AUSFTA
Submission No: 146

Sidley, Kristine (REPS)

From: bshaw@ama.com.au
Sent: Wednesday, 21 April 2004 10:28 AM
To: Committee, Treaties (REPS)
Subject: AMA submission to J SCoT on AUSFTA

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BY:

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

copy by email: jsct@aph.gov.au

Dear Sir

I attach the Australian Medical Association's submission on the draft Australia-US Free Trade Agreement (AUSFTA), together with the accompanying letter. Hard copies of these, with a signature on the letter, are in the mail. We look forward to hearing from you.

Thank you for granting us an extension of time to make this submission.

Best wishes

Bruce Shaw
Senior Policy Adviser, Aged & Acute Care and Therapeutics
Medical Practice Department
Australian Medical Association
PO Box 6090, Kingston ACT 2604
Canberra, Australia
phone: 02 6270 5445
fax: 02 6270 5499
mobile: 0438 628 182
email: bshaw@ama.com.au

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 draft Australia-United States Free Trade Agreement

21 April 2004

Overview

In general, and subject to a number of conditions we outline in this brief submission, the Australian Medical Association (AMA) is at this stage satisfied with assurances we have been given by Australian Government negotiators that the draft Australia-US Free Trade Agreement (AUSFTA) of itself protects the essential framework of the Australian health system.

It is clear that the implementation stage of the various elements of AUSFTA will be crucial to how the agreement works in practice, and thus whether it will be of benefit to the Australian community.

To this end, the AMA welcomes the positive consultations we have had with the Australian Government negotiators.

We look forward to ongoing consultations during the implementation phase, to enable us to work cooperatively with the Government and its officials to ensure the best possible outcomes from the opportunities provided by AUSFTA.

The Pharmaceutical Benefits Scheme (PBS)

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

- 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.

Pricing

Australian Government assurances that the draft AUSFTA will not lead to overall increases in the prices of drugs on the PBS is basic to our support.

The AMA remains concerned at suggestions, for example at a meeting on 9 March 2004 of the US Senate Finance Committee, that Australian PBS prices for patented drugs would increase as the result of the AUSFTA

The reference pricing system whereby the Australian Government negotiates the prices of drugs listed on the PBS must be strengthened and maintained on the basis of incremental cost-effective analysis.

In a real sense, the PBS does not simply purchase pharmaceutical products on behalf of the Australian community, but health outcomes – what the products provide.

Accepting that the existing PBS processes already 'provide opportunities to apply for an adjustment to a reimbursement amount', if clause 4 of Minister Vaile's letter on the PBS is simply a re-statement of this situation without affecting how it operates, we would suggest that it would allay many concerns in the community if this point was made publicly and formally by the Government.

The AMA will continue to work with Government and other stakeholders to seek to ensure that the PBS is enhanced and made still more effective.

Transparency

Medicines play a vital role in Australia's enviable record of health standards and outcomes. Such a

role is clearly reliant upon the quality use of medicines (QUM), which is the central objective of the National Medicines Policy.

It is apparent to the AMA that the Australia-US Free Trade Agreement offers an opportunity to ensure a vital transparency which does not presently exist, largely because of the constraints of "business-in-confidence" expectations which currently underlie the whole process of Pharmaceutical Benefits Scheme (PBS) listing.

The AMA supports greater transparency across the whole paradigm of PBS processes.

The AMA advocates that transparency must apply to all parties – including pharmaceutical companies as well as the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Pricing Authority (PBPA).

The AMA is concerned that the "commercial in confidence" secrecy surrounding research data including the identity of the comparator drugs used in evaluations of clinical efficacy, risk, and the cost effectiveness of new medicines is a major restraint on the quality use of medicines in Australia.

This information is included in applications to the PBAC. In order for the use of medicines to be consistent with QUM practices, it is imperative that all the information considered by PBAC be available to clinicians to ensure best outcomes for patients.

This degree of transparency will enhance clinical knowledge, increase trust in the system, and put patient outcomes above perceived commercial risk.

It will also serve an important role in informing clinicians of the reasons why some medications are listed with authority restrictions.

This greater transparency across the whole PBS approval process is fundamental to the support for the AUSFTA by the AMA.

Review of PBAC recommendations

On the issue of the AUSFTA's provision for review of PBAC recommendations, the AMA believes that the "independent review process" required by the draft AUSFTA must be truly independent, and not dominated by any sectional interest, be that industry, professions, consumers, or government.

Any such reviews should:

- focus on the issues of concern and not re-open the whole application;
- be undertaken by a specialised subcommittee comprising experts relevant to the subject of the requested review;
- consider only that information provided to the PBAC, and relevant to the requested review;
- report back to PBAC, and not directly to government;
- be pragmatic, and facilitate, not delay, the PBAC approval processes for PBS listing of pharmaceuticals.

The implementation of this "independent review process" will be critical to the effectiveness of the Australia-US Free Trade Agreement in genuinely enhancing the Australian PBS.

Patents

The AMA acknowledges the importance of effective intellectual property laws to support and encourage research and development of innovative medicines.

The existing Australian patent laws provide effective support for a viable innovative medicines industry in Australia.

In implementing the AUSFTA, the AMA will oppose any mechanisms which will delay the availability in Australia of appropriate of bioequivalent brand substitutes once medicines go off-patent.

The AMA would be concerned about any move to more closely align Australian patent laws with US patent laws. For example, 'use patents' can allow the patenting of particular uses of common compounds effectively increasing patent time. This does not reward genuine innovative research and can adversely impact on access and availability.

The AMA endorses the need for ongoing meaningful consultation on the intellectual property provisions of the AUSFTA, and looks forward to being closely involved in these consultations.

Intergovernmental consultation arrangements

The AMA notes and endorses assurances we have been given that the Medicines Working Group envisaged as part of the AUSFTA will be merely a consultative forum, and have no role in either rule-making or decision-taking.

We would be very concerned if this group of federal health officials from the US and Australia assumed any role in either rule-making or decision-taking, which would constitute a breach of Australian sovereignty.

Workforce issues

The AUSFTA chapter on Cross-Border Trade in Services includes provisions aimed at encouraging the professional bodies of Australia and the US to develop mutual recognition arrangements.

We understand that this will involve agreement between the individual States in the US and Australia. Accordingly, it is not likely to be a swift process.

The AMA endorses the need for meaningful consultation before any moves in this direction, and looks forward to being closely involved in any such consultations.

Conclusion

As the peak body representing the medical profession in Australia, the AMA will keep a watchful eye on the AUSFTA implementation processes, 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

Australian Medical Association Limited
ABN 37 008 426 793

42 Macquarie Street, Barton ACT 2600; PO Box E115, Kingston ACT 2604
Telephone: (02) 6270 5400 Facsimile: (02) 6270 5499

Website: http://www.ama.com.au/

President: Dr William Glasson
Secretary General: Dr Robert Bain

21 April 2004

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

copy by email: jsct@aph.gov.au

Dear Sir

I attach the AMA's submission on the draft Australia-US Free Trade Agreement (AUSFTA).

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 to be considered by the Federal AMA Therapeutics Committee, which met last weekend.

Yours sincerely

Robyn Napier
Chair, AMA Therapeutics Committee

rn:bvs