AMA

Opening statement by the Australian Medical Association (AMA) to the Joint Standing Committee on Treaties hearing into the draft Australia-United States Free Trade Agreement, at 11.30 am Monday 3 May 2004 in Committee Room 2R1, Parliament House, Canberra

Mr Chairman and members, thank you for the opportunity to give evidence to you, further to our written submission, on the Australia-United States Free Trade Agreement (AUSFTA). The scope of the FTA is widespread and its impact will be felt in many sectors of our society. The main area of interest for the Australian Medical Association in the AUSFTA lies in the possible impact on the Pharmaceutical Benefits Scheme (PBS). We do have some interest in other chapters that could impact on our health system, including intellectual property, workforce, investment, and quarantine.

The PBS

The AMA opposed the inclusion of the PBS within the AUSFTA.

Australians' access to health services in general and pharmaceuticals in particular is enviable. Our system provides a clear pathway for all Australians to access medications they need for preventative care, disease treatment and modification, palliative care and maintenance of a life-style which would be curtailed or indeed ended in the absence of such medication. The PBS allows a subsidy to apply to pharmaceuticals with co-payments expected of Health care cardholders of $3.80 and for the rest of the population of $23.70. Once thresholds are reached, there may be no expected co-payment for the remainder of the year that the threshold has been exceeded.

The level of subsidy to the citizens of Australia range from nil to very substantial for the chemo-therapy agents for cancer care. Access is also widened to indigenous Australians in remote locations through innovative schemes under 'Section 100' arrangements. The most prescribed item by volume on the PBS, lipid lowering agents, cost in general $70-$80 per month: an individual pays $3.80, $23.70 or $nil. For this category alone, a $1 cost increase would cost $14 million per month to government.

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. 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.

There are concerns around the listing of products onto the PBS, the conditions applied to those medications under "Restricted Benefits" or "Authority required" provisions. The best way of resolving many of the concerns from industry, the profession and from the Pharmaceutical Benefits Advisory Committee (PBAC), would be to ensure that the PBS is in no way diminished. That the subsidy that Australians receive is maintained. That the best and fairest price is agreed to, such that the level of subsidy required is not escalated. If the required subsidy per medication is increased, the overall cost of the PBS will continue to escalate. We need to ensure the PBS remains viable. The reference pricing system whereby the Australian Government negotiates the prices of drugs listed on the PBS must be strengthened and maintained.

It is possible that inclusion of the PBS within the AUSFTA could enhance the vital role of the PBS within the Australian health system, subject to a number of conditions. The implementation of the AUSFTA will be crucial to how the agreement works in practice, and how it will benefit the Australian community. Reducing the access and affordability to medicines would not be acceptable to the AMA.

PBS transparency

The AMA believes that transparency is fundamental to the quality use of medicines (QUM) in Australia, and thus supports greater transparency across the whole paradigm of PBS processes. The AMA is concerned that the commercial in confidence secrecy surrounding research data including the identity of the comparator drugs used in evaluations of the cost effectiveness of new medicines is a major restraint on QUM. 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 patient management. Such transparency across the whole PBS approval process is fundamental to AMA support for the AUSFTA. It would allow a clear understanding of PBS listings and restrictions.

Review of PBAC recommendations

The AMA believes that the "independent review process" of PBAC recommendations 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 information originally 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.

This will be critical if the AUSFTA is to genuinely enhance the Australian PBS, as claimed.

Pharmaceutical 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. We must also ensure that any changes to Australian patent laws do not delay availability of new medicines, increase the cost of medicines in Australia, or hinder innovative Australian research.

Intergovernmental consultation arrangements

The AMA would be very concerned if the Medicines Working Group, envisaged as part of the AUSFTA, were to assume any role in setting rules or making decisions relating to the PBS. This would undermine Australian sovereignty. We note and endorse assurances that this group of federal health officials from the US and Australia will be strictly a consultative forum.

Workforce issues

The AUSFTA chapter on Cross-Border Trade in Services includes provisions to encourage Australian and US professional bodies to develop mutual recognition arrangements. We understand 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 involvement in direct consultations.

Conclusion

As the peak body representing the medical profession in Australia, the AMA will be vigilant on the progress of the AUSFTA processes, to ensure the Australian patients' rights are protected.

Dr Mukesh Haikerwal AMA Vice President 3 May 2004