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Re the current consultation: Advertising therapeutic goods in Australia:

Mark Butler, the Parliamentary Secretary for Health, has recently released two papers at the NMP Forum:

- a position paper on the promotion of therapeutic goods - produced by the Regulatory Policy and Governance Division of the Department of Health and Ageing (DoHA), dealing with the promotion of so-called "higher-risk" therapeutic goods to health professionals, advocating strengthened and more consistent self-regulation.
- a consultation paper on advertising arrangements - produced by the Regulatory Reform Section of the TGA, dealing with advertising of "lower-risk" therapeutic goods to consumers, outlining options regulatory reform.

While both strengthened self-regulation and regulatory reform of current advertising requirements is long overdue there are two serious flaws here:

- Firstly there is no such thing as high and low risk therapeutic goods, dependant on circumstance all goods with a therapeutic potential may be high risk. Examples abound –low dose aspirin (unscheduled) was found to have a higher potential for serious bleeds than warfarin (S4) in the elderly in the BAFTA trial, the glucosamine sulphate potassium complex tablets sold in supermarkets contain enough potassium to compete with a prescribed potassium supplement tablet, quinine for a person who has been sensitised may be equally deadly whether it comes in a soft drink bottle or as prescribed medicine.
- Secondly, no group should be offered self regulation unless it comes in a context of sufficient legislated regulation. In the case of the therapeutic goods industry there is such a poor record with self regulation that the individual member of this industry should not be offered self regulation without a proven prior track record of ethical behaviour. And there should be the ability to withdraw self regulation from QUM offenders. Self regulation should be seen as a privilege for those who are proven and continue to be worthy.

As complaints about complementary medicines and devices far outnumber those of so-called "higher-risk" therapeutic goods why was the Complementary Health Care Council of Australia was left out of the "Working Group on Promotion of Therapeutic Products". Their Code of Practice is arguably the weakest and least transparent of all industry Codes.

Independent monitoring, code revision and complaint resolution would be more effectively and efficiently carried out by one authority with representation from all stakeholders; rather than the current diverse mess. The CRP needs to be thoroughly reinvented – we need a "**new** CRP". Failure to comply with authority determinations would lead to the imposition of civil or criminal penalties and the withdrawal of the privilege of self monitiring

Now as to the comments requested

TGA Consultation Paper: Improving Advertising Arrangements for Therapeutic Goods in Australia.

This paper is about the advertising of therapeutic goods to consumers. It seems to have been promulgated for an ideal world the real world is unfortunately quite different .
There are numerous complaints about breaches of the Therapeutic Goods Advertising Code that are upheld by the Complaint Resolution Panel (CRP), sent on to the TGA because of industry non-compliance, with no feedback to the consumer leaving an impression of TGA inaction.
Apart from wasting money false advertising claims can delay or reduce or prevent effective therapies. However only acute catastrophic failures caused by misleading advertising involving scheduled medications seem to interest or motivate TGA action. Deaths due to the misguided use of homeopathics based on false promotion are not unknown and yet this is an area where the TGA has failed completely to act to prevent such promotion. The onus should be shifted from proof that the advertising may cause harm provided by the consumer to a requirement that manufacturers can only make claims that they substantiate and in a manner that the consumer can understand the full implications and ramifications of such claims ie self serving half truth must be ceased.

Crucial issues that the consultation paper fails to address

The current system is largely reactive and this is not satisfactory. A proactive system that can prevent problems from arising in the first place would be a far better model for adequate consumer protection. (The inertia of reactive system favours manufacturers and their bottom line.)
Many complaints occur because the TGA does not evaluate so-called “lower risk” Listed medicines and devices for efficacy. Sponsors self-certify that they hold the evidence to substantiate the indications and/or claims made for a Listed medicine or the intended purpose of a medical device but only a relatively small proportion of sponsor’s new entries on the Australian Register of Therapeutic Goods (ARTG) are checked by the TGA. This has resulted in a proliferation of products in the market place with dubious or no health benefits and public summary information on the ARTG which cannot be substantiated by clinical evidence.
The lack of transparency of the current system is appalling to the point where even if it is not intended the role of the is as a co-conspirator in the promotion of a whole range of shonky and useless medications. Many manufacturers continue to make excessive promotional claims about their product and providing minimal or no information about known adverse effects including drug-drug interactions. Product names such as “Fat Magnet”, “Weight Loss Accelerate” and “Slim-Me” are equally misleading and deceptive and should never have been allowed and medical device sponsors use similar strategies too..

Research has shown that many consumers do not understand that a product containing an AUST L number has NOT been evaluated for efficacy.

The failure by the TGA to evaluate listed medicines has lead to a serious misconception by consumers and many health professionals that all complementary medicines containing the same ingredients are equally effective. The reality is that complementary medicines, especially herbal medicines, are complex products with numerous biologically active components. This means that evidence of benefits (and risks) are specific to the product tested and cannot necessarily be extrapolated. People would

understand that all wines made from pinot noir grapes are not the same and still have no concept that this diversity applies equally the herbal medication made from the same herb. The end result is that is difficult for consumers and health professionals to know which complementary medicines available in the Australian market offer a genuine health benefit and which do not. This situation is most unsatisfactory for both consumers and health professionals and also limits the development of an evidence-based complementary medicines industry.

Important policy initiatives additional to those outlined in the consultation paper. Suggestions have been made to try and improve the current unsatisfactory situation. The following should be supported.

- AUST L medicines, currently unlisted homoeopathic and anthroposophic medicines and so-called "lower-risk" medical devices should include on their label and promotional material the statement**, "This medicine (or device) has not been evaluated by Australian health authorities for efficacy".** The US Food & Drug Authority uses a similar disclaimer. And **the TGA already insists on such a disclaimer for drugs imported under the special access** scheme so there is well established precedent here. In fact it is a complete hypocrisy for the TGA to insist that one category of unevaluated drugs bear this warning whilke allowing another category of unevaluated drugs free rein. And such a disclaimer would at least be an accurate statement of the current regulatory situation.
- **The provision of better information about the benefits and risks of so-called "lower-risk" therapeutic goods.** Research by the NPS has convincingly demonstrated that consumers and health professionals need access to an up-to-date, independent source of information about complementary medicines. Below are 3 suggested approaches:
    - Use product monographs prepared by the Canadian Natural Health Products Directorate augmented with specific information about whether or not products on the Australian market were identical (or bio/phyto/equivalent to) products proven in clinical trials. They can also be used to limit claims made by sponsors and ensure appropriate warnings and other information was provided in promotional material.
    - Require sponsors to add key evidence supporting each indication on the ARTG with entries checked by TGA staff. Sponsors would only be allowed to use clinical trial evidence relating to other products where their own product has been shown to have therapeutic equivalence. This could be added to the public summary document currently available on the TGA web site.
    - Set up an opt-in independent evaluation system. Sponsors could choose to submit their product for independent evaluation of its effectiveness by paying an additional fee. Products shown to be efficacious for specific indications by well-conducted clinical trials, ethically promoted, and with appropriate consumer medicines information would be awarded a trademark of approval similar to the Australian National Heart Foundation "red tick". These products would not require the disclaimer "This medicine has not been evaluated by Australian health authorities for efficacy". In the survey of pharmacy 1,121 pharmacy customers

mentioned above, 87 per cent thought complementary medicines should have a 'tick of approval' from a recognised government body. The proposed complementary medicine cooperative research centre (CRC) could be an appropriate body to undertake this work.

Options suggested

All options listed, except the following, reappeared as consultation questions and will be dealt with under that heading.

The CRP could refer directly to the TGA all matters relating to efficacy of the products.

- This has been done with Listed weight loss products and products containing glucosamine and ginkgo biloba. **It has not been effective**.
- In 2007, the TGA was asked to review the efficacy of all ingredients used in Listed weight loss products in the hope that up-stream evaluation would reduce the need for down-stream complaints. It was suggested that all ingredients that lacked evidence of efficacy for weight loss should be proscribed for use in such products until such time as a sponsor convinced the Complementary Medicines Evaluation Committee that new evidence was available. Industry concern apparently watered down the scope of this review to a draft document (released in February 2009) that merely reviewed the evidence that might support a claim for weight loss products. A number of consumer and health professional organisations wrote submissions expressing concerns about the limitations of the draft document, especially the lack of any implementation plan. A public consultation was called, in Canberra, on October 26, 2009. Many concerns were reiterated and **the TGA promised to revise the document. Eight months later no more has been heard.**
- **In short, the TGA Office of Complementary Medicines has shown no interest in evaluating the efficacy of Listed complementary medicines, no interest in correcting gross misinformation about these products on the ARTG.**
- **Based on this experience there is no good reason to support the new CRP referring matters of efficacy to the TGA.**

Consultation questions

Are the current arrangements for advertising of therapeutic goods in Australia known to you?

- Yes.

Should these be better known or understood?

- Information is available on the Therapeutic Goods Advertising Code Committee (TGACC) web site and the TGA web site. However, in order to find out how to submit complaints one must follow a link to another web site (CRP) which has a very useful online complaint form and advice. Unfortunately, the TGA site provides no Internet link to the CRP site.
- The TGA web site should provide cross-links to the CRP web site and the TGACC & CRP web sites should be consolidated. In addition, the National Prescribing Service (NPS) web site should also contain information about how to complain about unethical promotion and cross-link to the above.

- The TGA and/or the NPS should also educate consumers and health professionals on the importance of submitting complaints about promotion (as a crucial part of post-marketing surveillance) as the U.S. FDA is currently doing with their “Bad Ad Program”.

Do you have comments or complaints about the current advertising arrangements?

- See above.

Do you find advertisements for therapeutic goods helpful?

- No. What they mostly do is to promote the ”pill = cure” and/or “newer is better” messages and these are for the most part highly counter productive. Only very rarely are products promoted in a balanced way that incorporate their use into a proper therapeutic management plan.

Should the current pre-approval process be retained?

- Advertising approvals officers, acting under delegation from the Secretary, are not evaluators and do not have either support for, or in some cases the expertise required, to evaluate claims based on the indications. In addition, given that the pre-approval process only applies to certain media, it misses many problems and is a cost burden on industry.
- It can be argued that it would be more cost-effective to replace the pre-approval process with a less-expensive (but still funded) promotional monitoring program (including industry, health professional and consumer education) as long as the monitoring program interfaced with a complaint process capable of imposing effective sanctions (the TGPA).

Should the TGA publish on its web site products removed from the ARTG?

- The TGA web site should include products removed for any reason, for example when a review finds that the sponsor cannot substantiate indications listed on the ARTG, or when a sponsor de-lists a product themselves rather than face a review.
- The TGA web site should also include details of all complaints (and their outcome) referred to it by other bodies such as the CRP and the CHC Complaint Resolution Committee.
- It would also be helpful for the TGA web site to list all new products added to the ARTG on a weekly basis.
- All the above information should be made available by subscription to a TGA email alert system.

Should the CRP be reconstituted as an independent body?

- Yes, with the caveats that it is truely independent, can adequately deal with conflicts of interests and in addition to current CRP functions takes over from the existing system of a plethora of inconsistent industry Codes and complaint systems. **In other words a new independent and streamlined body needs to be created.**

Should the CRP consider complaints about all forms of advertising?

- **Yes! Yes! Yes!** It is time-wasting and inefficient that advertisements to consumers in leaflets, brochures, catalogues, shelf talkers, etc have to go to industry self-regulatory bodies (ASMI or the CHC) when the same advertisement in other media goes to the CRP.

Could trivial or straightforward complaints be better dealt with rather than requiring CRP consideration?

- Straightforward matters such the lack of a required warning should be dealt with by the new CRP administrative staff and not require consideration by the new CRP *per se.*

Should civil penalties apply for breaches?

- Clearly, the new CRP and/or the TGA need to be able to use civil penalties such as infringement notices and enforceable undertakings involving fines, corrective advertising orders, de-listing products and refusal to list a product substantially similar to one that had been cancelled.
- In addition, the funds generated should be applied to the monitoring, complaint and educational system instead of being lost into general revenue.