained). The committee should be empowered to apply meaningful sanctions against non-compliant sponsors, to enforce the industry association codes of practice and to engage in dialogue with sponsors to work towards outcomes that support the best interests of the public and the industry.

There should be transparency and immediacy in the complaints process, clearly defined timelines must be set up and these should be transparent to consumers, TGA and industry, the committee should be held to meeting these timelines to ensure complaints are handled efficiently and effectively, in relation to both the determination of the complaint and the applicable corrective action. This is essential to garner the respect and confidence by all users of the system.

Members that constitute the panel should be placed on individual merit and qualifications, rather than being placed as a representative of a body regardless of relevant expertise. The panel requires genuine consumer representatives who represent a 'typical/ reasonable consumer of complementary medicines'. The panel requires genuine health care professionals with expertise in a range of different modalities within the spectrum of complementary medicine, to represent the interests of their peers relating to advertising directed at health care professionals and to provide technical expertise in matters of interpretation and validity of evidence. The profile of members that make up the current Advisory Committee on Complementary Medicines (ACCM) is an indicative representation of the calibre and expertise required

The panel should have a mechanism for referring matters to the TGA or to the expert advisory committee (in proposal 3) when they are beyond the scope or expertise of the panel (e.g. when a complaint is made about the validity or evidence to support an ARTG indication featured in an advertisement). In turn TGA should have a defined and transparent mechanism for deferring advertising complaints to the panel to review, to eliminate duplicate pathways for complaints.

A disadvantage identified in relation to option 2 (b) is the potential that the cost could be more expensive than a TGA run process. We would reason that this is not necessarily the case especially if run or facilitated by the industry association, and the inefficiencies with the current system generate significant cost to industry and negative impact to consumer confidence.

Proposal 3: Provision of advice in relation to advertising matters

Two options are suggested in relation to proposal 3:

Option 1: Status quo - maintain the current system.

Option 2: Establish an expert advertising advisory committee.

Blackmores supports option 2: Establish an expert advertising advisory committee.

Blackmores supports that the establishment of an expert advisory committee will be a useful investment for industry, however regardless of whether a new committee is established or the TGACC remains, the important focus should be on the composition of this committee/ council being appropriate for supporting the National Medicines Policy objectives. Addressing the issues identified with the pre-approvals and complaints process should be conducted by a properly and correctly constituted committee with the appropriate level and breadth of CM expertise.

It is inappropriate for those making technical decisions in judgement of complementary medicines to have no qualification or relevant experience. To positively influence the pre-approvals and complaints process, this committee requires a makeup of members who are placed on individual merit and qualifications, rather than being placed as a representative of a body regardless of relevant expertise.

The responsibilities of the committee should be to govern the TGAC, reviewing and revising it for relevance and currency, removing overly prescriptive restrictions, allowing sponsors to appropriately advertise their products and communicate important health information to consumers.

We would expect the committee to be able to expertly advise and provide concise training to advertisers of complementary medicines on all legislative requirements in relation to advertising.

Proposal 4: Investigation and enforcement powers

Option 1: Status quo - maintain the current system

Option 2: Enhance investigation and enforcement powers

Blackmores supports in principle option 2: Enhance investigation and enforcement powers

Blackmores agrees that an enhancing investigation and enforcement powers will motivate advertisers towards compliance. Benefits of bolstering the system will be most noticeable by influencing the behaviour of advertisers who under the current system knowingly and repeatedly breach the legislation with little consequence. Enhanced penalties and actions should apply to breaches that endanger health and safety of public.

Increasing penalties well beyond that of the current penalty structure will be of most benefit in changing behaviour for advertisers that take advantage of the current systems inefficiencies to deliberately advertise in breach of the legislation, without financial ramifications. However, the fines in table 2 appear to be disproportionate, this is due to the inclusion of one fixed figure per breach. A fair and appropriate modification to the penalty structure would be to adopt a scale of fines where by the penalties have a minimum and maximum range which is determined based on discretion, where by measures such as persistence and repeat offenders and or size of dollar value associated with the financial benefit of the offending behaviour could be used to determine the applicable penalty per breach.

An increase in enforcement powers and penalty units will require all advertisers to place an increased focus on compliance risk. The potential impact to business costs will be in the area of staff training, implementation of process and procedure changes, use of consultants and legal services. It is anticipated that increased cost to businesses will be born across all touch points of advertising, including sponsors, agencies, advertisers and publishers/ broadcasters.

Sections of the Therapeutic Goods Advertising Code (TGAC) are subjective and therefore high penalties are not an appropriate mechanism for breaches of these areas. When there is certainty that a non-subjective breach of the TGAC, Act or regulations has occurred then higher penalties may be appropriate. When an advertisement has been pre-approved, penalties should not apply.

We request more detail regarding the proposed risk profiling system; in particular the criteria for the higher risk categorisation and the process for review or removal from the high risk category this is required to provide an impact evaluation.

Proposal 5: Advertising of higher risk medical devices

Option 1: Status quo - maintain the current system.

Option 2: Prohibit the advertising of higher risk medical devices.

Blackmores in principle support option 2: Prohibit the advertising of higher risk medical devices, to the general public, with considerations.

This proposal has minimal impact for complementary medicines; however this proposal needs to be considered in conjunction with the impact of proposal 6. The status quo regarding advertising to healthcare professionals such as Naturopaths, Herbalists and Homoeopaths enables the dissemination of product safety information regarding contraindications and drug interactions, section 42DL (1) (f) of the Therapeutic Goods Act 1989 prevents the advertising (to consumers) of any products containing ingredients that appear in schedule 3, 4 or 8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Exceptions to this prohibition appear in Appendix H of the SUSDP. If a similar provision were to be included into the Act regarding these higher risk medical devices and a change occurs regarding the certain healthcare professionals being treated as consumers for the purpose of advertising, the risk is that relevant product safety information concerning contraindications with higher risk medical devices could not be communicated to Naturopaths, Herbalists and Homoeopaths.

Proposal 6: Advertising directed to health professionals

Two options are proposed to ensure that only appropriately qualified health professionals are exempted from the advertising requirements:

Option 1: Status quo - maintain the current system.

Option 2: Update the exemption for health professionals in section 42AA of the Act to only recognise health practitioners regulated under the *Health Practitioner Regulation National Law.*

Blackmores emphatically supports option 1: Status quo - maintain the current system; the proposed option 2 is unfounded and unduly restrictive. We have proposed an alternative "option 3".

Option 2 suggests that section 42AA of the *Therapeutic Goods Act 1989*be amended so that healthcare professionals not currently regulated under the *Health Practitioner Regulation National Law* and covered by the National Registration and Accreditation Scheme will be treated as consumers for the purpose of advertising of therapeutic goods.

It is Blackmores' view that this proposal is overly restrictive as:

- complementary medicine practitioners are highly regulated and are part of professional associations;
- the Australian Register of Naturopaths and Herbalists, which is open for registrations from July 1 2013, mirrors the Federal Governments National Registration and Accreditation Scheme for other health professionals;
- complementary medicine practitioners are highly educated practitioners with approximately 500 people graduating from Australian education providers annually; and
- If proposal 6 is accepted, it may have a significant impact on the complementary and alternative health therapies market in Australia.

The following paragraphs address these issues in further detail.

Current regulations in relation to Therapeutic Goods

Advertising of therapeutic goods is regulated by: *Therapeutic Goods Act 1989*; *Therapeutic Goods Regulations 1990*; *Therapeutic Goods Advertising Code 2007*; and *The Poisons Standard 2012*.

The above legislation provides that advertisements for therapeutic goods directed at the following people are exempt from complying with the *Therapeutic Goods Advertising Code 2007*; and Part 5 of *Therapeutic Goods Act 1989*(See sections 42AA and 42DL of the *Therapeutic Goods Act*):

> (a) medical practitioners, psychologists, dentists, pharmacists, optometrists, chiropractors, physiotherapists, nurses, midwives, dental hygienists, dental prosthetists, dental therapists or osteopaths; or
>
> (b) persons who are:
>
> > (i) engaged in the business of wholesaling therapeutic goods; or
> >
> > (ii) purchasing officers in hospitals; or
>
> (c) herbalists, homoeopathic practitioners, naturopaths, nutritionists, practitioners of traditional Chinese medicine or podiatrists registered under a law of a State or Territory; or
>
> (d) a class of persons specified under subsection (1A).

This enables these professionals to access information that is technical and scientific in nature, includes reference to scheduled substances for the purposes of medicine interactions, reference to restricted or prohibited representations for the purposes of advising on warnings, cautions and contraindications.

Currently herbalists (other than Chinese herbal medicine practitioners registered by the Chinese Medicine Board of Australia), homeopathic practitioners and naturopaths are not regulated under the National Registration Accreditation Scheme.

The Impact Statement states that the reason behind the proposed change to the *Therapeutic Goods Act* is that the TGA has no formal assurance that practitioners not included in the National Registration Accreditation Scheme are able to exercise specialist judgment when either:

(a) treating consumers with advertised therapeutic goods; or

(b) advising consumers about the use of advertised therapeutic goods.

This suggestion is both misleading and unsubstantiated as the majority of Naturopaths and Western Herbalists belong to professional associations which require members to be adequately insured, have minimal standards of education, adhere to ongoing professional development and adhere to ethical standards as will be expanded upon in subsequent paragraphs.

Furthermore there is no evidence to demonstrate restricting the information provided via therapeutic goods advertising information to non-NRAS registered practitioners will deliver a safer level of care and surety to consumers, if health professionals were not able to access this information, as would be the case under option 2, that this would actually increase the potential for harm to consumers. Further, this would encourage a greater use of the internet for product knowledge, which would likely increase the illegal purchase of that are not regulated by the TGA to be used for patient care, thus placing the population at an even higher risk.

The current complementary alternative medicine market in Australia

The Australian complementary medicine industry is a significant industry in Australia which contributes significantly to the economy through tax revenues, export and general growth. If option 2 of this proposal in the Impact Statement is accepted and advertising of therapeutic goods is restricted for non-NRAS registered health professionals, this may have a significant impact on the complementary and alternative medicines industry in Australia and thus a negative impact on the Australian economy and healthcare provision as:

(a) the Australian complementary medicine industry is valued at approximately $1.5 - $2.5 billion (excluding education and health insurance);[1]

(b) 2 in 3 Australians use complementary medicines each year;[2]

(c) the market is growing between 3-12% per year.[3] For example, the number of people who reported having consulted a complementary alternative medicine practitioner increased from around 500,000 in 1995 to almost 750,000 in 2004-2005;[4]

(d) according to the 2006 census, 8,600 people were employed as complementary alternative medicine practitioners. This number may be broken up as follows:

(i) chiropractor – 2,488;
(ii) naturopath – 2,982;
(iii) acupuncturist – 948;
(iv) osteopath – 776;
(v) traditional Chinese medicine practitioner – 480; and
(vi) homeopath – 236.[5]

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1 National Institute of Complementary Medicine http://www.nicm.edu.au/understanding-cm/facts-and-statistics, accessed 27 June 2013.

2 Ibid.

3 Ibid.

4 Australian Bureau of Statistics, "*41.2.0 – Australian Social Trends, 2008*", http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/4102.0Chapter5202008, accessed 27 June 2006.

Naturopaths, herbalists and homeopathic practitioners are highly regulated professions

Complementary alternative medicine practitioners are regulated by a number of different associations set out in Schedule 1 of the *Therapeutic Goods Regulations.* These associations include (in addition with the current number of members, where available):

(a) Alumni Association of Natural Medicine Providers Inc (**AANMP**);

(b) Australian Natural Therapists Association Limited (**ANTA**) – 5,900 members;[6]

(c) Australian Traditional Medicine Society (**ATMS**) – 11,800 members;[7]

(d) Australian Naturopathic Practitioners Association (**ANPA**);

(e) Complementary Medicine Association (**CMA**);

(f) National Herbalists Association of Australia (**NHAA**);

(g) Naturopathic Practitioners Association (**NPA**); and

(h) Society of Natural Therapists and Researchers (**SNTR**).

Each association requires that in order to be eligible, practitioners must meet certain requirements as to qualifications and training. For example:

(a) the Australian Naturopathic Practitioners Association requires that full members have a minimum of an Advanced Diploma of Naturopathy from an accredited school or university within Australia;

(b) the Australian Natural Therapists Association Limited requires that all members complete government recognised courses. Additionally, the Association does not recognise courses delivered completely by distance education.

Each association also requires that all members comply with strict codes of ethics, which include that members meet certain requirements as to continuing professional development.

In addition, on 1 July 2013, the Australian Register of Naturopaths and Herbalists will begin accepting registrations from naturopaths and herbalists.

The Register will, for the first time, set independent uniform national standards in training and practice for naturopaths and western herbal medicine practitioners, and develop a Register of practitioners who meet those standards. In particular, the Register will ensure minimum standards of education and practice in practitioners.

The Register will mirror the statutorily regulated Boards administered by the Australian Health practitioner Regulation Authority of the National Registration and Accreditation Scheme.

As a result of the associations listed above requiring that members have specific qualifications and training and the Australian Register of Naturopaths and Herbalists mirroring the requirements of the National Registration and Accreditation Scheme, there is a low risk that complementary alternative medicine practitioners will not be able to exercise specialist judgment when either:

(a) treating consumers with advertised therapeutic goods; or

(b) advising consumers about the use of advertised therapeutic goods.

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5 Ibid.

6 http://www.australiannaturaltherapistsassociation.com.au/about/default.php, accessed 20 June 2013.

7 http://www.atms.com.au/who-we-are/, accessed 20 June 2013.

Complementary alternative medicine practitioners and education

According to a November 2005 paper prepared by La Trobe University entitled *The Practice and Regulatory Requirements of Naturopathy and Western Herbal Medicine*[8] in 2003 there were:

- 47 naturopathy and western herbal medicine education providers in Australia offering a total of 104 undergraduate and postgraduate courses;
- 19 campuses were planning new undergraduate and/or postgraduate courses between 2003 and 2008;
- approximately 500 graduates annually (350 naturopaths and 150 western herbal medicine practitioners); and
- courses in naturopathy and western herbal medicine ranged from 2 to 4.5 years. The mean course contact hours also varied. For naturopathy, science content ranged from 300 hours to 1275 hours, and clinical training ranged from 198 to 1275 hours. For western herbal medicine, science content ranged from 507 hours to 923 hours, and clinical experience ranged from 100 hours to 441 hours.

As a result, complementary alternative medicine practitioners are highly educated and would therefore be qualified to advise consumers about the use of advertised therapeutic goods. This conclusion is reinforced by the fact that the professional associations require that members take part in continuing professional development.

Complementary alternative medicine practitioners are recognised by private health insurers

Due to the growing use of complementary and alternative medicine practitioners by consumers, the majority of private health funds offer rebates for consultations with approved complementary alternative medicine practitioners.

Approved complementary and alternative medicine practitioners are those who are members of a professional association that meet the requirements of the *Private Health Insurance (Accreditation) Rules 2011*.

The rules require that the association must:

(a) be a national entity which has membership requirements for the profession;

(b) provide assessment of the health care provider in terms of the appropriate level of training and education required to practise in that profession; and

(c) administer a continuing professional development scheme in which the health care provider is required, as a condition of membership, to participate; and

(d) maintain a code of conduct which the health care provider must uphold in order to continue to be a member; and

(e) maintain a formal disciplinary procedure, which includes a process to suspend or expel members, and an appropriate complaints resolution procedure.

(See Rule 10 of the *Private Health Insurance (Accreditation) Rules 2011*).

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[8] La Trobe University, "*The Practice and Regulation of Naturopathy and Western Herbal Medicine*", November 2005, http://health.vic.gov.au/__data/assets/pdf_file/0004/320188/naturopathy-final1106.pdf, accessed 20 June 2013.

The rules ensure that a large proportion of complementary alternative medicine practitioners are heavily regulated and must meet strict qualification, ethical and other professional obligations.
If the requirements set out in the *Private Health Insurance (Accreditation) Rules 2011* are good enough to abate any concerns for private health insurers as to the qualifications, experience and operations of complementary alternative medicine practitioners, the requirements should also be sufficient for the TGA.

Option 2 of proposal 6 in the Impact Statement is not consistent with maximising competition

The object of the competition law in Australia, in particular the *Competition and Consumer Act 2010*, is to enhance the welfare of Australians through the promotion of competition and fair trading and provision for consumer protection (section 2 of the *Competition and Consumer Act 2010*).
Option 2 of proposal 6 in the Impact Statement is not consistent with maximising competition as it unduly restricts competition amongst health practitioners (including complementary and alternative medicine practitioners). In particular, it reduces the number of health practitioners (including complementary alternative medicine practitioners) who can advise consumers as to the suitability of an advertised therapeutic good.
In certain circumstances a complementary and alternative medicine practitioner will be better placed than a health practitioner registered under the National Register and Accreditation Scheme to advise a patient as to the use of an advertised therapeutic good due to their experience with the therapeutic good. In particular, this can include use of the Blackmores Professional range of products. Option 2 of proposal 6 could therefore be contrary to consumer protection.

Conclusion

As outlined above, option 2 of proposal 6 of the Impact Statement is unduly restrictive as it does not take into account the fact that:

- complementary alternative medicine practitioners are highly regulated and are part of professional associations;
- the Australian Register of Naturopaths and Herbalists, which is open for registrations from July 1 2013, mirrors the Federal Governments National Registration and Accreditation Scheme for other health professionals; and
- complementary alternative medicine practitioners are highly educated practitioners with approximately 500 people graduating from Australian education providers annually.

Proposed alternative 'Option 3':

1. If the TGA still requires further assurances that complementary alternative medicine practitioners can exercise specialised judgment, a suggested option is to amend section 42AA of the *Therapeutic Goods Act 1989* should be amended so that complementary and alternative medicine practitioners must be either:

    (a) a member of recognised professional association, whereby the association meets similar requirements as that set out in the *Private Health insurance (Accreditation) Rules 2011*, specifically rule 10 (see part 8 above). As the majority of complementary alternative medicine practitioners are

already members of the associations outlined in part 5 above, it is unlikely that this amendment would cause any significant detriment; or

(b) a member of the Australian Register of Naturopaths and Herbalists, once it begins operating in July 2013.

2. The impact statement makes no reference to the other professionals that are listed in section 42AA of the *Therapeutic Goods Act 1989.* Currently persons engaged in the business of wholesaling therapeutic goods; or who are purchasing officers in hospitals; are not considered consumers for the purposes of advertising of therapeutic goods. It is important that professionals such as these are retained in 42AA, to enable them to have access to product information that is technical and scientific in nature, includes reference to scheduled substances for the purposes of medicine interactions, reference to restricted or prohibited representations for the purposes of advising on warnings, cautions and contraindications.

    (a) Furthermore the absence of the inclusion of purchasing officers for pharmacy chains from 42AA is notable. It is inconsistent that these professionals are missing from the list. It is important and an expectation that as part of their job these individuals would be receiving and reviewing information that is more technical in nature than a consumer advertisement.

    (b) We require a clear delineation between genuine consumers receiving consumer advertising versus professionals receiving technical product information to be established. Clarity on this matter will provide advertisers with a clear set of rules and enable the appropriate distribution of compliant information to the distinctly different groups.

3. One of the disadvantages the consultation paper has identified with 'maintaining the status quo' is that advertising to some nationally regulated practitioners, such as medical radiation practitioners, occupational therapists and Aboriginal and Torres Strait Islander health practitioners would continue to be subject to all the controls designed to apply to advertising directed to the general public. A suggestion to mitigate this disadvantage would be to amend section 42AA to include the aforementioned NRAS registered practitioners. This would enable advertisers to advertise therapeutic goods to these health practitioners without applying the controls applicable to consumer advertising. The option of including these practitioners into section 42AA seems a logical and reasonable approach.

We would like conclude by indicating our broad support for the CHC submission to this consultation, there will be areas where our submissions differ, however we are aligned on the issues of most significance.

Yours sincerely,

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Blackmores Ltd