IVD AUSTRALIA

The Project Officer,
Advertising Consultation
Regulatory Reform Section
Therapeutic Goods Administration
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Re: Consultation on Improving Advertising Arrangements of Therapeutic Goods

Please find attached IVD Australia's Response to the Consultation Paper: ***Advertising Therapeutic Goods in Australia***

IVD Australia commends the Parliamentary Secretary and the TGA on their considered approach to this difficult area and looks forward to working with them and the Therapeutic Goods industry to develop a consistent and even handed result.

Please contact the undersigned if there are further Questions regarding this Response.

Yours sincerely,

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27th August 2010

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IVD AUSTRALIA RESPONSE TO CONSULTATION PAPER ON "*ADVERTISING THERAPEUTIC GOODS IN AUSTRALIA*"

IVD Australia welcomes the Government's Review of the Advertising of Therapeutic Goods. We believe the current mechanisms are cumbersome and confusing for sponsors and introduce an overhead burden on sponsors of therapeutic goods that is not required. On the other hand the current procedures are also confusing and complicated for consumers and healthcare professionals seeking to complain about advertising of therapeutic goods.

We would offer the following specific comments on the Consultation Paper;

A) Throughout the Paper, the term "medicines" is often used rather then the more general term "therapeutic goods". The Health sector consists of more than prescription medicines and the Medical Device sector is equally important as the Pharmaceutical sector. As the recently formed peak body representing the *in vitro* diagnostics sector, IVD Australia would like to see a consistency in approach across all parts of the Therapeutic Goods sector and part of that is a recognition that health is not only about medicines.

B) Protection of Consumers – The Paper refers to concerns that the current system is not working to "protect consumers as well it might". IVD Australia believes however that generally what consumers are looking for is accurate and understandable information through advertising, not protection. The "system" should work to minimise the risk of misleading or inaccurate information rather than impose a blanket ban on particular forms of advertising.

   However IVD Australia is not in favour of changing the current restrictions on the advertising of Schedule 4 and Schedule 8 medicines to consumers nor on the current restrictions that apply to Schedule 3 products.

C) The paper alludes to the increases in workload within the CRP due to the number of complaints dealing with issues of efficacy of therapeutic products. IVD Australia believes that issues regarding efficacy issues should be best dealt with by the by TGA and that all complaints of this nature should be directly referred to the appropriate Office within TGA for response.

D) IVD Australia believes that the current sanction for a breach or repeated breaches of removal from ARTG is an appropriate penalty. Whilst it is acknowledged that it would prevent the advertising of a particular brand from a specific sponsor subject to a sanction, there is nothing in the legislation to prevent the same product being reintroduced onto the ARTG under a different brand name and /or a different sponsor and then the same breaches recurring. IVD Australia would support changes to the TG Act that would allow the TGA to refuse to register or list a similar product that had been removed previously from the ARTG following complaints regarding advertising.

E) IVD Australia is seeking a consistent approach to both HCPs and Consumers from both the Code of Conduct process currently being undertaken and this Review of Therapeutic Goods Advertising. The current arrangements are ad-hoc and confusing and mean that complainants have a number of separate bodies to approach regarding Complaints. These include the various Industry Associations, the Complaints Resolution Panel and the TGA depending on the type of product, the nature of the advertisement and whether the sponsor is a member of an Industry Association.

IVD Australia believes that it would be much more efficient if there where a common Therapeutic Goods Advertising Complaints Agency (TGAC) that was charged with accepting all complaints, both consumer and HCP, and then either dealing with the complaint directly or referring the complaint to the appropriate body to deal with it in the case of Industry Association matters or to the TGA if it was a complaint regarding efficacy or safety of a product.

F) The current Review of the Promotion of Therapeutic Goods being undertaken by Industry after referral by the Parliamentary Secretary addresses some concerns of the Advertising Paper. This Review seeks to strengthen the voluntary Codes of Conduct of the Industry Associations in the Health Sector (including IVD Australia) and has been asked to

   a. determine a set of common high level principles to which all codes should adhere; and
   b. review whether a common complaints mechanism covering all Health Sector Codes could be constructed; and
   c. determine if a mechanism requiring non- Association members to adopt and be subject to an Industry code as a condition of ARTG inclusion can be devised.

G) The current arrangements require preapproval of advertisements of non-prescription medicines if these are to be made on broadcast media such as TV, radio, cinema or mainstream print media such as newspapers or magazines or if they are to be displayed outdoors. It does not cover advertising made indoors such as via in-store promotions or the internet and does not cover advertising of Medical Devices.

IVD Australia believes that this is an inconsistent and clumsy approach and would recommend that the pre-approval process be removed. Sponsors with products covered by the existing arrangements should understand the restrictions imposed by the Therapeutic Goods Advertising Code and be able to produce advertisements that meet these restrictions.

Thus all sections of the Health Sector will be treated equally and no prior approval would be required. However, the TGACA would need to be aware of this change and could expect an increase in the number of complaints regarding advertisements to consumers for non-prescription medicines for an initial period.

Consultation Questions

Overall awareness of the arrangements for advertising of therapeutic goods:

Questions for consideration:
Are the current arrangements for advertising of therapeutic goods in Australia known to you? Should these be better known or understood?
Do you have comments or complaints about the current advertising arrangements?

IVD Australia and its Members are certainly aware of the current arrangements governing the advertising of therapeutic goods in Australia. We believe however that the arrangements are not well understood in general by the community or by healthcare professionals (HCPs).

IVD Australia has a number of comments to make regarding these arrangements;

a) The current document regarding the Regulation of Advertising of Therapeutic Goods in Australia on the TGA Website is out of date as the last revision was 2004. In addition the paper is slanted principally at the advertising of medicines (both prescription and non-prescription) and tends to forget the advertising of Medical devices, including *in vitro* diagnostics. It implies that complaints about Medical Device advertising to HCPs needs to be directed to the TGA whereas it is currently Industry Associations such as IVD Australia and MTAA that would deal with these complaints.

   The current arrangements apply only to some communications media and not others. Given the rapid growth in social media such as Facebook, Twitter and LinkedIn and to advertising on the internet in general, the revision of the arrangements is well overdue. The TGA Paper on the advertising of Therapeutic Goods indicates that internet advertising is not covered by the Complaints Resolution Panel whereas as the TGACC Website indicates that it is. The fact that that the complaints handling process is split between at least 3 groups is confusing for complainants and also for sponsors.

b) The current arrangements are covered by a plethora of Acts, Regulations and various Codes of Conduct, including the Therapeutic Goods Act (TG Act), The Therapeutic Goods Regulations (TG Regs), the Therapeutic Goods Advertising Code (TGAC), the Trade Practices Act, various State Consumer Protection Agencies and at least 7 different Industry Sector Codes of Conduct. No wonder consumers and HCPs find it confusing and daunting to consider complaining or even raising a question regarding a product advertisement they may feel has mislead or confused them.

Using the advertising arrangements:

Questions for consideration:
Do you currently use the arrangements to place approved advertisements?
OR
Do you find advertisements of therapeutic goods helpful?

Members of IVD Australia do use the current arrangements at present but in a limited manner. A number of IVD Australia members advertise directly to the public as they sell Point-of-Care (POC) or near patient tests. This particularly apply to blood glucose meters and home pregnancy test kits but there are a variety of consumer tests becoming available for other parameters including INR and HbA1c.

IVD Australia's major concern with the approval process is that currently Members are not permitted to refer to serious diseases in their advertising. It is very difficult to do this when the intended purpose of the IVD is to assist in the monitoring of a serious disease such as diabetes or serious conditions such as coagulation disorders.

The pre-approval process:

Questions for consideration:

Should the current pre-approval process for advertising be retained?

If so, should all forms of advertising be considered in this process?

- Advertising of non-prescription medicines in print, radio and television do require pre-approval, but others do not eg internet, in-store promotion.

IVD Australia does not favour retention of the current pre-approval process.

At present the only products that require pre-approval are those non-prescription medicines advertised on broadcast media, in cinemas and in mainstream print media. There is no requirement that advertisements used in in-store advertising, on leaflets delivered to homes or via store promotions or in brochures or catalogues are subjected to pre- approval.

Hence the current process is ad-hoc and arbitrary. IVD Australia suggests that either all advertisements to consumers be subject to pre-approval or none.

To subject all advertisement to pre-approval would greatly increase the cost of advertising in the Health Sector generally and would greatly increase the time fame to put a product to market. Hence we believe that this is not a viable option.

Removing the restriction on pre-approval would mean that advertisers of non-prescription medicines would be able to get to market quicker and with less cost. The onus however would then be on Sponsors to ensure that their advertisements for all products were compliant with the TG Act and the TG Regs and the TGAC. In the short term this would mean that there may be an increase in complaints regarding these types of product but sponsors at present are aware of the restrictions. This would make for a level playing field for all Sponsors and ensure the onus is squarely on the Sponsor to ensure that their advertisement is compliant.

Complaints Mechanisms:

Questions for consideration:

Should the Therapeutic Goods Administration (TGA) publish on its website information related to products removed from the Australian Register of Therapeutic Goods (ARTG)?

- In order to enhance the transparency of regulatory processes, it is proposed that the TGA will regularly publish on its website those products that have been removed from the ARTG as a result of a regulatory decision.

Should the Complaints Resolution Panel (CRP) be reconstituted as an independent body?

- Currently the CRP is made up of nominees from industry associations, professional organisations, peak consumer organisations and the TGA, and has an independent chair.
- Virtually all complaints considered by the CRP are related to members or potential members of the industry associations represented on the Panel.
- If an independent complaints resolution body is to be maintained, any perceptions of conflicts of interest could be addressed by requiring members to be independent of the therapeutic goods and advertising industries.

Should the CRP consider complaints about all forms of advertising?

- Some media for non-prescription medicines and medical devices are within scope of the CRP's oversight e.g. print, radio and television, but others are currently exempt e.g. in-store promotion.
- Many complaints handled by the CRP are essentially trivial and straightforward and may be better dealt with in another way.

Should civil penalties apply for breaches of the regime?

- More broadly, there are no provisions for seeking civil penalties or enforceable undertakings for breaches of the advertising provisions of the legislation.
- Any revised sanction and penalty arrangements need to provide a regime that is both a real deterrent against transgression, and ensures the effective remediation of advertisements that are found to be in breach.
- The sanctions regime under the legislation could be strengthened to include civil penalty contravention provisions and court-imposed remedial action for advertising breaches.
- The TGA could also be given the power to refuse to list a product that was substantially similar to one that had been cancelled unless and until the relevant remedial action had been taken.

IVD Australia recommends that the TGA should have the ability to publish regularly a list of products removed from ARTG including the name of the Offending Sponsor.

However, IVD Australia also recommends that the TG Act be amended to prevent the re-inclusion of a product under the same or a similar name with another sponsor until the conditions imposed as a penalty for the breach have been met i.e. publication of a withdrawal or retraction. In the case of serial breaches regarding the same or similar products the TGA should have the right to require a Sponsor to show cause as to why a product or product group should not be permanently restricted from inclusion of the ARTG. In such cases the TGA must be prepared to prosecute Sponsors for breaches of the ACT and send a clear message that attempts to deceive consumers or HCPs will not be tolerated.

IVD Australia recommends that the CRP be disbanded and replaced by a Therapeutic Goods Advertising Complaints Agency (TGACA). The TGACA should have representation from Industry Associations, Professional Associations, Consumers and the TGA and should be funded by the Government directly via a block grant. This Agency would enable the Government to indicate clearly to the community that it takes the advertising of Therapeutic Goods as a serious matter and one of community importance. It should be funded separately from the TGA as its decisions need to be seen as separate from the TGA's charter to ensure the safety of therapeutic goods supplied in the Australian market. It should retain the ability to refer complaints regarding the safety and efficacy of therapeutic goods directly to the TGA for action and to require the TGA to prosecute or otherwise take action against breaches of the TGA Act, TG Regs or TGAC.

IVD Australia further recommends that the TGACA also act as the central Receipt point for complaints regarding the promotion of Therapeutic Goods in general, including those regarding promotion to HCPs by Sponsors. Such Complaints could be referred by the TGACA to the appropriate Industry Association for determination.

IVD Australia recommends that the TGACA (or the CRP if retained) should have members drawn from a number of different backgrounds. The current Complaints Resolution Panel benefits from Industry representation and this should continue in either form. It is difficult to see how the CRP (or TGACA) could have all its members independent of the Health Sector. IVD Australia believes there would be a problem in finding people who are truly independent. Even at present, the Consumer representatives on Complaints Panels are usually chosen for their views on the Advertising process and are thus not truly independent.

IVD Australia recommends the TGACA be empowered to accept complaints regarding all types of advertising. The present system is confusing and it is absurd that an advertisement can be complained about if it is placed in a magazine but not if it is used in an in-store promotion.

Complaints regarding efficacy should be referred directly to TGA but they must have an upgraded facility to deal with these.