CONSULTATION: THERAPEUTIC GOODS ADVERTISING CODE PROPOSED IMPROVEMENTS INCLUDING PROPOSED FRAMEWORK FOR SCHEDULE 3 (S3) MEDICINE ADVERTISING
submission from The Communications Council

12 October 2017

Introduction

The following submission is made by The Communications Council (TCC) on behalf of its members in response to the above consultation paper and specifically the 5 statements it asks of stakeholders:

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- Minimising 'subjectivity in interpretation of the new code'.
- The principles and specifics of the new code listed in section 4.3 and whether any form of guidelines would be useful and what form such guidelines should take.
- Specific amendments proposed in sections 4.3 & 4.4.
- Should the Price Information Code of Practice (PICOP) remain in the new code or outside or are there any other alternatives to consider?
- The proposed option for S3 Direct to Consumer (DTC) Advertising.

TCC is well placed to provide both answers and recommendations to all of the above by virtue of our specialist healthcare credentials.

We are positioned to provide both commentary and recommendations on these issues because of our specialist healthcare communications committee (HCC), which includes a significant number of the major healthcare communication companies who work on a daily basis with the regulations affecting therapeutic goods and services, across all media. Our scope of experience is not limited to advertising, promotion and PR. It also includes reviewing clinical papers and evidence to help develop and support therapeutic claims that can be used in advertising/promotional materials. Developing educational programmes for therapeutic goods and services to help empower the general public in their optimum use along with specialist education programmes directed to healthcare professionals to assist them in dealing with their patients'/customers' healthcare issues are two examples of this. We believe we have a unique understanding of the consumers' mindset in relation to how they view therapeutic products and services as a result of communicating with them on a daily basis via advertising and regularly commissioning and reviewing consumer research on healthcare issues.

Question

Do Stakeholders support minimizing subjectivity in the interpretation of the new code?

While this is an admirable aim in principle, in practice it will be difficult to achieve since advertising is built on subjectivity i.e. 'it speaks to the heart first, and then the head' to quote an old advertising maxim.

Without wishing to provide a paper on 'how advertising works', it should be remembered that in all markets and especially those of products of similar substances with similar indications, then it is the task of the advertising agent to provide advertising that distinguishes one brand from the other, while remaining inside the regulations. An old example of this was advertising for the ANADIN analgesic brand (now owned by Pfizer) in the UK, which built its market superiority in the sixties and seventies via a simple claim "Nothing works faster than Anadin." While legally this at best means all products had the same speed of action, which was clinically proven, the 'interpretation of the claim by consumers as shown in consumer research, was that Anadin was 'believed to be

the fastest acting analgesic available OTC'. As such it is difficult to see how 'subjectivity' can be minimized. This is especially so when one of the prime tests of an ad is: 'is it misleading directly or by implication?' this requires a judgement by whoever is involved in assessing the claim and will differ by individuals' interpretation of the criteria on which they base their judgement. This is ably demonstrated amongst TGACC members' differing viewpoints when dealing with appeals on the non-approval of ads by ASMs.

The enforced removal of any subjectivity in making judgements, apart from being difficult to enforce, has the potential to reduce advertising to purely announcement of availability and price – hardly democratic.

Guidelines

Guidelines to provide clearer and more specific details of what is and what is not permitted in respect of advertising of therapeutic goods.

We would thoroughly endorse this proposal, especially in the absence of a formal pre-approvals system and no advice centres.

We recommend that this is available from TGA in conjunction with the new code via the website and in hard copy. We also believe it should have a key role in the new formal education system being proposed with copies of the Guidelines being one of the key educational tools explained and given to the participants in the programme.

In terms of content it will require to be written in simple easy to understand plain English with plenty of examples that will demonstrate different aspects of compliance and of non-compliance. Such examples, to avoid any possible legal ramifications should, we suggest, be of imaginary rather than actual products. We at HCC have had experience of providing these before for the original TGACC educational programme and would be happy to do so again for the new code as well as assisting in its distribution and understanding by our members.

A start on guidelines for the current code was started by a TGACC sub-committee, some years ago – TC 's representative was a member. This draft will undoubtedly be available in TGACC archives and will provide a useful starting point if not template for the new code's guidelines.

Section 4.3 recommendations

TCC supports the TGACC's various original recommendations for inclusion in the new code, as outlined in the above.

Section 4.4 recommendations

Subjectivity: As mentioned above attempts to remove or minimize subjectivity while to be applauded, will be difficult if not impossible to enforce.

Examples: Our belief is that the place for these in NOT in the new code, but in the accompanying guidelines and the new formal education programme.

Guidelines: As mentioned above, we are in favour of providing accompanying guidelines with examples in those guidelines.

Price Information Code of Practice (PICOP)

We agree that consumers have a right to be informed of pricing of therapeutic goods as part of their empowerment to help self manage their minor health problems.

Price advertising is currently carried out almost exclusively by pharmacists/pharmacy chains as a retail-marketing tool. Given that it is legal for pricing of both OTC and Prescription products to be made available Direct to Consumer (DTC) and are often in the same communication material, it would seem sensible for it to be included in the new code, but in its own special sub-section, with a corresponding explanatory piece in the accompanying guidelines.

With regard to communication of pricing information to Healthcare Professionals (HCPs), such as GPs and Specialists, then this is for separate discussion as it raises the issue of regulating communications with HCPs, which is not covered by the new code, only by industry codes, which only affect their members.

Options for an Advertising Framework for S3s (Pharmacist Only) medicines

Overview:

We welcome the intent to broaden the DTC advertising of S3 substances and support the specific requirements to inform consumers, to manage the higher risks associated with these substances, but at the same time to recognize that they have been determined suitable for consumer access without a subscription.

However the key to this will lie in the interpretation of the criteria for deciding whether a substance should be included in *Appendix 'H'* and therefore able to advertise DTC.

We have already made a detailed submission on S3s and DTC on May 5 and most of its recommendations still remain relevant. There are a number of key issues we have identified which need to be covered.

1.0 The Process:

While on the grounds of simplicity we would have preferred to see a replacement of the *Appendix H* process with one that automatically allows all S3s by default, to use DTC advertising unless there is an exception e.g., adverse interactions, potential for inappropriate use etc., we accept that a decision appears to have been made to still utilize the *Appendix H* process.

In light of this we certainly support the option to set up a comprehensive working group of jurisdiction; to consider existing S3 substances and recommend to the delegate those that should be included on *Appendix H*. We would also recommend as outlined in our May 5 submission the regular review of new S3 substances, be they the result of down-scheduling or new products in their own right.

The key of course remains in the interpretation of the criteria for inclusion or not, of the substances in *Appendix H.* This 'interpretation' both from the working group and the Delegate him/herself will inevitably be open to the personal opinions of individuals in spite of the objectivity required. It is for consideration that the Minister via the Delegate lays down a principle that the substance's appropriateness be approached from a 'positive' rather than a 'negative' viewpoint. In other words – "Why should this substance NOT be classified for *Appendix H* inclusion", rather than "Are there any reasons why it should be included in *Appendix H*?"

2.0 Restrictions on inclusion in *Appendix H*

Again we support the proposal to set up a working group to agree these restrictions. We believe the examples quoted in Section 6.3 are all relevant. However we also believe there will be others to be considered e.g. the nature and possibility and incidence of side effects.

We would also recommend that the working group as a start considers the criteria used in those jurisdictions similar to Australia with a good track-record of down-scheduling with DTC rights i.e. UK and Canada to name but two and at the same time to consider those substances allowed DTC advertising in these jurisdictions.

3.0 Factors to be considered by the Delegate

The current framework specifies that 'in making a decision on whether or not a substance should be included in S3, the delegate MAY consider the following matters.' (Section 6.1).

We are in favour of retaining these but suggest that the option 'may be considered' be replaced with a directive 'must be considered'.

Again we recommend looking at the factors considered by Delegates or their equivalents in other similar jurisdictions.

4.0 The Specific requirements for Advertisements containing S3 substances

We agree with the recommendations contained in Section 6.2 but suggest that given the importance of these warnings that it is made mandatory to include ALL of them or a standard English equivalent in ALL material and in ALL media i.e. 15 sec radio/TV, digital and display as well as in standard size and types of advertising.

Substance v. Product

This issue was raised in our submission of May 5 and we believe it is still relevant i.e. consumers buy products not substances.

The same substance can be used in different forms with different scheduling for different indications e.g. acyclovir for herpes of the mouth (cold sores) – an open seller, or

Ophthalmological ointment for ocular herpes – prescription only.

Pre-Education

As has been recognized, this is essential for pharmacists and that sponsors not pharmacy associations, must supply the necessary educational tools for the pharmacists to aid in their consultations with customers as patients.

While most pharma companies with S3s will also have a prescription division and thence experience of educating HCPs of varying types together with access to specialist HCP communication agencies, we suggest that certain basic guidelines on timing and content of pre-education, are laid down in the code and expanded on in the

accompanying Guidelines. In particular attention should be drawn to the time it takes to ensure pharmacy staff are prepared before DTC advertising commences. It should also be noted that while Pharmacy Assistants are still regulated as consumers for advertising regulatory purposes in Australia, they still have a role to play with S3s, which is to refer customers to the pharmacist if they are looking for an S3. This will require some very basic pre-education on the product and its indication(s) to assist in that referral process.

We also believe that it is important that GPs are informed of the rescheduling of the product/substance. While most major pharma companies will automatically advise GPs of the re-scheduling as part of their marketing communication strategy, it is for consideration that providing basic awareness to GPs should be made a mandatory part of the HCP pre-education process.

The Role of TCC/HCC

Given our experience in therapeutic products advertising and communication as listed in the Introduction, together with our involvement with the TGACC and regulatory affairs for the last 18 years, we believe we can provide a very useful role in helping develop the final details of the new advertising regulations and their implementation.

We also believe we have the credentials to provide a role in monitoring, reviewing and helping refine and improve the new regulatory process on an on-going basis.

We would be happy to discuss this with you further at a separate occasion.