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AMA

Submission No: 2

30 April 2004

Committee Secretary
Joint Standing Committee on Treaties
Department of House of Representatives
Parliament House
Canberra ACT 2600

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BY:.....

copy by email: jsct@aph.gov.au

Dear Julia

I attach the AMA's submission to the Joint Standing Committee on Treaties inquiry into the Agreement between Australia and New Zealand for the establishment of a Joint Scheme for the regulation of therapeutic products.

We are happy for this to be regarded as a public submission, and look forward to the opportunity to discuss these issues with members of the committee at its public hearings.

Please contact Mr Bruce Shaw in the AMA Federal Secretariat on (02) 6270 5445, email bshaw@ama.com.au to arrange for our appearance at the hearings.

Thank you for the extension of time to enable our submission.

Yours sincerely

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Robyn Napier
Chair, AMA Therapeutics Committee

rn:bvs

AMA

PO Box 6090, Kingston ACT 2604 Australia

Australian Medical Association

Public submission

AMA submission to the Joint Standing Committee on Treaties inquiry into the Agreement between Australia and New Zealand for the establishment of a Joint Scheme for the regulation of therapeutic products

30 April 2004

Background

Australia and New Zealand are moving towards the establishment of a Trans Tasman Therapeutic Products Agency by 1 July 2005 to replace the Australian Therapeutic Goods Administration (TGA) and Medsafe in New Zealand.

As part of this process, a Trans Tasman Interim Advertising Council for Therapeutic Products was established in May 2003. At short notice the Australian Medical Association (AMA), the New Zealand Medical Association (NZMA), and 2 other medical organisations were each invited to provide one nomination from which one person would be chosen to represent the entire medical profession of Australia and New Zealand.

The AMA's nomination of the chair of the AMA Therapeutics Committee, Dr Robyn Napier, (supported by the NZMA) was accepted to represent the entire medical profession throughout Australia and New Zealand.

As part of this responsibility, the AMA has kept the NZMA and Australian medical organisations briefed on the work of the interim advertising council.

Overview

The AMA supports each of the four central objectives of the National Medicines Policy (NMP):

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines; and
- Maintaining a responsible and viable medicines industry.

In line with the NMP, ultimately the current Therapeutic Goods Administration and its successor Trans Tasman body exist to ensure the availability of safe products to consumers.

The AMA regards the Trans Tasman harmonisation process as an opportunity to strengthen the necessary processes. It is vital to get this right, at the outset of Trans Tasman harmonisation.

The AMA's concerns about the process of Trans Tasman "harmonisation" of therapeutic goods regulation include:

« a considerable head of steam had developed before there was any move to involve medical representatives;
- the process has largely occurred without the knowledge of the public;
- the process is occurring against a backdrop of enormous pressure on a number of fronts, including:
  > PBS spending;
  > from pharmaceutical companies and others to open up direct to consumer advertising;
  > to "down-schedule" medicines to categories where direct to consumer advertising is possible.

Therapeutic advertising

The Interim Advertising Council (I AC) was established to implement the recommendations of the report of a Review of the Advertising of Therapeutic Products in Australia and New Zealand. The IAC has been developing a single draft advertising code, which is proposed to be the benchmark for the advertising of therapeutic products in both Australia and New Zealand.

The current draft Trans Tasman Therapeutics Products Advertising Code includes provisions to:

- strengthen the ability to respond quickly to inappropriate advertising;
- encourage all stakeholders to accept responsibility in this area;
- protect public health and safety by ensuring that the system is effective and transparent with regular public reporting and independent auditing.

It is proposed that there will also be effective legislative sanctions in cases where advertisers do not comply with regulatory requirements.

A common set of broad advertising principles is being developed which will be supported by legislation in both countries.

The medical profession believes that the current draft Therapeutics Products Advertising Code sets an appropriately high standard, and therefore should provide effective control of these issues.

However, some other interested parties view the Current draft advertising code as a threat, and want to lower standards.

The AMA is concerned that this strenuous lobbying may have the ability to alter the code to subvert its principles. For example:

1. Consultative meetings may be stacked with interested parties.
   - Dr Robyn Napier represents the medical profession in two countries. Medical practitioners do not have time nor the ability to easily attend day time consultative meetings. There is a trust that a representative of a large professional group has the authority of that large group. "Over-represented" groups may possibly bias consultative meeting recommendations.
2. The AMA is concerned that the many different types of complementary health care therapists will all lobby for representation on the Advertising Council and may well achieve that.
   - This "over-representation" will potentially jeopardise that safety for the community for which therapeutic regulation exists.
   - The obvious alternative is that if indeed the variety of complementary or alternative therapists are represented it is only reasonable that the medical profession have similar and preferably greater representation.
   - The interim advertising council has only one medical profession representative, whereas complementary therapies have two at the moment with a proposal for even more to come.
   - The permanent Advertising Council should have medical representation from both Australia and New Zealand.
3. The media lobby has succeeded in having inserted into the code exemptions from the definition of advertisement for:
   - "entertainment" programs;

- communications where there is no exchange of valuable consideration.

4. The medical profession believes that these are serious flaws in the draft code which should be addressed. They will in effect permit direct to consumer advertising of therapeutic goods.

5. The medical profession believes that advertisements for all substances, devices and therapies with any therapeutic claims should undergo a pre-approval process.

- This should include foodstuffs making therapeutic claims.
- The AMA is concerned that there is a serious suggestion that foods will be able to make therapeutic claims with far fewer checks than products marketing themselves as therapeutic. The fairly obvious outcome of this would be that many manufacturers and suppliers will stop describing their products as drugs and start marketing them as foods, with major implications for the quality use of medicines in this country.
- « The TGA's (and the Trans Tasman agency's from July 2005) role in ensuring that advertising or promotional claims governing the efficacy of therapeutic products is being undermined (on both the resource and effective powers fronts) by the proposed food regulatory provisions.
- This is an issue that must be addressed before trans Tasman harmonisation is finalised.

Direct to consumer advertising (DTCA)

Currently direct to consumer advertising of prescription medicines is banned in Australia, but allowed in New Zealand.

Australia's current regulatory environment permits direct to consumer advertising for non-prescription drugs.

The AMA strongly supports the ban on direct to consumer advertising of prescription medicines because the experience of DTCA in the USA and New Zealand is that the advertising does not promote genuine information about effective available therapies, but rather promotes particular products which may not always be efficacious, cost-effective, or safe for particular conditions. While the AMA supports the availability of consumer information about medicines and health, DTCA is inconsistent with the quality use of medicines.

Funding

An underlying issue is that of the funding of the TGA, which is on a full cost recovery from industry basis.

The AMA strongly advocates that there must be a 'public policy' component of post-harmonisation agency funding, with budgetary funding from both governments, as there should be now for the TGA.

This would enable the TGA and its post harmonisation successor, for example, to engage in public education activities which were so vital during the Pan recall last year, and to fund travel costs associated with its councils and committees, as is the case with other consultative mechanisms within the health portfolio.

While the Government pays the travel and associated costs of participation for representatives on other public policy councils, committees, working parties, and other forums in the health sector in order to ensure that all views can be properly represented, nominating organisations are expected to fund the full costs of participation for their nominated member on the interim advertising council.

It is neither reasonable nor appropriate to expect self-funded participation for a government council established to discuss and recommend on vital issues of public policy.

With meetings of the interim advertising council alternating between Australia and New Zealand, the cost to non-profit representative bodies such as the AMA has been considerable.

Restructure of the drug scheduling process

The AMA is concerned at the current structure, membership, processes, and culture of secrecy of the National Drug and Poisons Scheduling Committee (NDPSC).

AMA President, Dr Bill Glasson, has written to the Federal Minister for Health and Ageing, Tony Abbott, to express the AMA's concern. Mr Abbott's response indicated that these issues would be addressed as part of the trans Tasman harmonisation process.

The NDPSC is responsible for recommending to Australian and New Zealand governments the scheduling and access over all drugs and poisons - pharmaceutical, veterinary, and agricultural.

In the AMA's view, the dysfunctionality of the committee has led to several unfortunate recommendations at recent meetings of the NDPSC which could adversely affect the health of the Australian community. I will briefly list some of these decisions and our concerns.

The Galbally Review of the NDPSC in 2001 recommended that the NDPSC be split in 2, to divide the medicines and poisons areas.

The AMA agrees that the NDPSC structure has become unwieldy. The NDPSC seems unable to provide considered decisions on the medical issues of scheduling of drugs and poisons that are vital to the health of the community.

Currently, members of the NDPSC are appointed to try to provide expertise, and to represent each jurisdiction (the Commonwealth, New Zealand, and all Australian States and Territories), as well as key professional and sectoral interests.

The AMA understands that, while there are some medical practitioners on the committee, they mostly represent their jurisdictions, and not medical expertise.

The medical profession is not one of the 5 representational areas with a current member on the NDPSC.

In the short term, the AMA has asked the Government to redress the lack of representation of the medical profession on the NDPSC.

Complementary medicines

One of the concerns expressed by many health care professionals and consumer groups is the inadequate regulation of complementary therapies, substances and devices, and the inability of legislation to provide protection to the consumer for health benefit claims being made with no evidence and no disclosure of risk.

The medical profession would hope that Trans Tasman harmonisation could facilitate the closing of some of the loopholes that are used to promote health care claims that are not supported by evidence.

As discussed, our concern is that the imbalance of representation on the Advertising Council will

jeopardise this possibility.

Conclusion

As the peak body representing the medical profession in Australia, the AMA is keen to continue participation in the trans Tasman harmonisation process, to ensure the protection of Australian national interests.

The AMA would welcome the opportunity to discuss these issues with the committee at its public hearings.

Dr Robyn Napier
Chair, Federal AMA Therapeutics Committee
Representative of Australian and New Zealand medical profession on the Trans Tasman Interim Advertising Council for Therapeutic Products